



ESCRS 2021 ALCON ABSTRACTS

Including Alcon Sponsored Studies and Investigator Initiated Trials

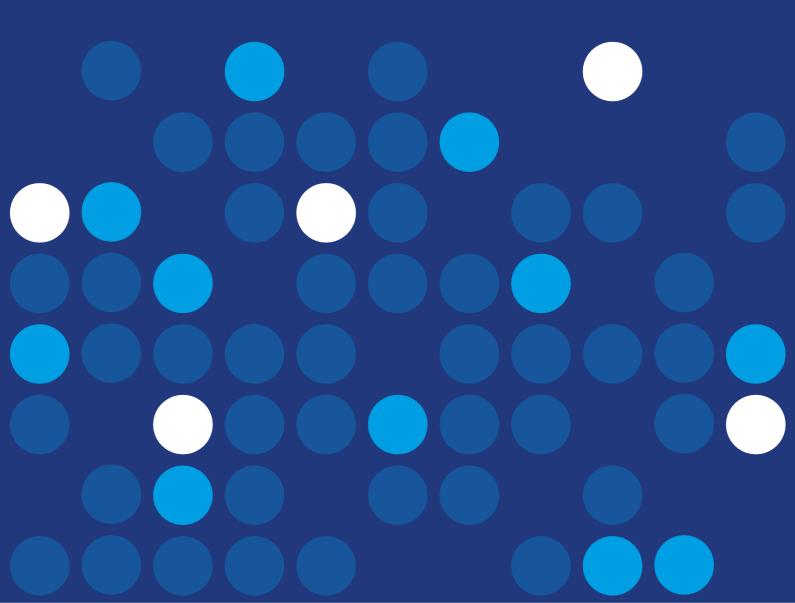








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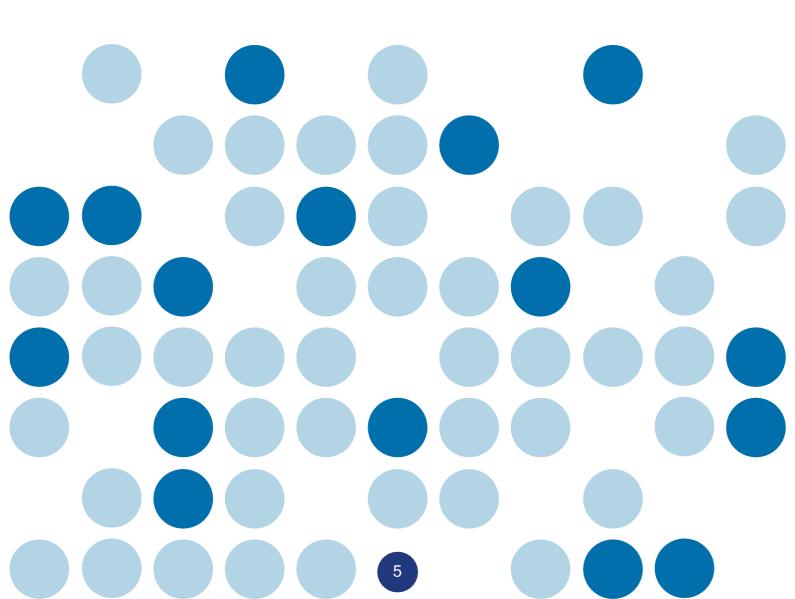






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AT-IOLs









A Cost-effectiveness Analysis of AcrySof IQ Vivity IOL from Private Health Fund Perspective in Australia

First Author: C Bala, Australia

Poster - Alcon Supported

Available Online

Abstract Details

Purpose

AcrySof IQ Vivity is the first and only Extended Depth of Focus IOL (EDoF) with the Wavefront-Shaping X-WAVE technology and a clinically proven monofocal visual disturbance profile. The objective of this study was to conduct a cost-effectiveness analysis of AcrySof IQ Vivity IOL vs. standard aspheric monofocal IOL, from a private health fund perspective in Australia.

Setting

Australia Private Health Fund Perspective

Methods

A Markov model was developed using the following health states: well, need for spectacles (near/distance/progressive), severe visual disturbances (glare/haloes/starbursts) - with/without spectacles, and death. Model inputs (transition probabilities, discount rates, utilities, and event rates) were sourced from a randomized clinical study (NCT03010254), published literature, and expert opinion. IOL costs (Vivity-AU\$615, and AcrySof SN60WF-AU\$290) were derived from the published prostheses list. A lifetime time horizon (30 years) was considered, and cost and health outcomes were discounted at 5% per annum. Model outcomes included incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY) gain. Sensitivity and scenario analyses were also conducted.

Results

Bilateral implantation of AcrySof IQ Vivity IOL provided greater vision related quality of life (QALY gain of 0.16) at an incremental lifetime cost of AU\$312 vs. monofocal IOL. Vivity incremental cost effectiveness ratio (ICER) vs. monofocal IOL was AU\$1,935/QALY, which is well below the medical technology cost-effectiveness thresholds (range: AU\$45,000-AU\$75,000) recommended by the Australian authorities. Results were most sensitive to the cost of IOL prosthesis, post-operative spectacle dependence, and disutility due to wearing glasses. The robustness of results was further confirmed by one-way sensitivity analysis, probabilistic sensitivity analysis, and scenario analyses.

Conclusions

AcrySof IQ Vivity is a presbyopia correcting IOL that is highly cost-effective treatment strategy and provides improved vision-related quality of life outcomes for patients.







Real-World Registry Evaluation of Satisfaction, Spectacle Independence and Vision Outcomes in German Patients Implanted with a Novel Wavefront-Shaping Presbyopia-Correcting Intraocular Lens

First Author: HC Gaeckle, Germany

Poster - Alcon Initiated Trial (#ILE871-P001)

Available Online

Abstract Details

Purpose

To report Real World patient satisfaction, spectacle independence, visual disturbances and vision outcomes with the ACRYSOF IQ Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL models DFT015, DFT315, DFT415, and DFT515 in German patients evaluated through routine clinical practice.

Setting

Multicenter, ambispective registry study conducted in Europe, the UK and Australia evaluating the performance of bilaterally implanted ACRYSOF Vivity and ACRYSOF Vivity Toric IOL in a real world setting through routine clinical practice.

Methods

This is a sub-analysis of subjects enrolled from German sites to date. After a minimum of 3 months post-op follow up per local clinical practice standards, subjects implanted with the AcrySof IQ Vivity and/or Vivity Toric IOL underwent subjective vision satisfaction and spectacle independence with validated PROMs questionnaires and patient reports of visual disturbances. We present the first interim analysis of outcomes observed at the enrollment visit to date.

Results

Currently 27 subjects are enrolled from four German sites of which 95.8% present with Binocular UCDVA \geq 20/25. The need to wear glasses is low with subjects reporting never/rarely needing to wear eyeglasses in bright light to see up close 61.5%, at arm's length 84.6% or far away 88.4%. 92% are very/fairly satisfied with their sight, 96% report none/some difficulty with their sight in their everyday lives, 88.5% no difficulty seeing to engage in an activity/hobby of their interest. Visual disturbances rates are low - None halos 92.3%, glare 84.6% or starbursts 96.2%. There are no unanticipated AEs to date. In this first Real World assessment of patients bilaterally implanted in Germany with the ACRYSOF IQ Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL suggests high levels of post-operative patient satisfaction with low needs to wearing spectacles and experiencing mild to none visual disturbances.

Conclusions







Spanish Site Outcomes of a Novel Wavefront-Shaping Presbyopia-Correcting Intraocular Lens – A Real World Registry Study

First Author: M Garcia-Gonzalez, Spain

Free Paper - Alcon Initiated Trial (#ILE871-P001)
10/9/2021 | 01:57 PM - 02:03 PM (CEST) | Auditorium

Abstract Details

Purpose

To report the Real World visual and subjective outcomes observed in routine clinical practice at the Clínica Rementería with the ACRYSOF IQ Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL models DFT015, DFT315, DFT415, and DFT515.

Setting

Clínica Rementería, Madrid, Spain.

Methods

This is a sub-analysis of 19 subjects enrolled to date in our clinic and evaluated using local clinical practice standards. After a minimum of 3 months and up to 6 months post-op follow up, subjects implanted with the AcrySof IQ Vivity and Vivity Toric IOL underwent visual acuity assessments at a range of functional distances in addition to subjective vision satisfaction and spectacle independence with validated Patient Reported Outcome Measures questionnaires and patient reports of visual disturbances. We present the first interim analysis of outcomes observed at the enrollment visit.

Results

The mean \pm standard deviation photopic binocular visual acuity (in logMAR) UDVA was -0.011 \pm 0.041, UIVA (66cm) was 0.100 \pm 0.086 and UNVA (40cm) was 0.208 \pm 0.143 with 94.7% of subjects presenting UDVA \geq 20/20. 94.7% subjects reported never/rarely needing to wear eyeglasses to see at arm's length and far away and 57.9% to see up close. Also, the majority report no difficulty with their sight in their everyday life and are fairly/very satisfied with their sight; none halos, glare or starbursts were reported by 78.9%, 94.7% and 94.7% respectively. There are no unanticipated adverse effects to date. This interim analysis at our site level subjects bilaterally implanted with the ACRYSOF IQ

Conclusions

Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL suggests very good distance, intermediate and near visual outcomes with high levels of vision patient satisfaction with low needs to wearing spectacles for intermediate and distance activities and also experiencing low to none photic visual disturbances. The study is ongoing and additional data may be included at the meeting.







Subjective and objective assessment of visual disturbances in patients implanted with three different presbyopia correcting IOLs

First Author: M Guarro, Spain

Free Paper - Investigator Initiated Trial (#52863693) 10/9/2021 | 01:33 PM - 01:39 PM (CEST) | Auditorium

Abstract Details

Purpose

To describe and compare the patient satisfaction (McAllinden test) and halometry (Light Distortion Analyser; LDA) of patients implanted bilaterally with three different presbyopia correcting IOLs (PC-IOLs). A non-diffractive PC IOL (Vivity) and two diffraction based models: ATLara (Zeiss) and Symfony (J&J) and a control monofocal IOL (AcrySof IQ, Alcon).

Setting

Vallès Ophthalmolgy Research. Barcelona.

Methods

Prospective Randomized Controlled Trial with 3 study groups Vivity(n=14), ATLara(n=12), Symfony(n=9) and a control group(n=13). Three months follow-up. Patients were implanted bilaterally with the same IOL model. All surgeries were performed by the same surgeon and functional examinations by two experienced optometrists. Visual disturbances were assessed subjectively (McAllinden) test and psychophysically (LDA). LDA is a device that uses multiple LEDs to characterize size of the visual disturbances through the Light Disturbance Index (LDI, ratio of the area of points missed and the total area explored) and Best fit Cicle, (BFC circle that best first the distortion area).

Results shown for Vivity; AT.Lara; Symfony and monofocal. McAllinden test: patients reporting "never" perceiving:

- Glare: 86%; 82%; 88% 92%
- Halos: 93%; 55%; 63%; 82%
- Starburst: 71%; 45%; 50%; 69%

Binocular LDA results:

- LDI (%): 9.04; 18.03; 15.00; 11.02
- BFCr (mm): 24.15; 33.99; 30.96; 26.11.

Conclusions

Results

Results of both subjective and psychophysical methods show that patients implanted with the non-diffractive PC-IOL Vivity present similar visual disturbances than those implanted with a monofocal IOL. Patients implanted with the other diffraction based PC-IOLs included in this study present higher perception of halos and starburst. The study is designed to include 20 patients per group. At the moment of the submission of this abstract recruitment is still ongoing. Results will be updated before the congress including a more detailed statistical analysis.







Visual acuity and patient satisfaction of patients implanted with three presbyopia correcting IOLs

First Author: M Guarro, Spain

Poster - Investigator Initiated Trial (#52863693)

Available Online

Abstract Details

Purpose

To describe and compare the binocular visual acuities and the patient satisfaction of patients implanted with three different presbyopia correcting IOLs (PC-IOLs). A non-diffractive PC IOL (Vivity) and two diffraction based models: ATLara (Zeiss) and Symfony (J&J) and a control monofocal IOL (AcrySof IQ, Alcon).

Setting

Vallès Ophthalmolgy Research. Barcelona.

Methods

Prospective Randomized Controlled Trial with 3 study groups Vivity (n=14), ATLara (n=12), Symfony (n=9) and a control group (n=13). Three months follow-up. Patients were implanted bilaterally with the same IOL model. All surgeries were performed by the same surgeon (MGM) and all functional examinations by the same experienced optometrist.

Visual Acuities were performed using ETDRS charts at distance (4m), intermediate (66cm) and near (40cm). Patient satisfaction was assessed using McAllinden test.

Results shown for Vivity; AT.Lara; Symfony and monofocal.

LogMAR VAs:

- Binocular BDCVA: -0.06; -0.04; -0.02; -0.06.
- Binocular BDCIVA: 0.11; 0.16; 0.23; 0.24.
- Binocular BDCNVA: 0.24; 0.27; 0.36; 0.45

With the McAllinden test, patients reporting "never" perceiving:

- Results
- Glare: 86%; 82%; 88% 92%
- Halos: 93%; 55%; 63%; 82%
- Starburst: 71%; 45%; 50%; 69%

Spectacle independence at

- Distance: 100%; 100%; 88%; 100%
- Intermediate: 93%; 91%; 75%; 77%
- Near: 50%; 27%; 38%; 15%.

All three PC-IOLs present good distance VAs and better intermediate and near than monofocal control group. Spectacle independence with PCIOLs is higher than for the monofocal, being slightly better in the case of patients implanted with Vivity. Patient satisfaction when perceiving Halos and Starbursts was higher with Vivity than other PC-IOLs, with a percentage of patients reporting "never" similar to the monofocal control group.

Conclusions

The study is designed to include 20 patients per group. At the moment of the submission of this abstract recruitment is still ongoing. Results will be updated before the congress including a more detailed statistical analysis.







Alcon Acrysof® Vivity® - A new EDOF lens – Clinical and optical performance over 18 months

First Author: KG Gundersen, Norway

Poster - Investigator Initiated Trial (#61478839)

Available Online

Abstract Details

Purpose

To evaluate the clinical and optical performance of the new AcrySof® Vivity® EDOF

Setting

Single surgeon eye clinic, Haugesund, Norway.

Methods

This study was a non-interventional single arm study of visual outcomes after successful bilateral cataract surgery or refractive lens exchange surgery with uncomplicated bilateral implantation of Alcon Acrysof® Vivity® IOL. All subjects were assessed during a single visit approximately 3 to 6 months after their surgery. Clinical evaluations included measurement of visual acuity at distance, intermediate and near, manifest refraction, defocus curve and subjective measures of visual quality.

Results

60 study subjects (120 eyes) were enrolled. Our refractive target was either binocular emmetropia or up to -0.5D of myopia (mini-monovision) in the non-dominant eye. Planned Mean Refraction Spherical Equivalent (MRSE)) was -0,25 D and we ended up with -0,27D. Uncorrected binocular defocus curved showed a peak of -0.04 (logMar) at -0,5 D of defocus, but with a broad performance profile. UCVA \geq 0,2 (logMar) was observed between -2,5 and +1.25D of defocus indicating broad optical performance. Patient satisfaction was excellent with contrast sensitivity and dysphotopsia profiles comparable to monofocal IOL's.

Conclusions

AcrySof® Vivity® EDOF IOL is based on a novel design using wavefront shaping technology. Theoretically, this lens is designed to provide a broad range of optical performance without sacrifizing optical quality. Compared to previous reports of dysphotopsia after difractive trifocal IOL implantation, this lens provide significantly less optical side-effects. Avoiding bilateral postoperative myopia presented the only significant clinical challenge using this lens.







Real World Vision Performance of a Novel Presbyopia-Correcting IOL in Subjects with Altered Cornea – A Multi-country Registry (EVOLVE Study)

First Author: L Kleineberg, Germany

Poster - Alcon Initiated Trial (#ILE871-P001)

Available Online

Abstract Details

Purpose

To report real world binocular distance, intermediate and near photopic visual acuities and visual disturbances of Acrysof Vivity and Acrysof Vivity Toric IOLs implanted in a subgroup of subjects with altered corneas.

Setting

Multicenter, ambispective registry study conducted in Europe, the UK and Australia evaluating the performance of bilaterally implanted Acrysof Vivity and/or Acrysof Vivity Toric IOL in a real world setting through routine clinical practice.

Methods

This is a sub-analysis of subjects with altered corneas enrolled to date. After a minimum of 3 months post-op follow up per local clinical practice standards, subjects implanted with the Acrysof Vivity and/or Acrysof Vivity Toric IOL underwent visual acuity assessments at distance, 66 cm and 40 cm (logMAR) and non-prompted visual disturbances (halos, starbursts and glare) were documented. We present the first interim analysis of outcomes observed at the enrollment visit to date.

Results

Currently, 17 subjects with ocular comorbidities have been enrolled. Altered corneas to date include post-LASIK, corneal dystrophy or dry eye. Binocular mean logMAR BCDVA was 0.018 (0.062); DCIVA 0.143 (0.123) and DCNVA 0.202 (0.194). Binocular mean logMAR UCDVA was 0.060 (0.082); UCIVA 0.134 (0.113) and UCNVA 0.228 (0.205). No halos, glare and starbursts were reported by 88.9%, 83.3% and 88.9% of subjects. There a no unanticipated AEs to date.

Conclusions

In this real world assessment of patients presenting altered corneas and bilaterally implanted with the Acrysof Vivity or Acrysof Vivity Toric IOL have shown very good distance, intermediate and near visual outcomes and very low levels of visual disturbances. The study enrollment continues and additional data may be presented during the meeting.







Real World Vision Outcomes of a Novel Presbyopia-Correcting IOL in Subjects with Ocular Comorbidities – A Multi-country Registry (EVOLVE Study)

First Author: F Llovet-Osuna, Spain

Poster - Alcon Initiated Trial (#ILE871-P001)

Available Online

Abstract Details

Purpose

To report Real World binocular distance, intermediate and near photopic visual acuities and visual disturbances the ACRYSOF IQ Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL models DFT015, DFT315, DFT415, and DFT515 implanted in a cohort of subjects with Ocular Comorbidities.

Setting

Multicenter, ambispective registry study conducted in Europe, the UK and Australia evaluating the performance of bilaterally implanted ACRYSOF Vivity and ACRYSOF Vivity Toric IOL in a real world setting through routine clinical practice.

Methods

This is a sub-analysis of subjects with ocular comorbidities enrolled to date. After a minimum of 3 months post-op follow up per local clinical practice standards, subjects implanted with the AcrySof IQ Vivity and/or Vivity Toric IOL underwent visual acuity assessments at distance, 66cm and 40 cm (logMAR) and non-prompted visual disturbances (halos, starbursts and glare) were collected. We present the first interim analysis of outcomes observed at the enrollment visit to date.

Results

Currently 39 subjects with ocular comorbidities have been enrolled. Ocular comorbidities to date include Glaucoma, ARMD, Dry Eye, PCO, eye-lid related conditions, Vitreous Detachment, Pseudoexfoliation. Binocular mean (SD) (logMAR) UCDVA was 0.046 (0.081); UCIVA 0.123 (0.119) and UCNVA 0.272 (0.170). Binocular mean (SD) (logMAR) BCDVA was 0.005 (0.072); DCIVA 0.108 (0.117) and DCNVA 0.254 (0.159). No halos, glare and starburst were reported by 89.7%, 87.2% and 89.7% of subjects. There are no unanticipated AEs to date.

Conclusions

In this Real World assessment of patients presenting ocular comorbidities and bilaterally implanted with the ACRYSOF IQ Vivity and/or ACRYSOF IQ Vivity Toric Extended Vision IOL we have observed very good distance, intermediate and near visual outcomes and high percentages of subjects without visual disturbances. The study enrollment continues and additional data may be presented during the meeting.







Predicted optical quality and halos with the Vivity EDF IOL in post-LASIK patients

First Author: S Marcos, Spain

Poster - Alcon Supported

Available Online

Abstract Details

Purpose

Patients that have undergone LASIK refractive surgery (particularly those who had the procedure decades ago) show excessively high amounts of corneal spherical aberration (SA, positive post myopic LASIK and negative post hyperopic LASIK, linearly correlated with pre-op spherical errors, SE). We investigated the impact of post-LASIK treatment on the optical performance of the new AcrySof TM IQ VivityTM Extended Vision Intraocular Lens (IOL) in comparison with the AcrySof TM IQ monofocal IOL and predicted the effect of corneal aberrations on the optical depth of focus (DOF) and halos with this extended depth of focus IOL.

Setting

Visual Optics and Biophotonics Lab, Institute of Optics, Consejo Superior de Investigaciones Científicas, Madrid, Spain; Fundación Jiménez-Díaz, Madrid.

Methods

Computer model eyes were built with simulated post-LASIK corneas (Marcos et al 2001 Llorente et al 2004) and the Vivity/Acrysof IOLs (proprietary designs by Alcon). LASIK surgeries had been performed >20yrs ago using Technolas 217-C excimer laser, Bausch&Lomb. Five corneas (pre-LASIK SE: -7.5-+4.5D, with post-LASIK SA -1.15-+0.78um) and a virgin cornea (0.28um SA). Optical aberrations were obtained by ray tracing on the model eyes. DOF was estimated as the dioptric range above which optical quality (Visual-Strehl,VS) was above 0.12 (±0.2logMAR). Halos were estimated as the diameter of the image of a point source that encircles 50% of the total energy.

Results

VS@far was >0.8 in virgin corneas both for Vivity EDOF (V) and Acrysof Monofocal (M) and ranged similarly from 0.23-0.54 from post-7.5--2.5D and +4.5D LASIK for both IOLs (5-mm pupils). VS@near was 0.25-0.27 with Vivity and 0.17-0.11with Monofocal (3-mm). DOF_V was 1.29 higher than DOF_M in virgin corneas and 1.19 in post-LASIK corneas (3-mm). The variation of DOF across post-LASIK eyes was 0.06 with Vivity and 0.26 with Monofocal. In virgin corneas and -2.5 post-LASIK, the halo metric was <2.2arcmin for Vivity and Monofocal. Larger halos (by 2.5-1.8arcmin) occurred with monofocal than with Vivity in -7.5 and -4.5D post-LASIK.

Conclusions

The Acrysof Vivity IOL increases Depth-of-focus in comparison with the Acrysof Monofocal IOL. Vision improvement with the Vivity at intermediate and near distances in comparison with the monofocal occurs both in normal and post-myopic and post-hyperopic LASIK corneas. Depth-of-focus with Vivity was almost completely independent of the sign and amount spherical aberration. Also, Vivity reduced the apparent halo size in patients after moderate myopic LASIK in comparison with the Monofocal IOL. Computer eye modeling suggests that the Vivity IOL is well indicated in post-LASIK patients.







Real-World Outcomes of a Novel Presbyopia-Correcting Toric IOL- Multi-country Registry (EVOLVE Study)

First Author: *N Reus, The Netherlands*

Poster - Alcon Initiated Trial (#ILE871-P001)

Available Online

Abstract Details

Purpose

To report the first real world results on visual acuity, refractive, and safety outcomes of the AcrySof IQ Vivity Toric Extended Vision IOL models DFT315, DFT415, and DFT515.

Setting

Sub-analysis of an international, ambispective registry study conducted in Europe, the UK and Australia evaluating the performance of bilaterally implanted AcrySof Vivity and AcrySof Vivity Toric IOL in a real world setting through routine clinical practice.

Methods

This is a sub-analysis of subjects enrolled to date and implanted with the toric version of the Vivity IOL. After a minimum of 3 months post-op and up to 6 months follow up per local clinical practice standards, subjects implanted with the AcrySof Vivity Toric IOL underwent visual performance assessments of visual acuity at distance, intermediate (66 cm) and near (40 cm) distances. Subject satisfaction, and spectacle independence recorded via validated questionnaires are reported. We present an interim analysis of outcomes observed at the enrollment visit.

Results

To date, 129 subjects are enrolled, of which 21 subjects have been implanted with the Vivity Toric IOL. Binocular mean (SD) (logMAR) UDVA was 0.02 (0.08), UIVA 0.08 (0.11) and UNVA 0.24 (0.15). All eyes had ≤ 0.50 D of manifest refractive cylinder after surgery. 95.3% of subjects reported rarely or never wearing glasses at arm's length and 93.2% are satisfied with their sight. No halos, glare and starbursts were reported by 76.2%, 76.2% and 95.2%, respectively. There are no unanticipated AEs to date.

Conclusions

Initial real world assessment of patients implanted with the toric version of the Vivity IOL suggests very good visual and refractive outcomes, high levels of patient satisfaction and a low need to wearing spectacles for distance and intermediate activities. Additional results on refractive outcomes and spectacle independence rates will be included in the paper.







Real-World Outcomes of a Novel Wavefront-Shaping Presbyopia-Correcting Intraocular Lens Implanted in Spanish Clinics

First Author: MA Teus, Spain

Free Paper - Alcon Initiated Trial (#ILE871-P001) 10/9/2021 | 01:15 PM - 01:21 PM (CEST) | Auditorium

Abstract Details

Purpose

To report Real World visual outcomes with the ACRYSOF IQ Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL models DFT015, DFT315, DFT415, and DFT515.

Setting

Multicenter, ambispective registry study conducted in Europe, the UK and Australia evaluating the performance of bilaterally implanted ACRYSOF Vivity and ACRYSOF Vivity Toric IOL in a real world setting through routine clinical practice.

Methods

This is a sub-analysis of subjects enrolled from Spanish sites to date. After a minimum of 3 months post-op follow up per local clinical practice standards, subjects implanted with the AcrySof IQ Vivity and Vivity Toric IOL in both eyes underwent visual performance assessments of visual acuity at distance, intermediate (66 cm) and near (40 cm) distances. Subject satisfaction and spectacle independence recorded via validated questionnaires and patient reports of visual disturbances are reported. We present the first interim analysis of outcomes observed at the enrollment visit.

Results

To date, 129 subjects are enrolled globally, with 69 subjects enrolled in Spanish sites. Mean UCDVA was 0.016 ± 0.080 logMAR (20/20 Snellen), mean UCIVA was 0.112 ± 0.119 logMAR (~ 20/25 Snellen) and mean UCNVA was 0.251 ± 0.159 logMAR (~20/32 Snellen). 94.1% fairly/very satisfied and 70.6% report no difficulty in seeing the prices of goods when shopping. The % of subjects reporting never/rarely needing to wear eyeglasses to see up close 63.3%, or at arm's length 88.3% or far away 94.1%. None halos 85.3%, glare 91.2% or starbursts 91.2%. There are no unanticipated AEs to date.

Conclusions

This first assessment of patients bilaterally implanted in Spain with the ACRYSOF IQ Vivity and ACRYSOF IQ Vivity Toric Extended Vision IOL evaluated in regular clinical settings suggests very good visual outcomes, high levels of vision patient satisfaction with low needs to wearing spectacles for intermediate and distance activities and also experiencing mild to none visual disturbances. The study is ongoing and additional data may be included in the paper.







A Cost-benefit Analysis of AcrySof IQ PanOptix Trifocal Intraocular Lens (IOL) from Patient Perspective in the USA

First Author: C Bala, Australia

Poster - Alcon Supported

Available Online

Abstract Details

Purpose

AcrySof IQ PanOptix is the first trifocal IOL approved by Food and Drug Administration (FDA) in the USA. It provides excellent visual acuity at distance, intermediate and near, very high spectacle independence, and very good patient satisfaction. The objective of this study was to conduct a cost-benefit analysis of AcrySof IQ PanOptix IOL vs. standard monofocal IOL, from patient perspective in the USA. Additionally, the incremental vision related quality of life gain and net monetary benefits of AcrySof IQ PanOptix technology for patients were assessed.

Setting

US patient perspective.

Methods

A de novo Markov model was developed with following health states: need for spectacles, patient reported bothersome visual disturbances (glare/haloes/starbursts), and death. Model inputs (transition probabilities, costs, discount rates, utilities, and event rates) were derived from the AcrySof IQ PanOptix FDA clinical trial, published literature, expert opinion, and other country specific sources. Model outcomes included total costs, quality adjusted life years (QALYs) and net monetary benefit. The model time horizon was lifetime (30 years) and cost and health outcomes were discounted at 3% per annum. In addition, sensitivity analysis and scenario analysis were conducted.

Results

Bilateral implantation of AcrySof IQ PanOptix provided greater vision related quality of life (QALY gain of 0.67) at an incremental cost of \$2,783 compared to monofocal IOL. The incremental cost per QALY gain was \$4,126/QALY. At commonly used willingness-to-pay (WTP) threshold of \$50,000 per QALY gain, net monetary benefit per patient with bilateral AcrySof IQ PanOptix IOL procedure was \$30,941. Results were most sensitive to the PanOptix PCIOL procedure cost, disutility due to wearing spectacles, cost of bifocal/progressive spectacles, and spectacle dependence rates. The robustness of results were further confirmed by one-way sensitivity analysis, probabilistic sensitivity analysis, and scenario analyses.

Conclusions

AcrySof IQ PanOptix IOL improves overall vision related quality of life and provides net monetary benefits for presbyopic cataract patients at commonly used WTP threshold of \$50,000 per QALY vs. monofocal IOLs. Presbyopic patients undergoing cataract surgery should be provided information on the clinical and cost benefits of AcrySof IQ PanOptix IOL for making informed treatment choices.







Comparison of visual outcomes after implantation of two diffractive trifocal toric intraocular lenses

First Author: A Benyoussef, France

Free Paper - Investigator Initiated Trial (#34835525)

10/9/2021 | 09:00 AM - 09:06 AM (CEST) | Hall 13 / Elicium Ballroom

Abstract Details

Purpose

To compare the performance of two diffractive trifocal toric intraocular lens designs in terms of refractive and visual acuity outcomes at different distances, rotation stability, different contrast VA and quality of vision.

Setting

University Hospital, Ophthalmology department, Brest, France.

Methods

In this prospective, multicenter, double blind, superiority study, 30 patients undergoing cataract surgery were randomized to receive one of two trifocal toric IOLs (PanOptix®, ALCON and Fine Vision PodF®, PHYSIOL). Outcomes analyzed 6+/- 2 weeks after surgery included binocular visual acuities at different distances, both uncorrected and corrected, astigmatism (by vector analysis), stability rotational (by measurement on photographs), defocus curve, quality of vision (with the SRD). The subjective quality of life and the patient satisfaction were also assessed, with by the NEI-RQL 42 questionnaire.

Results

The VA assessment seems in favor of PanOptix®toric for intermediate vision at 60 cm. In the 2 groups, 100% of the patients presented a VA < 0.1D logMAR in far vision, 75% in near vision, and for the intermediate distance (60cm), 83% of the PanOptix® group and 67% of the FineVision® group. Mean spherical equivalent was 0.24D +/-0.15D for PanOptix®toric and 0.0D +/- 0.40D for FineVision®toric. A percentage of successful astigmatism correction of 55% for PanOptix®toric and 60% for FineVision®toric is observed. Binocular defocus curves showed a plateau between 0.0D and -2.5D. The implants both appear stable at 1 month (< 3°). The reading speed is comparable between the 2 implants. Satisfaction is high, with a majority carrying out their activity's spectacle-free and we find halo-type glare as the main photic phenomena in both groups.

Conclusions

Toric version of multifocal IOLs is crucial to achieve emmetropia, required for optimized results. The 2 evaluated diffractive models confirm the interest of correcting corneal astigmatism starting at -0.75D with excellent outcome obtained with both. The slight difference found in this study for intermediate vision (60 cm) seems to be explained by a different optical concept between the 2 implants. The correction of astigmatism appears satisfactory, in particular due to the stability of the implant, and the quality of vision does not seem to be affected despite acceptable halos at night frequently described.







A prospective, comparative study of the whole range of vision outcomes between a trifocal IOL and an extended depth of focus IOL (PanOptix IOL and Tecnis Symfony IOL) in a Chinese population

First Author: G Zhang, China

Poster - Investigator Initiated Trial (#60043935)

Available Online

Abstract Details

Purpose

To compare whole range of visual outcomes, spectacle independence, and visual disturbances of PanOptix IOLs (TIOL group) versus Symfony IOLs (EDOF group) in a Chinese population.

Setting

A prospective, single site, non-randomized, comparative study in China/Xiamen eye Center, Xiamen University, Xiamen, Fujian, China.

Methods

37 subjects who underwent binocular cataract surgery were assigned to TIOL group (18 with 36 eyes) and EDOF group (19 with 38 eyes). Binocular uncorrected (UDVA) and best-corrected (BCDVA) distance visual acuities (5m), uncorrected intermediate (UIVA, 60cm) and near (UNVA, 40cm) visual acuities, distance-corrected intermediate (DCIVA, 60cm) and near (DCNVA, 40cm) visual acuities, modulation transfer function (MTF), spectacle independence and Chinese version validated Questionnaire for Visual Disturbance (QUVID) were evaluated 3 months postoperatively. Standardized logarithm of the minimum angle of resolution (logMAR) charts were used for VA measurement.

Results

Post-operative 3 months UDVA, BCDVA, UIVA-60cm, DCIVA-60cm, and MTF were not significantly different between groups (both P > 0.05). The TIOL group achieved significantly better UNVA-40cm (0.11 \pm 0.13 Vs 0.22 \pm 0.08), DCNVA-40cm (0.08 \pm 0.08 Vs 0.22 \pm 0.08) (both P < 0.05) and higher proportion of patients reporting never using spectacles for near vision than the EDOF group (83.33% Vs 47.37%, P < 0.05). QUVID questionnaire showed incidence of severe starbursts, halos, and glare were comparable in 2 groups 3 months after surgery (P > 0.05).

Conclusions

Compared to EDOF IOL, PanOptix IOL achieve better near-vision and higher spectacle independence, which resulted in superior whole range of visual outcomes with comparable visual quality in a Chinese population.







Clinical Outcomes with a Diffractive Trifocal Intraocular Lens – A Worldwide pooled analysis of prospective clinical investigations

First Author: T Kohnen, Germany

Poster - Alcon Initiated Trial (#A04431)

Available Online

Abstract Details

Purpose

To report the clinical and visual outcomes in a large cohort of subjects of different ethnicities implanted with a trifocal intraocular lens (IOL), the AcrySof PanOptix IOL Model (TFNT00) pooled from multiple clinical studies.

Setting

Pooled analysis of six prospective, controlled, multicenter clinical trials conducted in Australia, Japan, Korea, India, Germany, Netherlands, Italy, France, Spain, Denmark, USA, Brazil, Chile and Colombia evaluating the 3 to 6 months postoperative visual outcomes of subjects implanted bilaterally with AcrySof PanOptix IOL Model (TFNT00).

Methods

Descriptive summaries and graphical presentations of binocular Best-Corrected Distance VA (4m), Binocular Distance-Corrected intermediate VA (60/66 cm), Binocular Best Corrected Near VA (40cm), Binocular defocus curves were evaluated under photopic lighting conditions.

Results

Across studies, the average age of the study subjects (n=551) was approximately 63 years and mostly females (~60%). The mean Defocus curve VA from 0.00D to -3.00D ranged from 0.1 to 0.0 logMAR. Mean binocular distance-corrected and uncorrected VAs of 0.1 logMAR or better were achieved at distance (4 m), intermediate (60/66 cm), and near (40 cm).

Conclusions

The results from this pooled-analysis show very good visual performance (VA better or equal to 20/25) of the AcrySof IQ PanOptix IOL in photopic conditions across from distance to near distance and different levels of defocus. These benefits were observed in patients from different ethnicities and geographies around the World.







Quantification of functional intermediate and near range of acuity reserve of a Diffractive Trifocal Intraocular Lens – A Worldwide Pooled-analysis of prospective clinical investigations

First Author: R Lapid-Gortzak, The Netherlands

Free Paper - Alcon Initiated Trial (#A04431)

10/9/2021 | 08:00 AM - 08:06 AM (CEST) | Hall 13 / Elicium Ballroom

Abstract Details

Purpose

AUC metric is a useful tool to understand acuity reserve to changing visual demands as a function of optical defocus and distance. To quantify the functional range of intermediate and near visual acuity reserve of the trifocal intraocular lens (IOL), AcrySof IQ PanOptix IOL Model (TFNT00) in the largest cohort of subjects from different ethnicities.

Setting

A pooled-analysis of six prospective, controlled, multicenter clinical trials conducted in Australia, Japan, Korea, India, Germany, Netherlands, Italy, France, Spain, Denmark, USA, Brazil, Chile and Colombia evaluating the 3 to 6 months postoperative visual outcomes of subjects bilaterally implanted with the TFNT00 IOL.

Methods

Descriptive summaries and graphical presentations of photopic binocular defocus curve results overlaid with the visual acuity demand for a target size equivalent to 0.1 LogMAR (20/25) are plotted as a function of defocus to quantify the useful functional range of vision for physiologically relevant acuity demands. An area under the curve (AUC) metric was used to estimate the useful functional range of acuity reserve between 1m (1D) and 33 cm (3.0D).

Results

Across studies, the average age of the study subjects (n=551) was approximately 63 years and two thirds female. The mean Defocus curve VA from 0.00D to -3.00D ranged from 0.0 to 0.1 logMAR. The TFNT00 IOL provided 20/25 or better distance corrected VA from 40 to 60 cm. TFNT00 has \sim 2-3 lines of functional acuity reserve in the near range (-2.0 to -3.0D).

Conclusions

Acuity reserve analysis via AUC represents a novel methodology for interpreting defocus curves in terms of functional visual performance. This method demonstrated that the defocus curve of the TFNT00 IOL observed in patients from different ethnicities and geographies around the World provides sufficient acuity reserve to easily function in visual tasks in the near to intermediate distance range.







Video of a Novel Methodology for Measuring Intraocular Lens Performance via Acuity Reserve

First Author: R Lapid-Gortzak, The Netherlands

Video - Alcon Initiated Trial

Available Online

Abstract Details

Purpose

To validate a novel methodology of intraocular lens (IOL) assessment via acuity reserve analysis using area under the curve (AUC) to assess intermediate vision.

Setting

Study 1 was conducted at 17 sites in Australia, Chile, and Europe. Study 2 was conducted at 15 sites in Australia, Brazil, and Europe.

Methods

This video describes the analysis of acuity reserve using defocus curve results from 2 clinical trials (study 1: single-arm investigation of the AcrySof® IQ PanOptix® Trifocal IOL (model TFNT00; Alcon Research LLC); study 2: comparative investigation of AcrySof PanOptix Trifocal IOL vs the AT LISA® Trifocal IOL (model 839 MP; Carl Zeiss Meditec AG). Acuity reserve was calculated via AUC compared with visual demand (logMAR) at various distances. Study 1 validated the model; study 2 compared acuity reserve, for a range of defocus levels, for the 2 IOLs.

Results

The defocus curve (study 1) showed good visual acuity (i.e. > 20/25) at all defocus levels and the AUC estimate showed ≥ 2 lines of reserve at -2.5 D. Comparative post hoc analysis (study 2) demonstrated significantly improved acuity reserve with PanOptix vs AT LISA at 20 to 40 days postoperatively (P < .001) and 120 to 180 days postoperatively (P < .001).

Conclusions

Acuity reserve analysis via AUC represents a novel methodology for comparative IOL assessment, providing additional detail beyond defocus curve analysis. This method demonstrated that the PanOptix Trifocal IOL was superior to the AT LISA Trifocal IOL (model 839 MP) for visual acuity at near to intermediate distances.







Evaluation of short-term visual outcome of a diffractive trifocal intraocular lens (IOL) in Chinese myopic cataract patients

First Author: X Chen, China

Poster - Investigator Initiated Trial (#62206035)

Available Online

Abstract Details

Purpose	To evaluate short-term visual performance after implantation of a diffractive trifocal IOL (AcrySof IQ PanOptix) in Chinese myopic cataract patients.
Setting	Aier school of ophthalmology, Central south university, Changsha; Department of Ophthalmology, Shanghai Aier Eye Hospital; Department of Ophthalmology, Shanghai Aier Qingliang Eye Hospital.
Methods	23 Patients (39 eyes) who underwent cataract surgery combined with PanOptix IOL implantation with an axial length (AL) greater than 24.5mm were enrolled and divided into two subgroups: high myopic group (subgroup1: 26≤ AL≤ 30.5mm) and low-mediate myopic group(subgroup 2).
Results	There are 15 patients (25 eyes, 27.45 ± 1.32 mm) in subgroup 1 and 8 patients (14 eyes, 25.10 ± 0.37 mm) in subgroup 2. UDVA, UIVA and UNVA in subgroup 1 were 0.06 ± 0.09 , 0.01 ± 0.08 , and 0.02 ± 0.08 , while 0.07 ± 0.10 , 0.02 ± 0.08 and 0.06 ± 0.08 in subgroup 2, respectively. Each subgroup showed the similar defocus curve that reached at a vergence of 0.00 D (far focus) at peak, then dropped slightly at -1.00 D, ascended from -1.50 D (intermediate focus) and peaked again at -2.50 D (near focus) similarly. CS under photopic and mesopic conditions were similar in both subgroups.
Conclusions	PanOptix diffractive trifocal IOL provides satisfied visual outcome, including good uncorrected distance, intermediate, and near acuity with non-compromised visual quality in Chinese myopic cataract patients 1 month postoperatively.







A prospective, randomized comparative study of two commercially available trifocal IOLs in a Turkish patient population

First Author: Aylin Kilic, Turkey

Poster - Investigator Initiated Trial (#56979001)

Available Online

Abstract Details

Purpose

To compare the effectiveness of two commercially available trifocal intraocular lenses intended for the correction of presbyopia.

Setting

Department of Ophthalmology Medipol Mega University Hospital Istanbul, Turkey.

Methods

This is a single-center, investigator-initiated, randomized clinical study of adults suitable for phacoemulsification cataract surgery or refractive lens exchange, with or without astigmatism correction. Patients were randomized 1-to-1 to receive bilateral implantation of either the AcrySof IQ PanOptix IOL (Alcon, Ft Worth Texas) (study lens) or the Trinova IOL (VSY Biotechnology GmBH, Leinfelden-Echterdingen, Germany) (control lens). The primary effectiveness endpoint is superiority of binocular distance corrected intermediate visual acuity at 60 cm (DCIVA), with secondary assessments including uncorrected distance, intermediate (60 cm) and near (40 cm) visual acuity, contrast sensitivity, defocus curves and visual disturbance assessment.

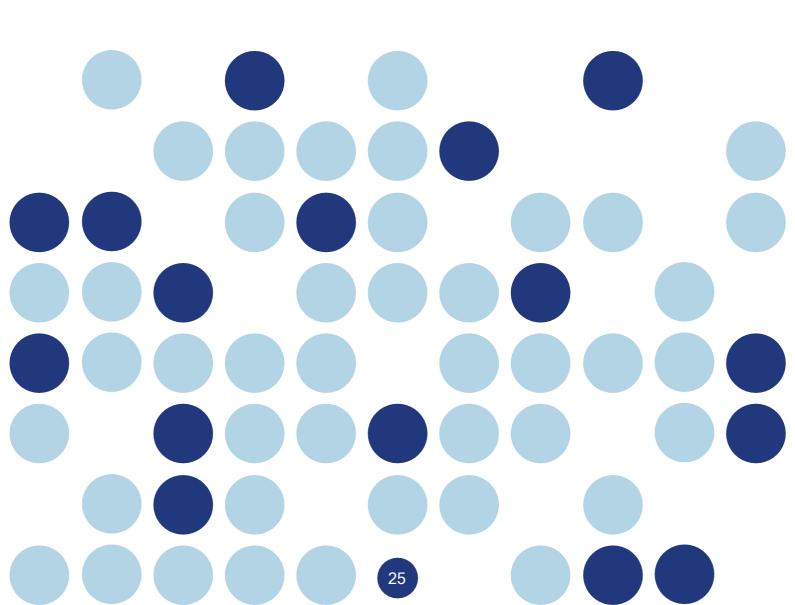
Results

To date, 17 patients have been enrolled in the study lens arm and 19 in the control lens. Mean patient age was 53 years (40 to 60). Mean preoperative spherical equivalent (SE) was 1.05 ± 2.50 D (+5.25 to -11 D) and mean cylinder was -0.48 ± 0.43 D (range -1.75 to 0 D). At 3-months, mean SE was 0.11 ± 0.28 D in the test group and -0.10 ± 0.73 D in the control group. Mean binocular logMAR UDVA was -0.03 ± 0.11 (test) and 0.01 ± 0.06 (control). Mean binocular logMAR UIVA was 0.04 ± 0.04 (test) and 0.22 ± 0.09 (control); binocular DCIVA 0.03 ± 0.07 (test) and 0.13 ± 0.11 (control) and binocular UNVA 0.02 ± 0.04 (test) and 0.19 ± 0.14 (control).

Conclusions

The initial analysis of this comparative trifocal IOL study indicate very good refractive outcomes with the first patients achieving excellent intermediate, near and distance visual acuity in both groups; The initial results indicate superiority of the PanOptix IOL for the primary endpoint of improvement in DCIVA, with a greater improvement in binocular intermediate vision by over 1 line.











Implanting monofocal low toric power IOL'S (T2) - Is it worth the extra work?

First Author: KG Gundersen, Norway

Poster - Investigator Initiated Trial (#49520381)

Available Online

Abstract Details

Purpose

To compare uncorrected and best-corrected visual acuity, low contrast acuity, residual refraction and ocular biometry after low cylinder power toric intraocular lens (IOL) or non-toric IOL implantation.

Setting

Single surgeon eye clinic.

Methods

This was a non-interventional comparative study of visual outcomes after uncomplicated cataract or refractive lens exchange surgery with either a low cylinder (T2) or non-toric (NT) IOL of similar design implanted (AcrySof® T2 IQ Toric IOL and AcrySof® IQ IOL). Subjects in both groups had to have been eligible for the low cylinder IOL based on biometry using Barretts toric calculator. They had to have uncorrected distance visual acuity (UDVA) of 20/32 (0.2 logMAR) or better at the time of their single diagnostic study visit. Clinical evaluation included the manifest refraction, visual acuity (VA), low contrast VA and ocular biometry.

Results

51 eyes implanted with T2 and 43 with NT were enrolled. The mean manifest refractive cylinder was statistically significantly lower (p < 0.01) and significantly more eyes had 0.25 D or less of refractive cylinder in the T2group (p = 0.03). The difference between groups was more evident with astigmatism against the rule. Uncorrected high contrast VA was statistically significantly better in the T2 group (p = 0.02) as was the percentage of eyes with 20/20 visual acuity (p = 0.05). Uncorrected low contrast visual acuity was not statistically significantly different in mesopic or photopic conditions. Low cylinder power toric IOL (T2) provided better uncorrected visual acuity and lower

Conclusions

residual refractive cylinder than a similar non-toric IOL after cataract surgery. Interestingly, the difference between groups was more evident with astigmatism against the rule compared to with the rule or oblique astigmatism. Investing the extra time to correct even low toric refractive errors provide better visual and refractive outcomes to the benefit for our patients.







Corneal incision enlargement in two preloaded intraocular lens injectors: an intraindividual in-vivo study

First Author: TM Yildirim, Germany

Poster - Investigator Initiated Trial (#42245927)

Available Online

Abstract Details

Purpose

The wound architecture, size and location of the corneal incision contributes to the amount of surgically induced astigmatism (SIA) in cataract surgery. The aim of this study was to assess enlargement of the clear corneal incision site and functional outcome in cataract patients, following the use of two preloaded intraocular lens (IOL) injectors.

Setting

The David J Apple International Laboratory for Ocular Pathology, Department of Ophthalmology, Heidelberg University Hospital, Heidelberg, Germany.

Methods

In this prospective, randomized, intraindividual comparative, clinical study, 58 paired-eyes were randomly assigned for implantation with two preloaded injectors: the AutonoMe with a Clareon IOL (Alcon, Fort Worth, USA) and the iSert with a Vivinex IOL (Hoya, Tokyo, Japan). The size of the corneal incision, 2.0 for the iSert and 2.2 for the AutonoMe, was measured before and after phacoemulsification, and after IOL implantation. Patients were examined 3 months after surgery to assess keratometry, subjective refraction, and visual acuity.

Results

The incision enlargement was 0.20 (\pm 0.10) mm for the AutonoMe and 0.29 (\pm 0.10) mm for the iSert, with statistically significant difference, P<0.05. The final wound size after IOL implantation with the AutonoMe was 2.41 mm, with the iSert 2.35 mm. The mean absolute SIA in the iSert eyes, was 0.50 (\pm 0.25) D, and in the AutonoMe eyes, it was 0.45 (\pm 0.20) D, P>0.05. The 3-month postoperative uncorrected and corrected distance visual acuity (UDVA and CDVA) were similar in both groups, with a UDVA of 0.10 and 0.12 logMAR and CDVA of -0.04 and -0.03 logMAR, respectively for Clareon and Vivinex.

Conclusions

The iSert injector caused more enlargement of the corneal wound during IOL implantation compared to the AutonoMe. Despite the initially different incision sizes, the final incision size was similar in both groups. Functional outcomes were similar in both groups.







Preloaded injectors used in a clinical study: videographic assessment and laboratory analysis of injector nozzle damage

First Author: R Khoramnia, Germany

Poster - Investigator Initiated Trial (#42245927)

Available Online

Abstract Details

Purpose

A clinical comparison of current preloaded IOL injectors combining different safety and performance aspects has yet to be presented. The aim of the presented study was to evaluate quality and duration of implantation of 2 preloaded intraocular lens (IOL) injectors and assess postimplantation damage.

Setting

The David J Apple International Laboratory for Ocular Pathology, Department of Ophthalmology, Heidelberg University Hospital, Heidelberg, Germany.

Methods

In this prospective, randomized, comparative study with laboratory investigation, implantation videos and postuse injectors from 60 paired eyes of 30 bilateral cataract patients were included. Patients' eyes were randomly assigned for implantation with 2 different preloaded injectors: the AutonoMe with a Clareon IOL (Alcon Laboratories, Inc.) and the iSert with a Vivinex IOL (Hoya Corp.). Videos were reviewed for events during the implantation procedure, and the duration of each step of implantation. Injectors' nozzles were examined under light and scanning electron microscopy. Damage was graded and correlated with the IOL power. Three-months postoperatively, IOLs were assessed for material changes.

Results

IOL delivery was without any critical events. The implantation took 56 seconds with the AutonoMe and 44 seconds with the iSert (P < .05). Most AutonoMe injectors (97%) showed no damage or slight deformation. In most of the iSert injectors (80%), short or extended cracks were present, and damage lengths correlated with the IOL power. All IOLs were free of material changes, including glistening, 3 months postoperatively.

Conclusions

Both preloaded IOL injectors allowed a safe and convenient IOL delivery. Implantation of the Clareon IOL took, on average, slightly longer than that of the Vivinex IOL, mostly due to a slower IOL unfolding. The AutonoMe showed less nozzle tip damage than that of the iSert.







Changes in Straylight in the Immediate Postoperative Period after Cataract Surgery

First Author: *N Reus*, *The Netherlands*

Poster - Investigator Initiated Trial (#41855129)

Available Online

Abstract Details

Purpose

Straylight is an optical phenomenon where light is scattered in the eye thereby reducing the contrast of the retinal image. With cataract surgery, the opacified lens is replaced for a clear artificial intraocular lens (IOL). This leads to a decrease in straylight and subsequent improvement of visual disturbances. However, it is not known how the level of straylight changes in the immediate postoperative period and when it can be deemed stable. The purpose of the present study is to study the amount of straylight in eyes of patients in the immediate postoperative period.

Setting

A prospective, single-center, single-surgeon pilot study with the objective to study the amount of straylight in eyes of 25 patients in the immediate postoperative period, study and compare the clarity characteristics of the Clareon and the Vivinex XY1 monofocal IOLs, and investigate which parameters may affect straylight after cataract surgery.

Methods

Interim and sub-analysis of subjects enrolled to date. Patients underwent uncomplicated cataract surgery by means of phacoemulsification in both eyes, 2 weeks apart. One eye was randomly selected to be implanted with a Clareon CNA0T0 IOL (www.alcon.com); the fellow eye received a Vivinex XY1 IOL (www.hoyasurgicaloptics.com). Cataract surgery was performed in the visually worst eye first. Straylight was measured with the C-Quant straylight meter (www.oculus.de) preoperatively, and 1 day, 1 week, 1 month, and 3 months after surgery.

Results

To date, 9 subjects have been enrolled; data up to 3 months have been obtained in 4. Preoperative straylight (mean [SD]) was 1.45 (0.19) log(s). Straylight 1d, 1w, 1m, and 3m after surgery was 1.24 (0.18), 1.10 (0.19), 1.14 (0.22), and 1.14 (0.24) log(s) for the Clareon IOL. For the Vivinex IOL, it was 1.40 (0.17), 1.14 (0.21), 1.11 (0.15), and 1.25 (0.18) log(s). Straylight values at 1w were statistically significantly lower than 1 day after surgery for both IOLs (p<0.05). Straylight at 1 week was comparable to the pseudophakic norm (p=0.14 and p=0.42).

Conclusions

Initial results show that straylight values already appear to be stable 1 week after uncomplicated cataract surgery. In addition, straylight values with Clareon and Vivinex XY1 IOLs are very comparable to the pseudophakic norm. As this study is ongoing, additional results will be presented in the paper.







Effectiveness and Safety of the Clareon Monofocal Intraocular Lens: Outcomes From a 12-Month Multicenter Study

First Author: W Maxwell, USA

Free Paper - Alcon Initiated Trial (#ILJ466-C-001)

10/10/2021 | 08:06 AM - 08:12 AM (CEST) | Hall 13 / Elicium Ballroom

Abstract Details

Purpose

This registration study assessed effectiveness and safety of the novel Clareon intraocular lens (IOL; model SY60WF; Alcon Vision LLC).

Setting

Sixteen clinical sites in the United States.

Methods

This was a prospective, single-arm, unmasked clinical trial in subjects requiring cataract surgery. Subjects were adults ≥22 years old. Following phacoemulsification, 350 subjects received the Clareon IOL unilaterally; 342 completed the study. Monocular corrected distance visual acuity (CDVA) and uncorrected distance visual acuity (UDVA) were evaluated. The primary effectiveness endpoint was the percentage of subjects with CDVA ≥0.3 logMAR at Month 12. Safety was assessed by monitoring adverse events (AEs). Visual acuity and safety outcomes were compared with historical safety and performance endpoint (SPE) rates.

Results

At 12-months, 99.7% of subjects achieved monocular CDVA \leq 0.3 logMAR; 99.7% and 86.8% achieved monocular CDVA of \leq 0.34 (20/40 or better) and \leq 0.04 logMAR (20/20 or better), respectively. Over 95% of subjects achieved mean monocular UDVA \leq 0.3 logMAR; 97.1% and 57.6% achieved monocular CDVA of \leq 0.34 and \leq 0.04 logMAR, respectively. Mean monocular CDVA and UDVA were -0.052 and 0.043 logMAR, respectively. AEs were within SPE limits. The most common nonserious ocular AE was posterior capsule opacification (5.4%). Serious AEs were less than1% and none were assessed as related to the device. There were no observations of glistenings at 12 months.

Conclusions

Results of this study support the effectiveness and safety of the Clareon IOL. Visual acuity outcomes with the Clareon IOL exceeded the SPE rates for monocular CDVA, and AEs were within the limit of historic SPE rates.







Two-Year Multinational Evaluation of a New Aspheric Hydrophobic Monofocal Intraocular Lens

First Author: RMMA Nuijts, The Netherlands

Free Paper - Alcon Initiated Trial (#ILI466-P003)

10/10/2021 | 08:00 AM - 08:06 AM (CEST) | Hall 13 / Elicium Ballroom

Abstract Details

Purpose

To report the visual acuity, refractive, and safety outcomes of the Clareon® (Alcon Vision LLC) aspheric, hydrophobic, monofocal, intraocular lens (IOL) 2 years after implantation.

Setting

Conducted at study centers in Australia (n = 3), France (n = 2), Germany (n = 2), Italy (n = 2), the Netherlands (n = 2), Spain (n = 5), and the United Kingdom (n = 3).

Methods

This is a prospective, multinational, single-arm trial assessing the long-term (3-year) safety and effectiveness of the Clareon® IOL implanted bilaterally in adults (≥ 22 years of age) who required bilateral cataract extraction (www.clinicaltrials.gov identifier: NCT03316885). Subjects are attending 12 study visits (9 post-implantation) over approximately 36 months. The primary study objectives are to demonstrate the long-term (3-year) visual acuity and adverse event (AE) outcomes of the Clareon IOL, and the one-year visual acuity and AE outcomes compared to historical safety and performance endpoint rates as reported in EN ISO 11979-7:2014. We present the 2 year interim results.

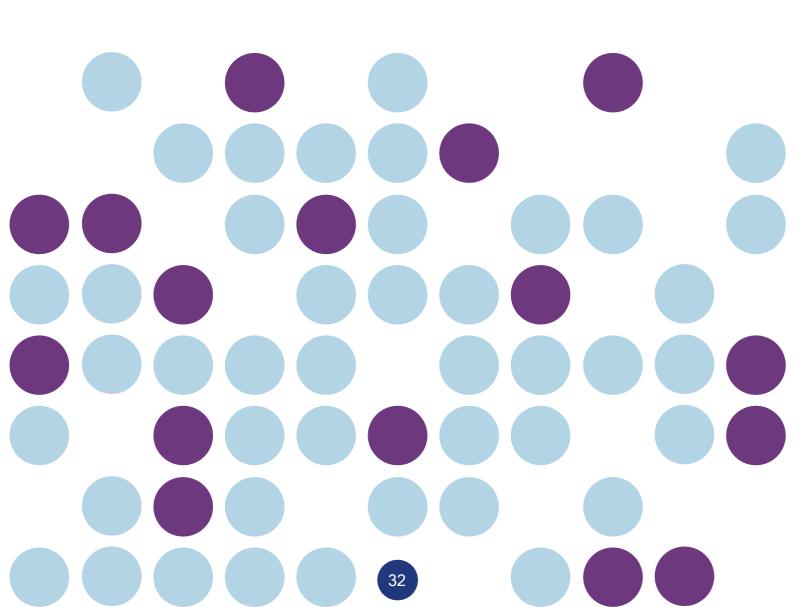
Results

245 subjects were enrolled; 215 were implanted. At 2 years, postoperative mean corrected distance visual acuity (CDVA) was 0.03 logMAR in first and second eyes, and >96% of eyes had CDVA 20/25 or better. Mean manifest refractive spherical equivalent was within target (emmetropia) by 1-week and maintained at 0.06 D in first and second eyes at 2 years. There were no unanticipated AEs. Clinically significant posterior capsule opacification (PCO) was reported for 3 first (1.4%) and 5 second (2.4%) eyes, and clinically significant PCO requiring Nd:YAG laser capsulotomy was reported for 3 first (1.4%) and 5 second (2.4%) eyes.

Conclusions

The 2-year visual outcomes were excellent and had stable refractive results. There were no unanticipated AEs, and very low rates of PCO and Nd:YAG capsulotomies were observed.











Agreement of the Aladdin, AL-Scan, Argos, IOLMaster 700, Lenstar LS 900 and OA-2000 optical biometers

First Author: R Montés-Micó, Spain

Free Paper - Investigator Initiated Trial (#56714317) 10/10/2021 | 04:57 PM - 05:03 PM (CEST) | Hall 11

Abstract Details

Purpose

To evaluate the agreement between various biometric parameters using six opticalbiometers based on different optical technologies.

Setting

University of Valencia, Spain.

Methods

In this study 150 eyes of 150 patients were measured with the Aladdin, AL-Scan, Argos, IOLMaster 700, Lenstar LS 900 and OA-2000 optical biometers. Keratometry (K1 and K2), J0 and J45 vectors, central corneal thickness (CCT), anterior chamber depth (ACD), lens thickness (LT), axial length (AL), white-to-white (WTW) and pupil size (PS) were measured with each device by the same examiner. The agreement between the biometers was assessed by applying a Bland-Altman analysis. The average difference, the confidence interval (CI) of the average difference at 95%, and 95% limits of agreement (LoA) were also ascertained.

Results

We found statistically significant differences between biometers for all parameters evaluated (p<0.001) varying as a function of the parameter analyzed. The LoA-width of some comparisons for K1 and almost all for K2 were >0.50 D. A similar pattern was found for J0/J45. For CCT, quite a lot comparisons showed LoA-width values of >25µm. LoA-width for ACD ranged from 0.366 to 0.175 mm and for LT was about 0.2 mm. AL showed a highest LoA-width of 0.225 mm. The LoA-width for WTW was, in most cases, about $\geq\!0.50$ mm. The LoA-width for PS ranged from 1.578 to 3.541 mm.

Conclusions

The outcomes found by the six biometers showed statistically significant differences between most ocular parameters. Depending on the specific parameter and its use, the biometers may still be interchangeable since the clinical impact may be negligible.







Comparison of Refractive Prediction Error after Cataract Surgery in Long- and Short-Axial length Eyes between Optical Biometer with Segmented Refractive Index and Traditional Optical Biometer Using Equivalent Refractive Index

First Author: T Kojima, Japan

Poster - Investigator Initiated Trial (#59244749)

Available Online

Abstract Details

Purpose

To compare the postoperative refractive prediction error (RPE) after cataract surgery in long axial length (≥26 mm: group L, 90 eyes) and short axial length (≤22 mm: group S, 44 eyes) eyes between optical biometer using segmented refractive index (SRI) and a traditional optical biometer using equivalent refractive index (ERI).

Setting

Multicenter study with 5 sites in Japan.

Methods

The study included 461 eyes of 461 patients (mean age 73.8±8.4 years) who underwent cataract surgery. IOL power calculation has performed using Barrett UII, and RPE has compared between SRI biometer (ARGOS) and ERI biometer (IOLMasterTM700, OA-2000). The cases were randomly divided into two groups, a learning group and a validation group, and the optimization constants were determined in the learning group for the SRI biometer. The optimization constants were then applied to the validation group and compared with the results of ERI biometer.

Results

The RPE (mean \pm standard deviation diopter (D)) in the ERI and SRI biometer were significantly different in group L (90 eyes) with 0.08 \pm 0.41D and -0.09 \pm 0.42D, respectively, and in group S (44 eyes) with 0.19 \pm 0.53D and 0.31 \pm 0.47D, respectively (group L: p < 0.0001, group S: p = 0.033). The RPE of the validation group using optimization constants for SRI biometer in the group L has significantly smaller than that using ERI biometer (0.00 \pm 0.41D, p = 0.0014), and no difference in the group S (0.18 \pm 0.53D, p = 0.892).

Conclusions

The RPE using the SRI biometer values has slightly myopic in the long axial length eyes and hyperopic in the short axial length eyes compared to that using the ERI biometer, and optimization of the Barrett formula constants for SRI biometer achieved the better RPE in the long axial length eyes than the traditional ERI biometer and similar accuracy in short axial length eyes.







Evolution of fluid system in cataract surgery

First Author: H Suzuki, Japan

Video - Investigator Initiated Trial (#59222157)

Available Online

Abstract Details

The evolution of the fluid system in cataract surgery is remarkable. We presented a novel method for observation of the anterior chamber using slitlamp "slit side view" in 2017 and 2019 ASCRS. In this time, we visualized the relationship between changes in intraocular pressure and the anterior chamber depth. Usefulness of the new handpiece was also verified.







Clinical Burden Associated with Uncontrolled Intraocular Pressure in Cataract Surgery

First Author: C Hsiao, USA

Poster - Alcon Supported

Available Online

Abstract Details

Purpose

During cataract surgery, deviation of intraocular pressure (IOP) from physiological ranges is often transient, but can lead to poor patient outcomes in some cases. The purpose of this literature review was to investigate the complications associated with uncontrolled intraoperative IOP.

Setting

N/A

Methods

A targeted literature search was conducted in PubMed. The search was designed to target English language studies that analyzed complications associated with uncontrolled IOP during cataract surgery. The search was not restricted by date of publication or study design.

Results

Seven articles were identified. Deviation from physiological IOP can cause complications in cataract surgery. Large fluctuations may induce corneal endothelium damage. The sudden IOP drop during occlusion break surge decreases anterior chamber depth, which may result in posterior capsule rupture (PCR). Elevated IOP impairs ocular blood flow and may increase PCR risk by breaking down the posterior capsule-anterior hyaloid membrane barrier. High IOP system settings (maximum 85 mm Hg) significantly increase day-1 postoperative corneal edema (12% vs. 4%, *P*=0.04) and anterior segment inflammation (Cells: 30% vs. 6%; Flare: 30% vs. 7%; *P*=0.01) versus low IOP settings (maximum 69 mm Hg).

Conclusions

Uncontrolled IOP during cataract surgery is associated with an increased risk of PCR and postoperative complications. This review highlights the importance of monitoring and controlling intraoperative IOP to minimize fluctuations and prolonged exposure to high IOPs.







Cataract Equipment and Diagnostics

Predictive accuracy of the Optiwave Refractive Analysis (ORA) intraoperative aberrometry device for the new Clareon monofocal IOL

First Author: L Spekreijse, The Netherlands

Free Paper - Investigator Initiated Trial (#42147873) 10/10/2021 | 04:45 PM - 04:51 PM (CEST) | Hall 11

Abstract Details

Purpose

To evaluate refractive outcomes for the Clareon® monofocal IOL in terms of achieved target refraction for the ORA® Intraoperative Wavefront Aberrometry device (Alcon Laboratories,Inc.) and preoperative noncontact biometry.

Setting

University Eye Clinic Maastricht, Maastricht University Medical Center, the Netherlands.

Methods

Prospective observational clinical trial. Patients with bilateral age-related cataracts undergoing phacoemulsification, either by delayed sequential surgery or on the same day, were included in the study. Exclusion criteria were an increased risk of refractive surprise or complicated surgery. Implanted IOL power was based on noncontact optical biometry data using the Barrett Universal II formula (BU-II), optimized for the Clareon®IOL. Postoperative subjective refraction was measured four to six weeks after surgery. Catquest-9SF questionnaires were completed preoperatively and three months after surgery.

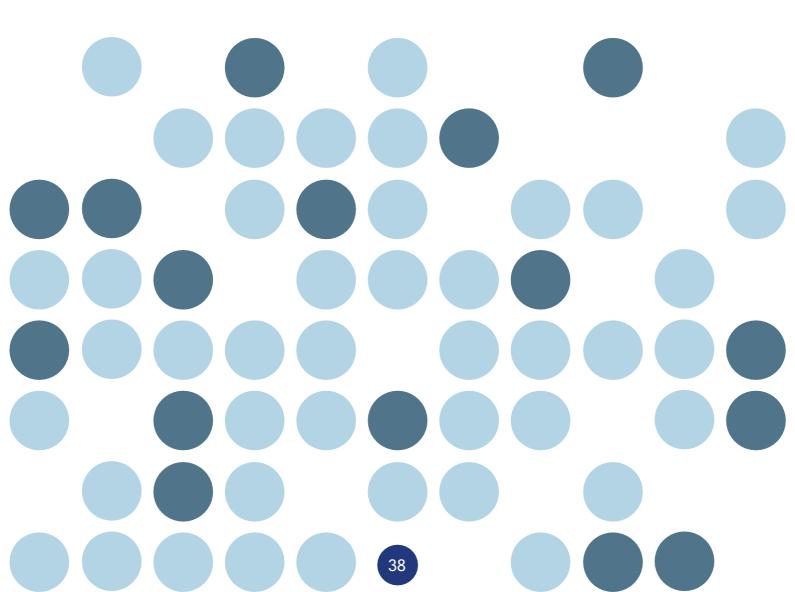
Results

One hundred eyes (51 patients) were included. The percentage of eyes within 1.0D, 0.75D, 0.50D and 0.25D of target for ORA vs. BU-II were 84%, 72%, 57% and 21% vs. 97%, 88%, 77% and 53%, respectively. Mean absolute prediction error was significantly higher for ORA vs. preoperative biometry (P<0.001). After global optimization, the prediction accuracy of ORA improved significantly (P<0.001). Catquest-9SF questionnaires showed improved levels of ability at three months after surgery (P<0.001).

Conclusions

This study showed lower percentages of eyes within target refraction for ORA (prior to lens constant optimization) compared to the BU-II formula when implanting the Clareon®IOL. However, prediction accuracy of ORA improved significantly after global optimization. Therefore, further intraoperative measurements, postoperative measurements, and optimization are needed to improve the ORA prediction for this IOL.

Lasers









StreamLightTM Single-Step Transepithelial Photorefractive Keratectomy (PRK)

First Author: D Gunn, Australia

Poster - Investigator Initiated Trial (#63571029)

Available Online

Abstract Details

Purpose

Transepithelial PRK was first described as a method of reducing post-operative pain and corneal haze and to speed visual recovery compared to conventional PRK. However, the initial two-step method of transepithelial PRK resulted in significant stromal dehydration, hyperopic shift, and inconsistent ablation of the peripheral epithelium. In recent years, there has been renewed interest in transepithelial PRK with the revised single-step method eliminating these issues. This study reports the 3-month safety and efficacy of a single-step, Transepithelial PRK using the StreamLightTM protocol.

Setting

Private Ophthalmology clinic, Brisbane, Australia.

Methods

In this retrospective single center consecutive case series, single-step transepithelial PRK was performed on 102 consecutive eyes, by a single surgeon. Epithelial and refractive ablation were performed using the Wavelight EX500 Excimer laser, with a 10 second interval between the two modes. The Alcon WaveLight Wavefront Optimised Profile nomogram was used for all eyes, except for those with hyperopia and mixed astigmatism where the Wellington Eye Clinic nomogram was used. Postoperative assessments were performed at 1 week, 1 month, and 3 months, including visual acuity and subjective refraction.

Results

83 eyes completed 3-month follow up and were included in analysis. Preoperative spherical equivalent refractive error (SER) ranged from -7.50 to +3.00 D, and astigmatism from 0.00D to -4.00 D. By 3 months follow up, 94.1% of eyes had UDVA of LogMAR 0 or better, the mean SER was -0.05 \pm 0.35D and the mean astigmatism was -0.36 \pm 0.36D. 78 eyes (94.0%) were within \pm 0.50D of the target sphere and 68 (81.9%) were within \pm 0.50D the target astigmatic correction. Three eyes (3.6%) lost 1 line in CDVA and no eyes lost more than 1 line in CDVA.

Conclusions

StreamLightTM transepithelial PRK is a safe and effective procedure utilizing the revised single-step method and eliminates the issues faced in the initial two step transepithelial PRK procedure. Good refractive predictability was found at three months follow up.







Single-Step Transepithelial PRK (tPRK) vs conventional PRK: Refraction, corneal aberrometry and densitometry comparison

First Author: J Aramberri, Spain

Free Paper - Investigator Initiated Trial (#63571029) 10/8/2021 | 06:24 PM - 06:30 PM (CEST) | Hall 11

Abstract Details

Purpose

To describe and compare corneal densitometry, subjective refraction, visual acuity and corneal Higher Order Aberrations in patients after corneal refractive surgery: Singlestep transepithelialPRK vs alcohol-assisted PRK.

Setting

Begitek Miranza Clínica Oftalmologica. San Sebastián, Spain.

Methods

This retrospective, observational case series comprised 260 eyes from 135 patients who underwent single-step transepithelialPRK (tPRK) or alcohol-assisted PRK (aaPRK). The WaveLight EX500 excimer laser (Alcon Laboratories, Inc.) was used in all cases. Mean age was 34.38 ± 10.68 years. Preop MRSE was -2.89 ± 1.64 D. Visual acuity, refraction and Pentacam HR measurements were performed at the preoperative visit and at 3 months follow-up visit. Pentacam software was used to assess corneal optical densitometry in various ring-shaped zones for different corneal depths and anterior corneal higher order aberrations (6 mm area of analysis).

Results

There were no statistically significant differences in visual acuity and postoperative refraction. Corneal densitometry did not show statistically significant differences in all areas studied except for the central 2mm zone in the anterior 120um layer (GSI 21.32 \pm 1.87 and 22.15 \pm 3.01 in aaPRK and tPRK respectively). HOA RMS showed statistically significant differences (p<0.001): HOA 0.55 \pm 0.15 μ m and 0.66 \pm 0.20 μ m, and Z(4,0) 0.37 \pm 0.15 μ m and 0.47 \pm 0.15 μ m for aaPRK and tPRK respectively.

Conclusions

Both aaPRK and tPRK using a single-step, "no touch" technique, demonstrated comparable visual and refractive outcomes. Differences in anterior central corneal densitometry and HOA were observed, but these were not clinically relevant.







Topography-Guided LASIK Versus Small Incision Lenticule Extraction (SMILE) for Myopia and Myopic Astigmatism: 4 year data of A Randomized, Prospective, Contralateral Eye Study

First Author: AJ Kanellopoulos, Greece

Free Paper - Investigator Initiated Trial (#18780061) 10/9/2021 | 09:09 AM - 09:15 AM (CEST) | Auditorium

Abstract Details

Purpose

To compare the safety and efficacy of topography-guided LASIK vs. contralateral eye SMILE for myopia and myopic astigmatism correction.

Setting

LaserVision Clinical & Research Eye Institute, Athens, Greece.

Methods

This prospective, randomized contralateral eye study included 44 eyes of 22 patients with bilateral myopia or myopic astigmatism. Treated eyes were divided into two groups: 22 eyes were treated with topography-guided LASIK and the fellow eye of each patient was treated with SMILE. The following parameters were evaluated preoperatively and up to 48 months postoperatively: uncorrected distance vision acuity (UDVA), corrected distance vision acuity (CDVA), refractive error, corneal keratometry, contrast sensitivity and retreatments.

Results

At 48 months, 92.4% of the LASIK group and 79.2% of the SMILE group had UDVA of 20/20 (P < .002) and 62.3% and 34.5%, respectively, had UDVA of 20/16 (P < .002). Spherical equivalent refraction (± 0.50 D) was 95.5% for the LASIK group and 76.3% for the SMILE group (P < .002). Residual refraction cylinder (≤ 0.25 D) was 81.8% for the LASIK group and 50% for the SMILE group (P < .001). 2 eyes of the Smile group underwent retreatment for -0.75 sphere, - 0.50 astigmatism at 14 months and -0.25 sphere and -1.00 cylinder in case 2 at 23 months.

Conclusions

Topography-guided LASIK was superior in all visual performance parameters studied, over long-term follow-up. The main difference between the two techniques likely derives from the eye tracking, cyclorotation compensation, and active centration control in the LASIK technology studied in contrast to the current technology available with SMILE-like procedures.







Astigmatism reduction with femtosecond laser-assisted corneal arcuate incisions combined with cataract surgery: comparison of two nomograms

First Author: P Casas, Spain

Poster - Investigator Initiated Trial (#38355109)

Available Online

Abstract Details

Purpose

To compare the effectiveness of two nomograms of femtosecond laser arcuate corneal relaxing incisions (CRIs) in reducing corneal direct astigmatism during cataract surgery.

Setting

Clinical University Lozano Blesa Hospital, Zaragoza, Spain.

Methods

All selected eyes were subjected to LenSx (Alcon) femtosecond-assisted cataract surgery and treatment for astigmatism was added in the same surgical act .

NOMOGRAM 1, based on Donnenfeld nomogram, place CRIs at 9 mm with 80% depth. where the Arc arc length was 35° or 44° depending on preoperative astigmatism.

NOMOGRAM 2, based on Woodcock nomogram, place CRIs at 8.0 mm with 90% depth where the. Aarc length was 42° or 50° depending on preoperative astigmatism. The primary outcome measure was the change in corneal astigmatism from preoperative to one month after surgery using Alpins vector analyses.

Results

Twenty-eight eyes of 28 patients with cataract and Placido disk-measured direct corneal astigmatism between 1.5 D and 2.5 D were included. Nineteen eyes were treated with nomogram 1 and 9 eyes with nomogram 2. The mean correction index (CI) was 0.36 ± 0.21 in nomogram 1 and 0.77 ± 0.22 in nomogram 2 (p= 0.06). The flattening index (FI) was 0.26 ± 0.26 in nomogram 1 and 0.88 ± 0.71 in nomogram 2 (p= 0.05). There were no significant differences in success index (SI) between groups. All patients improved the uncorrected visual acuity after surgery.

Conclusions

Femtosecond CRIs coadjuvant to cataract surgery allows to treat moderate degrees of keratometric astigmatism. Woodcock nomogram, with greater depth of action, less distance to the visual axis and longer arc lengths presents differences in results compared to Donnenfeld's nomogram. CI and FI closer to 1 in Woodcock nomogram show more predictable results than Donnenfeld's nomogram in moderate direct astigmatisms.







Cataract Surgery Complication Rates in Residency Programs: A Targeted Literature Review

First Author: J Pan, USA
Poster - Alcon Supported

Available Online

Abstract Details

Purpose

Residency programs serve as a gateway to train the next generation of surgeons. While residents proceed through the learning curve, a higher rate of complications may occur. Certain technologies could allow for the learning process needed while lowering the impact it can have on patients. A targeted literature search was conducted to contrast the overall complication rates and complication rates in complex patient cases for residents-in-training and experienced surgeons. Both conventional and femto-second laser-assisted cataract surgeries (FLACS) were reviewed.

Setting

N/A

Methods

The PubMed database was searched in August 2020, utilizing the following terms: cataract surgery OR phacoemulsification AND residency. The search was limited to the last 10 years (2010-2020). Conference abstracts published by the European Society of Cataract & Refractive Surgeons, American Academy Ophthalmology, and the American Society of Cataract and Refractive Surgery over the last three years were screened. Outcomes were overall complication rates and complication rates for complex cases when using conventional cataract surgery or FLACS.

20 studies were identified (single-arm = 14; comparative = 6). For conventional cataract surgery, overall complication rates for residents ranged from 1.3%-15.1% (n=7) and 0.8%-

Results

5.8% (n=4) for attendings. In complex cases, residents ranged from 6.5%-63.1% (n=5) and 3.5%-53.0% (n=3) for attendings. Common intraoperative complications by residents were posterior capsule rupture and vitreous loss (n=6, 0.9%-7.0% and 0.2%-6.7%). Among residents, a similar rate of intraoperative complications was observed between FLACS and

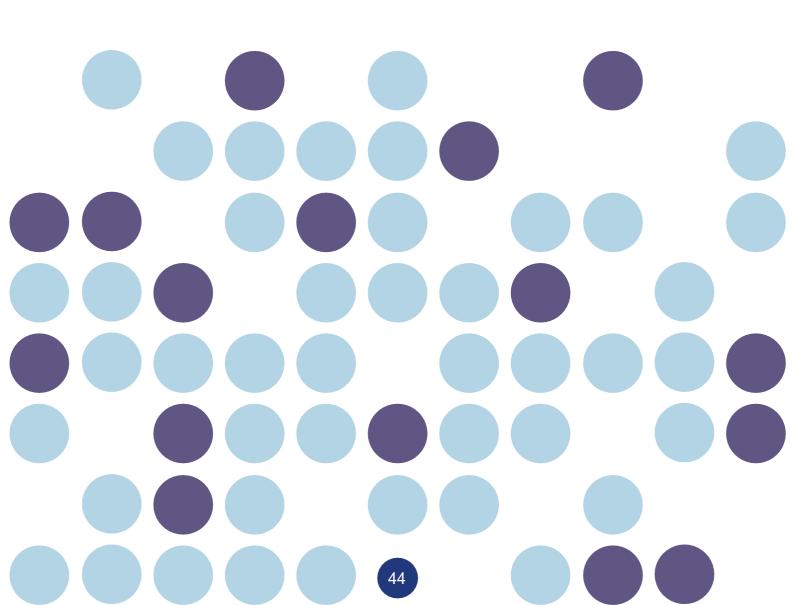
conventional cataract surgery (manual small-incision cataract surgery or phacoemulsification) in comparative studies (n=5). However, complex case complication rates may be lower for residents using FLACS compared to conventional surgery (n=2). Complications were more likely to occur during surgery performed by a resident than surgery performed by an experienced surgeon, overall and in complex cases. Technologies such as FLACS may be helpful in lowering complication rates in complex

cases for trainees in residency programs. Advanced technologies should be considered to address common intraoperative complications by residents. Remediating complications such as posterior capsule rupture that occur during phacoemulsification can improve patient outcomes and reduce impact on patients.

Conclusions



Dry Eye and Ocular Health









Dry Eye and Ocular Health

Comparison of two different preservative free lubricant eyedrops on the ocular surface in the early post-op of PRK. A prospective randomized, controlled pilot study.

First Author: R Cañones-Zafra, Spain

Free Paper - Investigator Initiated Trial (#60341187) 10/8/2021 | 06:00 PM - 06:06 PM (CEST) | Hall 11

procedure.

Abstract Details

Purpose

To compare the effect of a conventional preservative free (PF) artificial tear containing carmellose vs another one also PF, containing hyaluronic acid and hydroxypropyl-guar (HA+HP-guar), on the healing of the corneal epithelium and the ocular discomfort after bilateral photorefractive keratectomy (PRK) surgery.

Setting

Clinica Novovision Madrid, Spain.

Methods

In this on-going randomized, dual-arm, prospective, interventional, single masked study, a total of 34 eyes scheduled to have PRK to correct myopia were randomized in two groups. 22 eyes in the (HA+HP-guar) group (study eyes) and 12 in the carmellose artificial tear group (control eyes). In both groups ocular surface was evaluated at post-op days 1, 4, 7 and at the 1 month, measuring the diameter of the de-epithelized cornea and the degree of fluorescein punctate staining using the Oxford scale. A Visual Analogic Scale (VAS) pain evaluation was performed by the patient at every post-op visit.

Results

Both groups were comparable in terms of age, gender and preop refractive error magnitude (p<0.05). Statistically significant smaller de-epithelized area was observed at post-OP day 4 in the study group vs controls (0.13+/-0.4 mm vs 0.65+/-0.8 mm p=0.03). A statistically significant less ocular pain was observed at day 3 post-OP in the (HA+HP-guar) group (3.7+/-2.7 vs 5.3+/-2.3 p=0.04). No statistically significant differences were observed beyond post-op day 7 on the healing of the corneal epithelium and the self-perceived ocular discomfort between the two groups. The current ongoing study shows a faster healing of the corneal epithelium with the use of topical lubricants containing (HA+HP-guar) compare with the use of conventional carmellose artificial tears. This could be due to the trophic effect that the combination of hyaluronic acid and hydroxypropyl-guar could have on the epithelial cells of the cornea. This faster recovering seems to have a significant additional benefit reducing the ocular pain-discomfort in the first days after PRK surgery. Both artificial tears show no differences in the visual or refractive outcomes of the

Conclusions







Dry Eye and Ocular Health

Effect of preoperative tear film stability and osmolarity in the healing of corneal ephithelium and ocular discomfort after a photorefractive keratectomy surgery.

First Author: R Cañones-Zafra, Spain

Poster - Investigator Initiated Trial (#60341187)

Available Online

Abstract Details

Purpose

To evaluate preoperative tear film stability and osmolarity and its effect on the healing of the corneal epithelium and the ocular discomfort after bilateral photorefractive keratectomy (PRK) surgery.

Setting

Clinica Novovision Madrid, Spain.

Methods

A total of 32 eyes scheduled to have PRK to correct myopia were evaluated preoperative to obtain an automated assessment of tear film stability through non-invasive Keratograph® tear breakup time (NIKBUT) and its tear film osmolarity. Ocular surface was evaluated at post-op days 1, 4, 7 and at the 1 month, measuring the diameter of the de-epithelized cornea and the degree of fluorescein punctate staining using the Oxford scale. A Visual Analogic Scale (VAS) pain evaluation was performed by the patient at every post-op visit.

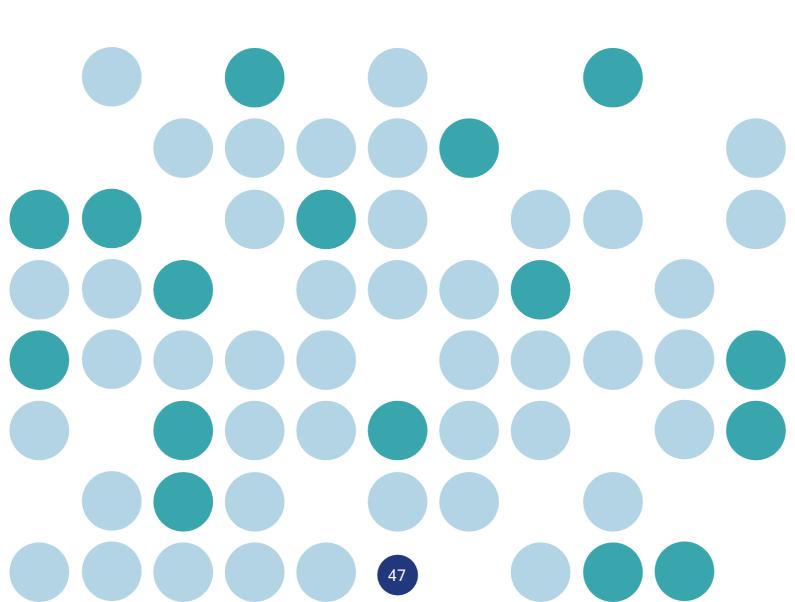
Results

Preoperative mean of inicial and mean NIKBUT was 13.66+/-7.04 sec (2.68-25), and 16.57+/-60.8 sec (6.17-25) respectively. Mean preoperative tear film osmolarity was 304.7+/-9.9 mOsm/L (288-325). No statistically significant correlations were observed between these two tear film parameters and the diameter of the de-epithelized cornea, the ocular pain, and visual or refractive outcomes. Only a statistically significant correlation was observed between a higher preoperative mean NIKBUT and a less grade of punctate staining in day 7 post-op (p:0.05 r:0.33).

Conclusions

The current study shows no correlation between preoperative tear film stability and osmolarity and the healing of the corneal epithelium, the ocular discomfort, and visual or refractive outcomes after a PRK surgery. Only a higher mean NIKBUT seems to have a significant additional benefit in fluorescein punctate staining grade in the Oxford scale at day 7 post-op.











Nd:YAG capsulotomy rates at 5 years after cataract surgery: a multivariate analysis from a real-world evidence study in Spain

First Author: D O'Boyle, Ireland

Free Paper - Alcon Initiated Trial (#ILA247-H001)

10/10/2021 | 09:00 AM - 09:06 AM (CEST) | Hall 13 / Elicium Ballroom

Abstract Details

Purpose

Posterior Capsule Opacification (PCO) is understood to be a multifactorial complication affected by several factors such as age, ocular comorbidities and IOL material and design. If untreated, PCO can result in reduced visual acuity, impaired contrast sensitivity and glare disability. Nd:YAG laser capsulotomies are performed to treat the condition, resulting in additional burden to patients and health care systems. The aim of this study is to assess the long term impact of IOL choice and other PCO related factors on subsequent Nd:YAG capsulotomy rates, from a Spanish hospital perspective.

Setting

This study is a retrospective cohort analysis of anonymised electronic medical records of cataract patients from two large Spanish regional hospitals of the Ribera Salud group in the Torrevieja-Vinalopó healthcare area, who are main providers of ophthalmic procedures in the Alicante region.

Methods

De-identified electronic healthcare records for 9,545 patients aged 65+ years who underwent cataract surgery during the period Jan 2007 - Dec 2017 from two large regional hospitals in Spain, were retrospectively analysed. 3,955 eyes were followed more than 5 years. At 5 years, Nd:YAG incidence proportions (95% CI) and adjusted odds ratios were calculated through multivariate logistic regression. Variables included in the multivariate analysis included: IOL implanted at the time of surgery, age, gender and related copathologies.

Results

At 5 years post-surgery, Nd:YAG incidence was significantly lower for AcrySof compared to the other models: 8.8% (CI 6.0%-11.6%) for AcrySof, 44.3% (CI 42.4%-46.2%) for Zeiss Asphina, 47.4% (CI 44.1%-50.6%) for AJL, 44.0% (CI 33.4%-54.7%) for IOL Tech. Adjusted odds for Nd:YAG capsulotomy were significantly higher for other IOLs compared with AcrySof (OR's = 9.54, 8.35, 8.02 for AJL LLASY60, Zeiss Asphina and IOL Tech Stabibag respectively (p < 0.001). Age at index (per 1 year increase OR: 0.98) and female gender (OR: 1.41) were also significantly associated (p < 0.001) with Nd:YAG capsulotomy. This study generated robust real-world evidence confirming the relationship between the IOL implanted at the time of cataract surgery and the incidence of Nd:YAG capsulotomy to treat PCO. After adjusting for factors associated with PCO, the results indicate that AcrySof IOLs have significantly lower Nd:YAG treatment rates compared to the other IOLs implanted at the study site during the 5 years follow-up after cataract surgery. Future research may be warranted to investigate the consequences of lens choice for patient quality of life and overall healthcare costs.

Conclusions







Direct ophthalmic healthcare resource utilisation and costs associated with the different single-piece monofocal intraocular lens types implanted during cataract surgery: Real-world evidence from Spain

First Author: D O'Boyle, Ireland

Poster - Alcon Initiated Trial (#ILA247-H001)

Available Online

Abstract Details

Purpose

Setting

Methods

Results

Conclusions

Cataract surgery is the most frequently performed surgical procedure in Spain and posterior capsule opacification (PCO) is the most common complication following cataract surgery. While Nd:YAG laser capsulotomy is the only effective treatment for PCO, it can place a financial burden on healthcare systems and be associated with a number of complications. The objective of this research was to provide a health economic analysis to estimate the post-operative costs associated with PCO and its treatment, Nd:YAG laser capsulotomy, according to different intraocular lens (IOL) types implanted at the time of cataract surgery. This research is a health economic analysis adapting the results from a clinical study of anonymised electronic medical records of cataract patients from two large Spanish regional hospitals of the Ribera Salud group in the Torrevieja-Vinalopó healthcare area who are main providers of ophthalmic procedures in the Alicante region.

Adjusted odds for Nd:YAG capsulotomy at three years post-cataract surgery from the clinical study findings underpinned the economic analysis. Compared with the AcrySof IOL, the odds of requiring Nd:YAG capsulotomy for the other IOLs implanted at the study site were as follows: Zeiss Asphina (OR: 5.21), IOL Tech (OR: 5.74), Medicontur (5.86) and AJL IOLs (OR: 8.85) (p < 0.001 for each pairwise comparison). The Nd:YAG procedure and associated additional consultation visit costs were sourced from Valencian Community tariffs (2016-2018).

For those eyes undergoing the Nd:YAG procedure to treat PCO, the total average cost associated with treating PCO was €242.48. Per each cataract surgery and stratifying by the type of IOL, the post-surgery costs associated with each IOL were as follows, AcrySof (hydrophobic): €12.01, Zeiss Asphina (hydrophilic-with-hydrophobic surface): €62.57, Medicontur: €70.38, IOL Tech: €68.94, and AJL: 106.29 (hydrophilic). The reduction in post-operative costs associated with AcrySof over other IOLs ranged from a factor of 5.21 (vs. Zeiss Asphina) to 8.85 (vs. AJL).

In this research, AcrySof IOLs were associated with reduction in costs related to Nd:YAG laser and its complications, ranging from a factor of 5.2 to 8.9 compared with Zeiss Asphina and AJL IOLs, respectively. Highlighting that the choice of IOL for cataract surgery, as a direct consequence of lower Nd:YAG rates, may translate into significant financial savings for Spanish hospitals and the healthcare system more generally. Furthermore, reducing the requirement for Nd:YAG capsulotomy could result in freeing up resources that could be reallocated elsewhere within the hospital, thus offering an opportunity to help alleviate demand on ophthalmic services.







To better understand and delineate indications for the use of multifocal implants in cataract surgery: A French Multicentric Study

First Author: D Monnet, France

Poster - Alcon Supported

Available Online

Abstract Details

Purpose

To identify the reasons for implanting or not a multifocal PC-IOLs to patients undergoing a cataract surgery in France, where only 5 to 6% of patients actually benefit from MF PC-IOLs.

Setting

This study has been sponsored by Alcon France, and conducted by Galilleo company France.

Methods

The study was carried out by using a questionnaire to be filled in by 10 surgeons on their consecutive patients with an operative indication of cataract between Oct and Dec 2020. Surgeons had academic or private practice and were familiar with use of multifocality. This questionnaire was divided into 3 parts detailing: medical objective or subjective reasons not to propose a MF PC-IOLs to the patient, as well as the reasons for the possible refusal of patients if the multifocal implant could be offered. The final decision of the type of lens implanted was collected. The study was conducted by a company specialized in conducting surveys (Gallileo Business consulting, Paris, France).

Results

The questionnaire was completed for 732 patients. The mean age of the patients was 70.4 years old, with a 60% of female predominance. In 68% (495/732), the surgeons could not offer PC-IOL MF, mainly for objective medical reasons in 54% (397/732) of cases. Among the 32% of eligible patients, the multifocal implant proposal was rejected by the patient in 41% of cases (98/237). In total, a multifocal lens was implanted in 19% of cases (139/732). Patients' decision to accept multifocality was significantly higher among those who had received information about MF PC-IOL before the visit: 74% (67/91) vs 48% (63/132), p <0.001.

Conclusions

This study, carried out on a population at the age of cataract, showed that multifocal implantation was possible in about one out of five cases. The main reasons for not offering PC-IOL MF were medical and objective (macular damage). We have shown that the level of acceptance of MF-PC IOLs by the patient depends on his level of knowledge of these implants. The objective criteria of eligibility for multifocal implants should be better defined. Finally, the level of therapeutic education in cataract surgery of patients can be improved with a direct impact on the acceptance of this technology.







Hospital Costs Associated with Cataract Surgeries in Europe: A Comprehensive Literature Review

First Author: Z Nagy, Hungary

Poster - Alcon Supported

Available Online

Abstract Details

Purpose

As the demand for cataract surgery continues to grow across Europe, health care providers will turn to health technology assessments and economic evaluations as a means of assessing the value of emerging cataract interventions or determining optimal resource allocation. The purpose of this study was to conduct a comprehensive review of the literature to identify hospital costs associated with cataract surgeries in Europe that could be used to inform future analyses.

Setting

N/A

Methods

A targeted search was conducted in Ovid EMBASE and MEDLINE for studies published between November 2014 and November 2019. Articles published in English that reported hospital costs (for diagnostics, procedures, monitoring, staff, facility, medications, anesthesia, consumables, complications, and administration/overhead) from Europe were included. Overall procedure-related costs were defined as the sum of costs accrued to diagnose, treat, and monitor a patient. All costs are reported in 2020 USD.

Results

The search identified thirty-two costs reported in seven articles from Finland, Greece, Norway, Poland, and the United Kingdom. The average overall procedure-related cost was \$1,886.88 per case in Finland (based on the cost of one-eye, second-eye, and bilateral cataract surgeries) and \$806.71 in Greece. Overall procedure-related costs for complex cataract surgery ranged from \$1,433.09 (for uncomplicated surgery using surgical adjuncts) to \$3,227.03 (for complicated surgery requiring a vitrectomy) in the United Kingdom. Higher costs were reported for cataract surgery for younger patients versus elderly patients in Poland (additional \$500.23), and for intraocular lens exchange versus repositioning in Norway (additional \$297.95).

Conclusions

Our review captured a variety of cataract surgery hospital costs from European countries that may be used when conducting economic analyses; however, it also highlights country- and procedure-specific data gaps in the literature. For example, hospital costs for cataract surgery were only available from five countries and costs for specific types of cataract surgery (eg, manual small-incision cataract surgery, phacoemulsification) were not identified. Future research should focus on the collection of hospital-related cataract surgery costs from additional European countries and on determining the costs for specific types of procedures.







