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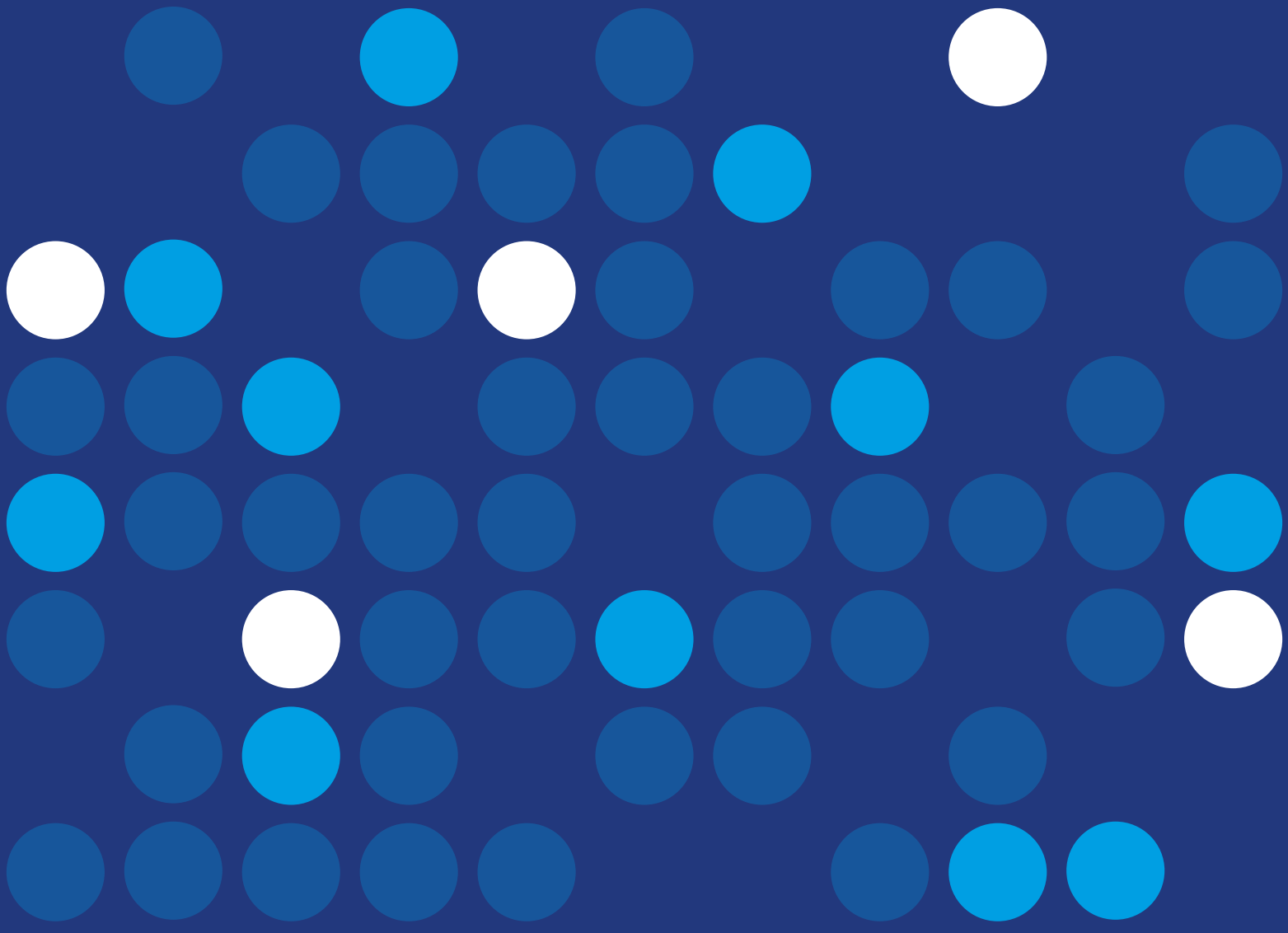

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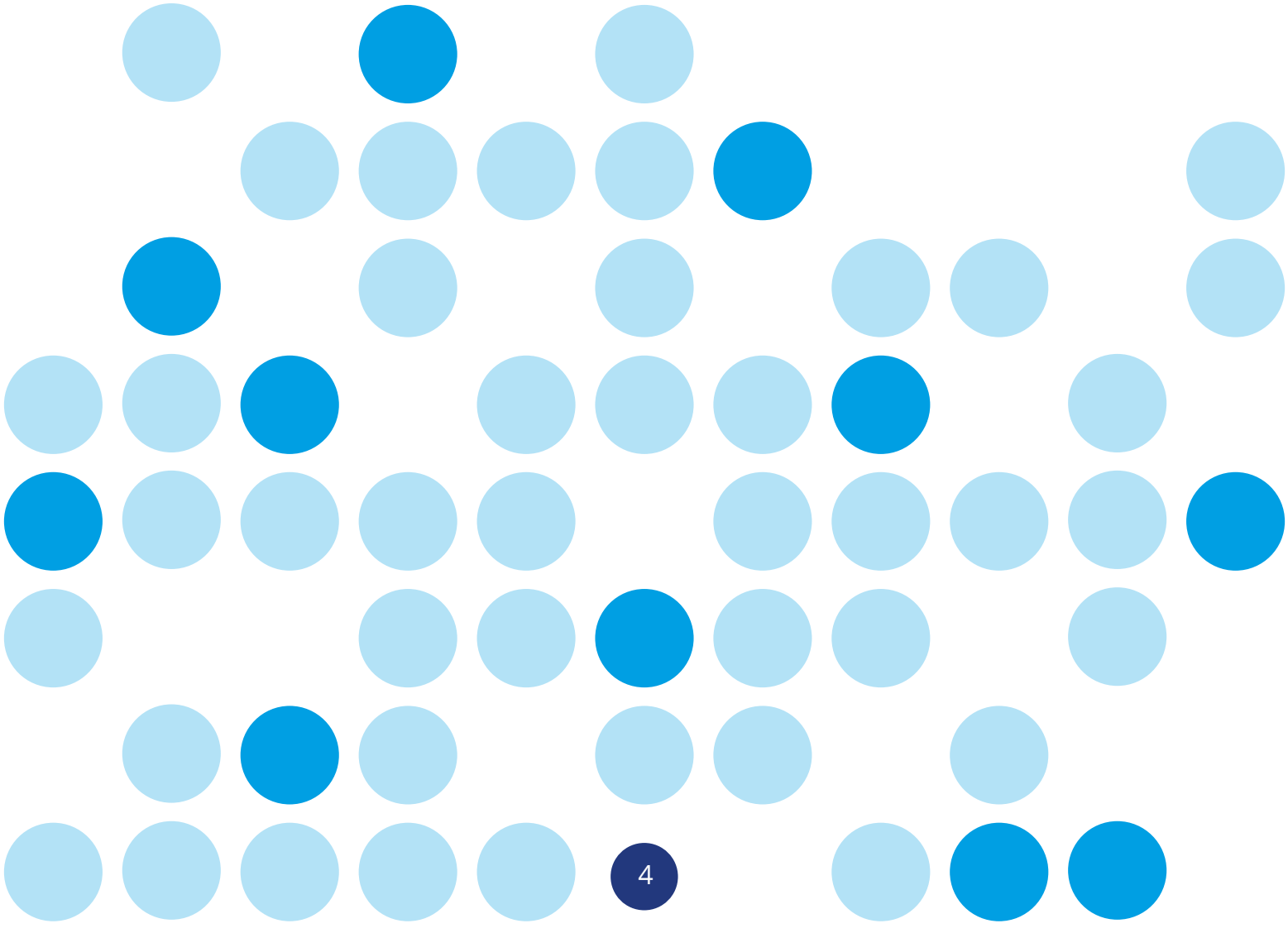
Monofocal IOLs



Multi-center clinical evaluation of a new hydrophobic, single piece monofocal IOL

First Author: *N. Bauer, The Netherlands*
Co Author(s): *F. van den Biggelaar, R. Nuijts, A. Martinez*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	A prospective, multicenter, single group safety and performance clinical trial to demonstrate the long-term (3 years) visual acuity, refractive and adverse event outcomes for the Clareon® IOL (Alcon). This paper presents 1-Year interim results.
Setting	Multicenter, 18 sites, single group study.
Methods	Subjects scheduled for bilateral cataract surgery with no ocular pathology other than cataract that could compromise visual function or the measurements are included. In each subject, the Clareon® IOL (Model SY60WF) was implanted in both eyes. Study examinations are performed preoperatively, 1 day, 1 week, 1 month, 6 months, 1, 2 and 3 years after cataract surgeries. Best corrected distance visual acuity (BCDVA), uncorrected distance visual acuity (UCDVA), manifest refraction, Slit lamp examination, ACD, PCO assessment and IOL observations are carried out at each visit.
Results	A total of 245 subjects were enrolled and 215 subjects were implanted. Of the 215 subjects implanted, 209 subjects were implanted bilaterally. At 1-year post-op, 205 subjects were still enrolled in the study. The mean age of the implanted cohort was 72.1 (8.07) years and 59% females. At 1 year, average monocular BCDVA remains 0.0logMAR with 85% of eyes having MRSE 0.50D or less in both eyes. Monocular BCDVA 20/25 or better is observed in at least 94% of eyes. Glistenings Grade 0 are reported in 99.5% of eyes at 1 year.
Conclusions	Sustainable good vision, stable refraction and mechanical stability outcomes with the Clareon® IOL up to 1 year. Low PCO and Nd:YAG remain up to 1 year with less than 3% of eyes reporting clinical significant PCO and only 0.5% requiring Nd:YAG treatment due to PCO. Based on these results the Clareon® IOL can be considered Glistening Free at 1 year.
Financial Disclosure	The study was supported by Alcon.

In vivo evaluation of the incision size and in vitro evaluation of the injector damage in two preloaded IOL delivery devices

First Author: *R. Khoramnia, Germany*
Co Author(s): *T.M. Yildirim, M. Dzhambazova-Baey, J. Weidler, T. Naujokaitis, S. Schickhardt, G.U. Auffarth*

Alcon Investigator Initiated Trial #42245927

Poster

Abstract Details

Purpose	The aim of the study is to compare the incision enlargement and cartridge damage after the use of two preloaded IOL delivery devices, Clareon® AutonoMe (Alcon) and Vivinex iSert (Hoya), intraindividually in patients undergoing cataract surgery.
Setting	The David J Apple International Laboratory for Ocular Pathology, University of Heidelberg, Heidelberg, Germany.
Methods	56 eyes (28 patients) without any other relevant ocular pathology are included in this prospective, bilateral, paired-eye, randomized, comparative clinical trial. The incision sizes before and after the implantation are measured with a caliper. The time needed for IOL implantation, insertion, unfolding and centration are measured using videos of the surgery. The tips of all used injectors are assessed in the laboratory (light and scanning electron microscopy) to check for potential damages (e.g. slight scratches, deep scratches, extensions, cracks, bursts). Visual acuities, refractive predictability and glistenings are evaluated 3 months after surgery.
Results	The wound stretch was 0.21±0.11 mm in the eyes treated with the AutonoMe injector and 0.29±0.10 mm in the eyes treated with the iSert injector. Light and scanning electron microscopy of the injector tips showed so far the following results: 1.) AutonoMe: 78% no damage, 22% slight scratches. 2.) iSert: 12% slight scratches, 13 % deep scratches, 38% slight cracks, 6% extensions, 31% cracks and bursts.
Conclusions	The AutonoMe injector causes less wound stretch of the incision site after the IOL implantation than its counterpart iSERT. Light and scanning electron microscopy of the tip of the AutonoMe injector showed less damage than the iSERT injector. The time needed for the implantation was comparable in both lenses. Complication and adverse event rates were also within those given ISO standards for posterior chamber IOL.
Financial Disclosure	The study is an Investigator Initiated Study #42245927 supported by Alcon.

Comparative assessment of the corneal incision enlargement of four preloaded intraocular lens delivery systems

First Author: *T. Kohnen, Germany*
Co Author(s): *J. Liu, P. Wolfe, V. Hernandez*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To comparatively evaluate the corneal incision enlargement and incision structure of AutonoMe, a new automated preloaded delivery system, to UltraSert, TECNIS iTec (iTec) and HOYA Vivinex™ iSert® (Vivinex) preloaded delivery systems.
Setting	Alcon Vision LLC, Fort Worth, TX, USA; Design: Experimental study
Methods	Sixteen (16) preloaded IOLs (20.0 D-21.0 D) per treatment group were delivered into the anterior chamber of human cadaver eyes through a 2.0 mm (Vivinex) or 2.2 mm (AutonoMe, UltraSert, and iTec) incision size. Corneal incision morphology was evaluated using optical coherence tomography (OCT) and incision sizes were measured using ASICO incision gauges before and after IOL delivery. Differences in mean incision enlargement between delivery devices were evaluated using a paired t-test.
Results	AutonoMe (0.29±0.03 mm) and UltraSert (0.29±0.03 mm) had the smallest average incision enlargement compared with iTec (0.31±0.03 mm) and Vivinex (0.36±0.06 mm). Vivinex had the largest corneal incision enlargement and was significantly larger than AutonoMe (p=0.001), UltraSert (p=0.001) and iTec (p=0.002). Representative OCT images of pre- and post-implantation incisions (cross sectional images of cornea) showed more incision gaping, corneal stromal damage and distortion for delivery systems with the largest incision enlargement: Vivinex and iTec.
Conclusions	The new AutonoMe preloaded delivery system protects the corneal incision during IOL implantation and causes smaller incision enlargement and less corneal stromal damage compared to iTec and Vivinex. Further clinical studies are necessary to confirm the effect of incision enlargement on wound healing and post-operative corneal morphology.
Financial Disclosure	Drs. Liu, Wolfe and Hernandez are employees of Alcon Vision, LLC. T. Kohnen: Consultant and Research for Abbott/J&J, Alcon/Novartis, Avedro, Oculentis, Oculus, Presbia, Schwind, Zeiss. Consultant for Allergan, Bausch & Lomb, Dompé, Geuder, Med Update, Merck, Rayner, Santen, Staar, Tear Lab, Théa, Thieme, Ziemer. Research for Hoya.

Anterior chamber depth (ACD) variability between the Clareon® and AcrySof® IQ IOL: a randomised trial

First Author: *M. Ullrich, Austria*
Co Author(s): *M. Ruiss, J. Hienert, A. Fisus, C. Pilwachs, N. Hirnschall, O. Findl*

Alcon Investigator Initiated Trial #39375661

Poster

Abstract Details

Purpose	Estimation of the postoperative anterior chamber depth (ACD) is still the main source of error in IOL power calculation. Haptic design and IOL material have an influence on the ACD. Our aim is to investigate the postoperative ACD variability between the hydrophobic AcrySof® IQ IOL (Alcon) and the Clareon® IOL (Alcon) made of a novel modified hydrophobic acrylic material.
Setting	Vienna Institute for Research in Ocular Surgery (VIROS), a Karl-Landsteiner-Institute, Hanusch Hospital, Vienna.
Methods	Patients scheduled for bilateral cataract surgery without any ophthalmic abnormality that could compromise visual function or the measurements were included in this study. In each patient the AcrySof® IQ IOL was implanted in one eye and the Clareon® IOL in the contralateral eye according to randomisation. Study examinations were performed preoperatively, 1 hour, 1 week and 6 months after cataract surgery. Slit lamp examination and ACD measurements using the IOL-Master 700 and AC-Master were carried out at each visit. Autorefraction, uncorrected distance visual acuity (UCDVA) and best-corrected distance visual acuity (BCDVA) were tested preoperatively and 6 months postoperatively.
Results	All patients have been included, in total 100 eyes of 50 patients. Follow-up visits will be completed in August 2020. Therefore final results will be presented at the ESCRS in Amsterdam.
Conclusions	We will analyse whether the new modified Clareon® IOL is not inferior to the AcrySof® IQ IOL in postoperative anterior chamber depth variability. The final conclusions of the study will be presented at the meeting.
Financial Disclosure	The study is an Investigator Initiated Study #39375661 supported by Alcon.

AT-IOLs

A comparative study of two trifocal toric intraocular lenses

First Author: *Y. Corbel, France*
Co Author: *B. Cochener-Lamard*

Alcon Investigator Initiated Trial #34835525

Free paper

Abstract Details

Purpose	To compare the performance of two different diffractive trifocal and toric intraocular lens (IOL) designs, evaluating refractive outcomes, visual acuity (VA) at various distance, rotation stability and quality of vision.
Setting	University Hospital, Ophthalmology department, Brest, FRANCE
Methods	In a prospective comparative multicenter double blind, superiority study, concerning 2 multifocal implants toric with a different design (PanOptix®, ALCON and Fine Vision PodF®,PHYSIOL), 30 patients were randomized in two groups. Data was collected 6 +/-2 weeks after the operation, assessing mono and binocular visual acuity at different distances, residual astigmatism (by vector analysis) and stability rotational (on photograph). The subjective quality of life and the patient satisfaction were approached by the NEI-RQL 42 questionnaire.
Results	The level of predictability in terms of refractive correction was in favour of PanOptix® toric for distance vision. Visual acuity at distance and near did not show any significant difference, while intermediate vision was better at 60cm with the PanOptix® toric and at 70cm for the Fine Vision® toric. Mean residual astigmatism was comparable for the 2 groups, less than 1D in all cases and 0.5D in 48%. The average rotation was 4.8° with the PanOptix® and 5.6° with PodF®; note that a patient had to undergo repositioning on D5 in this group. Spectacle Independence was obtained respectively in 96 and 94% of eyes, when all the patients declared to be satisfied and would recommend surgery.
Conclusions	The evaluated models combine the advantage of trifocality, optimizing the 3 main distances of vision, with that of a stable and efficient toric optic design. The 2 trifocal lenses provide excellent vision. The slight difference between the 2 models in intermediate distance would invite to consider the preferred distance of the patients, even the measurement of the length of the arms. The quality of vision is similar between the two lens models and correctly preserved.
Financial Disclosure	The study is an Investigator Initiated Study #34835525 supported by Alcon.

Visual outcomes and safety after bilateral implantation of a trifocal presbyopia correcting intraocular lens in a Korean population

First Author: *J.Y. Hyon, South Korea*
Co Author(s): *T. Kim, T-Y Chung, M. J. Kim*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To investigate the 3-month postoperative performance and safety after implantation of a trifocal intraocular lens (IOL) in a Korean population.
Setting	Clinical
Methods	Forty-four subjects (88 eyes) with bilateral cataract with expected postoperative corneal astigmatism of <1.00 diopter (D) and no ocular disease or eye condition underwent bilateral implantation of the AcrySof® IQ PanOptix® IOL (TFNT00). Postoperative examination at 3 months included binocular defocus curve; binocular best corrected distance visual acuity (BCDVA); monocular/binocular uncorrected VA (UCVA) at distance (4 m), intermediate (60 cm), and near (40 cm); binocular contrast sensitivity under photopic conditions with/without glare; and subjective outcomes of spectacle independence.
Results	Binocular defocus curve at 3 months after bilateral implantation showed mean acuity of 0.1 logMAR or better between +0.5 and -2.5D of defocus. Binocular BCDVA mean ± SD at 4 m was −0.05±0.07 logMAR. Binocular and monocular UCVAs were 0.03±0.1 and 0.08±0.12 logMAR (4 m), −0.03±0.11 and 0.05±0.13 logMAR (60 cm), and 0.03±0.12 and 0.09±0.13 logMAR (40 cm), respectively. Contrast sensitivity with glare was 1.67±0.13, 1.91±0.17, 1.54±0.21, and 1.14±0.20 log units at 3, 6, 12, and 18 cycles/degree, respectively. For near, intermediate, and distance tasks 84% 91%, and 96% of subjects reported spectacle independence, respectively.
Conclusions	In a Korean population, visual performance of the trifocal TFNT00 IOL 3 months postoperatively was <0.1 logMAR for binocular UCVA at all distances, with high rates of spectacle independence.
Financial Disclosure	The study was supported by Alcon.

Visual Results and Rotational Stability after Implantation of a toric panfocal Intraocular Lens: 3 Months results

First Author: *T. Kohnen, Germany*
Co Author(s): *K Pawlowicz, L Hinzelmann, W Ahmad, K Petermann, E Hemkeppler, C Lwowski*

Alcon Investigator Initiated Trial #34449955

Poster

Abstract Details

Purpose	To evaluate the visual performance after bilateral implantation of a toric diffractive aspheric multifocal intraocular lens (IOL) with a +2.17 diopter (60 cm) intermediate and a +3.25 diopter (40 cm) addition (add) power.
Setting	Prospective single-arm study at Department of Ophthalmology, Goethe University, Frankfurt, Germany.
Methods	Twenty-five patients (50 eyes) received bilateral implantation of the toric PanOptix IOL (AcrySof® IQ PanOptix®, Alcon Research, Fort Worth, TX, USA) pre-enrollment. Exclusion criteria were previous ocular surgeries excluding cataract surgery and refractive lens exchange and ocular pathologies or corneal abnormalities. 3 months postoperative examination included manifest refraction; monocular and binocular uncorrected (UCVA) and distance-corrected (DCVA) visual acuity in 4 m, 80 cm, 60cm and 40 cm; slit-lamp examination. 3 months postoperatively monocular and binocular defocus testing, binocular contrast sensitivity (CS) under photopic and mesopic conditions, and a questionnaire on subjective quality of vision, optical phenomena, and spectacle independence were performed.
Results	Mean spherical equivalent was 0.12 ± 0.380 D 3 months postoperatively. Monocular uncorrected VA was better than 0.14 LogMAR in all distances. Binocular defocus curve shows peaks at 0.00 D (-0.09 logMAR) and -1.50 D and -2.00D (-0.02 logMAR and 0.00logMAR). The worst values between far (4 m) and near distance (40 cm) was 0.04 logMAR at -1.00 D. Despite some optical phenomena, 92% of patients would choose the same IOL again and recommend it to others.
Conclusions	Visual performance of toric PanOptix IOL showed good VA at all distances; high patient satisfaction despite some optical phenomena; high spectacle independence 3 months postoperatively. Compared to the non-toric PanOptix IOL the toric version shows similar results regarding visual acuity and optical quality.
Financial Disclosure	The study is an Investigator Initiated Study #34449955 supported by Alcon.

Spectacle usage and its factors in cases after implantation of trifocal intraocular lens in Japanese patients

First Author: *Y. Ota, Japan*
Co Author(s): *H. Bissen-Miyajima, K. Hayashi, C. Igarashi, N. Sasaki*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To exploratory analyze factors that predict spectacle dependence following the implantation of trifocal intraocular lens (IOL).
Setting	Prospective multicenter study.
Methods	Sixty-six patients (age 66.2±7.5 years) with bilateral implantation of trifocal IOL (TFNT00: Alcon) were included in the analysis. Spectacle usage was assessed by patient questionnaire followed by a post-hoc correlation analysis of pre- and post-operative factors such as spherical equivalent (SE) and visual acuities (VA) at 5.0, 0.8, 0.6 and 0.4 meters.
Results	Although 54 of 66 (81.8%) patients used spectacles preoperatively, 51 patients (77.3%) achieved overall spectacle independence postoperatively. Fifteen patients used occasionally: 12 used for readings and 3 for reading and distance view. Majority of the patients requiring spectacles reported difficulty in reading small prints. None of the patients used spectacles for distance vision exclusively. The age of patients using the spectacles was higher than that of spectacle independent patients (P=0.02, Wilcoxon test). Post-op SE and uncorrected near VA, however, were not significant predictors of spectacle dependence (P=0.21, 0.06).
Conclusions	While the visual outcomes with this trifocal IOL were remarkable, a subset of patients required spectacles some of the time for near vision activities related with fine prints; and age may play factor in spectacle independence.
Financial Disclosure	One or more of the authors gains financially from product or procedure presented, … is employed by a for-profit company with an interest in the subject of the presentation, … receives consulting fees, retainer, or contract payments from a competing company, … research is funded, fully or partially, by a company producing, developing or supplying the product or procedure presented.

A comparison of contrast sensitivity, visual performance and quality of vision between a trifocal toric IOL and an extended depth of focus toric IOL

First Author: *R. Potvin, USA*
Co Author: *K.G. Gundersen*

Alcon Investigator Initiated Trial #41761671

Poster

Abstract Details

Purpose	To evaluate the clinical performance data, including contrast sensitivity, a defocus curve and quality of vision measures, for the AcrySof® PanOptix® and the Tecnis Symfony® toric intraocular lenses.
Setting	One clinical practice in Haugesund, Norway.
Methods	This study was a non-interventional two-arm comparative study of visual outcomes after successful bilateral cataract surgery or refractive lens exchange surgery with IOL implantation. Twenty-five subjects in each group assessed during a single visit between 3 months and 5 years after their surgery. There was no masking and no control group. Clinical evaluations included measurement of contrast sensitivity (with and without glare), visual acuity, manifest refraction, and subjective measures of visual quality and near vision. The primary measure of interest was the uncorrected binocular near visual acuity.
Results	The number of eyes with a spherical equivalent refraction within 0.50 D of plano was not significantly different between groups, nor was the number of eyes with ≤ 0.50 D of refractive cylinder (about 90% in each group for both measures). There were no differences between groups for distance or intermediate vision. The trifocal IOL provided significantly better near vision in both the uncorrected ($p = 0.009$) and best distance-corrected ($p = 0.014$) states. There were also no statistically significant differences in any low contrast acuity measures or sine wave contrast sensitivity measures at any distances or illumination conditions tested.
Conclusions	Low contrast acuity and contrast sensitivity were similar between IOLs at distance and near under photopic and mesopic conditions, suggesting similar visual quality. The only difference observed was better near vision with the trifocal IOL. For patients interested in less dependence on spectacles for near vision, the trifocal IOL may be preferred.
Financial Disclosure	The study is an Investigator Initiated Study #41761671 supported by Alcon.

Visual outcomes with a trifocal IOL in Indian patients

First Author: *A. Vasavada, India*
Co Author(s): *D. Ramamurthy, J. Reddy, P. Padmanabhan, N. Shetty, R. Sudhir*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To report the short-term Visual Acuity (VA) and Contrast Sensitivity (CS) of the AcrySof® IQ PanOptix® trifocal TFNT00 IOL after cataract surgery in an Indian population.
Setting	Multicenter (5 surgical sites) post-market investigation in India.
Methods	Observational, prospective, single-arm, unmasked, non-randomized multicenter study of Indian males and females subjects desiring an IOL that could provide correction of near, intermediate, and distance vision. Subjects completed 8 study visits: pre-op visit, operative visits for each eye, and post-op visits at 1-2 days (each eye), 1 month (each eye) and 3 months (both eyes). Binocular Best Corrected Visual Acuity (BCDVA) at 4 m, Binocular Distance Corrected Near Visual Acuity (DCNVA) at 40 cm, Intermediate Visual Acuity (DCIVA) at 60 cm, and Mean Binocular Mesopic Contrast Sensitivity with and without Glare.
Results	68 subjects were bilaterally implanted and 52 completed the study. 88.5% (46/52 and 96.2% (50/52) achieved BCDVA of 20/20 and 20/25 or better (respectively); 58.8% and 82.4% had 20/20 and 20/25 or better mean UCIVA (respectively); 47.1% and 82.4% had 20/20 and 20/25 or better mean UCNVA (respectively). Mean Mesopic Contrast sensitivity with glare was 1.53 ±0.28, 1.66 ±0.31, 1.62 ±0.35, and 1.16 ±0.42 log units at 1.5, 3, 6, and 12 cycles/degree, respectively. Mean Mesopic Contrast sensitivity without glare was 1.50 ±0.33, 1.67 ±0.27, 1.64 ±0.34, and 1.24 ±0.42 log units at 1.5, 3, 6, and 12 cycles/degree, respectively.
Conclusions	In an Indian population, PanOptix IOL demonstrates very good visual performance from distance to near.
Financial Disclosure	The study was supported by Alcon.

Vivity intraocular lens unilateral implantation in a patient that had previous LASIK surgery

First Author: *M. Guarro, Spain*
Co Author(s): *I. Goñi, S. Lopez, S. Ruiz*

Alcon Investigator Initiated Trial #59776347

Poster

Abstract Details

Purpose	To describe the refractive and functional results of one patient implanted with a non-diffractive presbyopia corrected intraocular lens (AcrySof® Vivity DFT015).
Setting	Vallès Ophthalmology Research, Barcelona, Spain
Methods	44 years old patient that had undergone bilateral LASIK 13 years ago (RE -4.25 -1.75x140º=0.6 decimal // LE +0.50 -1.75x80º=1.0 decimal). Clinical history shows that RE presents amblyopia with a best visual acuity (VA) of 0.6 decimal. At the moment of the diagnostic visit, the patient present a traumatic cataract in RE with a UCVA <0.05 decimal in RE and 1.0 in LE. We performed a visual function questionnaire (VFQ-25), topography, biometry, endothelial count and macular OCT. We used the ASCRS IOL calculator for postop myopic refractive surgery (http://iolcalc.ascrs.org/). Informed consent was obtained according to standard cataract surgery and after 1 week of the surgery, additional consent to disseminate his results to the scientific community. The surgery was performed according to the standard cataract procedure implanting an AcrySof® Vivity DFT015 of 20D IOL without complications.
Results	One-week postoperative, uncorrected decimal visual acuities (distance / intermediate (66cm) / near (40cm)) were for the RE 0.8 / 0.6 / 0.6 decimal and LE 1.0 / 1.0 / 1.0. Binocularly 1.0 / 1.0 / 1.0. Refractive refraction in the RE was +0.25-0.50x180 (not improving VA). The patient satisfaction was very high, showing a very good visual integration with the contralateral eye that still have accommodative function. Results at 1 month and 3 months follow-up will be included in the last version of the presentation, including a satisfaction questionnaire and visual disturbance analysis with the "Light Distortion Analyzer" device.
Conclusions	This case shows how the AcrySof® IQ Vitity DFT015 can be a good option in cases in which diffractive trifocal IOLs are not a clear indication. Diffractive based IOLs, as they split the wavefront, can induce a decrease of contrast sensitivity and increase the perception of visual disturbances. AcrySof® IQ Vivity DFT015 IOL do not split the wavefront and do not induce this kind of effects as, in distance vision, it provides a similar behavior than a monofocal IOL with the advantage of a good intermediate and a functional near vision.
Financial Disclosure	The study is an Investigator Initiated Study #59776347 supported by Alcon.

Clinical outcomes of a new non-diffractive presbyopia-correcting intraocular lens in Canada

First Author: *S. Holland, Canada*
Co Author: *A. Martinez*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To evaluate the effectiveness and safety of the new non-diffractive presbyopia-correcting intraocular lens (IOL), AcrySof® IQ Vivity (model DFT015) versus an aspheric monofocal IOL (model SN60WF) in the Canadian sub-population of a multicountry clinical trial.
Setting	Six investigational sites in Canada.
Methods	This prospective, multicentre, randomised, parallel-group, controlled, assessor- and patient-masked study included 6 cataract patients from Canada bilaterally implanted with DFT015 (n=39) or SN60WF (n=33). Refractive outcomes, binocular defocus curve and quality of vision (QoV Questionnaire, McAlinden) were assessed at Month 6.
Results	DFT015 demonstrated >0.5D extended range of vision at 0.2 logMAR compared with SN60WF. The visual disturbances profile was similar between groups, with low rates (<4%) of very bothersome and severe starbursts, halos and glare were reported in both groups.
Conclusions	In the Canadian sub-population of a large study, the non-diffractive presbyopia-correcting IOL DFT015 provided patients with an extended range of vision, while maintaining a visual disturbance profile similar to that of an aspheric monofocal IOL. This results show that DFT015 exhibits the advantages of a multifocal IOL, but without the photic phenomena generally associated with diffractive IOLs.
Financial Disclosure	The study was supported by Alcon.

Clinical outcomes of a new non-diffractive presbyopia-correcting intraocular lens in Australia

First Author: *F. Howes, Australia*
Co Author(s): *A. Martinez, U. Bhatt, C. Balachandran*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To evaluate the effectiveness and safety of the new non-diffractive presbyopia-correcting intraocular lens (IOL), AcrySof® IQ Vivity (model DFT015) versus an aspheric monofocal IOL (model SN60WF) in the Australian sub-population of patients of a multi-country clinical trial.
Setting	Three investigational sites in Australia.
Methods	This prospective, multicentre, randomised, parallel-group, assessor- and patient masked clinical study included 63 patients from three sites in Australia; 36 and 27 patients were implanted with DFT015 and SN60WF, respectively, and 34 and 27 binocularly-implanted patients completed the Month 6 visit. Binocular best-corrected distance visual acuity (BCDVA; 4 m), distance-corrected intermediate visual acuity (DCIVA; 66 cm), and distance-corrected near visual acuity (DCNVA; 40 cm) were assessed at Month 6. Defocus curves and quality of vision (using the Quality of Vision Questionnaire) were also assessed.
Results	Mean binocular DCIVA was improved for DFT015 (0.112 logMAR) versus SN60WF (0.301 logMAR) at Month 6, with a > 1-line difference (0.189 logMAR). DCNVA was improved with DFT015 versus SN60WF (0.364 vs 0.506 logMAR), with >1-line difference (difference of 0.142 logMAR); the between-group difference for BCDVA was <1 line (DFT015 -0.079 vs SN60WF -0.113 logMAR, difference of 0.034 logMAR). DFT015 showed a continuous extended range of vision of >0.5 D at 0.2 logMAR compared with SN60WF. For both groups, most patients were not at all bothered by starbursts, halos, and glare, with no reported severe visual disturbances in either group.
Conclusions	In the Australian sub-population of the larger clinical study, the new non-diffractive presbyopia-correcting IOL, AcrySof® IQ Vivity DFT015 provided patients with an extended range of vision, and improved near and intermediate vision versus the aspheric monofocal IOL SN60WF, while maintaining good distance vision and a visual disturbance profile comparable to an aspheric monofocal IOL.
Financial Disclosure	The study was supported by Alcon.

Clinical outcomes following bilateral implantation of a new non-diffractive, presbyopia correcting intraocular lens from two large confirmatory multicountry studies

First Author: *A. Mearza, UK*
Co Author(s): *A. Martinez, M. Guarro, C. McCabe*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To characterize the clinical outcomes following bilateral implantation with a new non-diffractive presbyopia correcting intraocular lens (IOL) AcrySof® IQ Vivity (model DFT015) versus an aspheric monofocal IOL (model SN60WF) from two large confirmatory multicountry studies.
Setting	Post-operative clinical outcomes obtained at 6-months from a combined 30 global investigational sites located in Australia (3), Canada (6), Spain (6), UK (4) and USA (11).
Methods	These prospective, multi-center, randomized, parallel group, assessor and patient masked studies included (study 1, OUS) 273 bilaterally implanted patients, of whom 268 completed the study (DFT015, n=151; SN60WF, n=117) and (study 2, US) 219 bilaterally implanted patients, of whom 217 completed the study (DFT015, n=106; SN60WF, n=111). Binocular best-corrected distance visual acuity (BCDVA; 4 m), distance-corrected intermediate visual acuity (DCIVA; 66 cm), and distance-corrected near visual acuity (DCNVA; 40 cm) were assessed at Month 6. Defocus curve and quality of vision (QoV study 1; QUIVID) study 2 were also assessed.
Results	Distance VA was similar between the groups (mean binocular BCDVA < 0.0 logMAR) while the observed means for binocular DCIVA indicated an improvement of > 1-line with DFT015. The observed means for binocular DCNVA indicated ~1-line improvement (OUS), and greater than 1-line improvement (US) favoring DFT015. DFT015 demonstrated a > 0.5 D extended mean binocular defocus range over SN60WF at 0.2 logMAR. The OUS rates of reporting not at all severe glare, halos, or starbursts were similar (<10% difference) between groups. Rates of US patients reporting “not at all bothered” by starbursts, halos, and glare were similar (<10% difference) between groups.
Conclusions	In comparison with an aspheric monofocal IOL, these two large-scale, independent confirmatory trials indicate that the DFT105 non-diffractive presbyopia correcting IOL improves near and intermediate vision without reducing distance vision. Patients bilaterally implanted with the DFT105 IOL reported low rates of visual disturbances comparable to an aspheric monofocal.
Financial Disclosure	The study was supported by Alcon.

Visual outcomes and patient satisfaction after implantation of a new non-diffractive presbyopia-correcting intraocular lens

First Author: *C. McCabe, USA*
Co Author: *A. Martinez*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	Extended-depth-of-focus intraocular lenses (IOLs) are intended to address the vision quality issues of both monofocal and multifocal IOLs by improving range of vision while maintaining high-quality distance vision and a monofocal-like visual disturbance profile. This study evaluated the functional vision outcomes and safety profile of a new non-diffractive presbyopia correcting intraocular lens (IOL) AcrySof® IQ Vivity (model DFT015) versus an aspheric monofocal IOL (model SN60WF).
Setting	Eleven sites in the USA.
Methods	This prospective, multicentre, non-randomized, parallel-group, confirmatory trial enrolled cataract patients, who were bilaterally implanted with DFT015 and SN60WF (106 and 113 patients, respectively). Co-primary and secondary effectiveness objectives for DFT015 versus SN60WF at Month 6 were to demonstrate non-inferiority in mean photopic monocular best-corrected distance visual acuity (BCDVA; 4m), superiority in mean photopic monocular distance-corrected intermediate VA (DCIVA; 66cm) and distance-corrected near VA (DCNVA, 40cm), and a greater range of defocus at 0.2 logMAR in the first operative eye. Cumulative rates of secondary surgical interventions and patient-reported visual disturbances (validated Questionnaire for Visual Disturbance, QUVID) were also analysed.
Results	Superiority of DFT015 to SN60WF in mean photopic monocular DCIVA (difference of -0.164 logMAR; p<0.001¬) and distance-corrected near visual acuity (difference of -0.156 logMAR; p<0.001¬), and non-inferiority in mean photopic monocular BCDVA (95% upper confidence limit of the difference was <0.1 logMAR margin), were demonstrated. The monocular defocus curve for DFT015 showed a greater negative range of defocus (difference of 0.54 D at 0.2 logMAR), compared with SN60WF. Most patients in both groups reported never being bothered by the surveyed visual disturbances.
Conclusions	This large study demonstrates that the non-diffractive presbyopia-correcting IOL DFT015 provides improved distance-corrected intermediate and near vision, increased depth of focus, versus the aspheric monofocal IOL SN60WF, while maintaining a similar distance vision and visual disturbance profile.
Financial Disclosure	The study was supported by Alcon.

Single site clinical outcomes of a new non-diffractive presbyopia correcting intraocular lens

First Author: *R. Pérez-Izquierdo, Spain*
Co Author(s): *A. Martinez, F. Poyales*

Alcon Initiated Trial

Free paper

Abstract Details

Purpose	To evaluate clinical outcomes of binocular implantation of a new non-diffractive presbyopia correcting intraocular lens, AcrySof® IQ Vivity Model DFT015 at a single site.
Setting	Miranza IOA, Madrid, Spain.
Methods	14 randomized subjects were bilaterally implanted with the DFT015 and 11 with SN60WF (aspheric monofocal control), respectively at a single site in Spain. At 6 months post-op, MRSE and binocular uncorrected and best corrected distance (UDVA, CDVA, 4m), intermediate (UIVA, DCIVA, 66cm) and near visual acuity (UNVA, DCNVA, 40cm) were assessed. Binocular defocus curve and quality of vision (QoV, McAlinden) were also assessed at 6 months.
Results	Binocular UDVA and CDVA were 0 logMAR or better for both DFT015 and SN60WF. DFT015 provided > 1 line improvement in DCIVA, UIVA, DCNVA and UNVA compared to SN60WF. The binocular defocus curve for DFT015 demonstrated >0.5 increased depth of focus at 0.2 logMAR compared to SN60WF. For both groups, rate of very bothersome starbursts, halos, and glare were similar and low.
Conclusions	In comparison with an aspheric monofocal IOL, these site level results indicate that the non-diffractive presbyopia correcting IOL improves near and intermediate vision without affecting distance vision while maintaining a monofocal visual disturbance profile.
Financial Disclosure	The study was supported by Alcon.

Spectacle independence after bilateral implantation of a new non-diffractive presbyopia-correcting intraocular lens

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Co Author(s): *A. Martinez, M. Guarro*

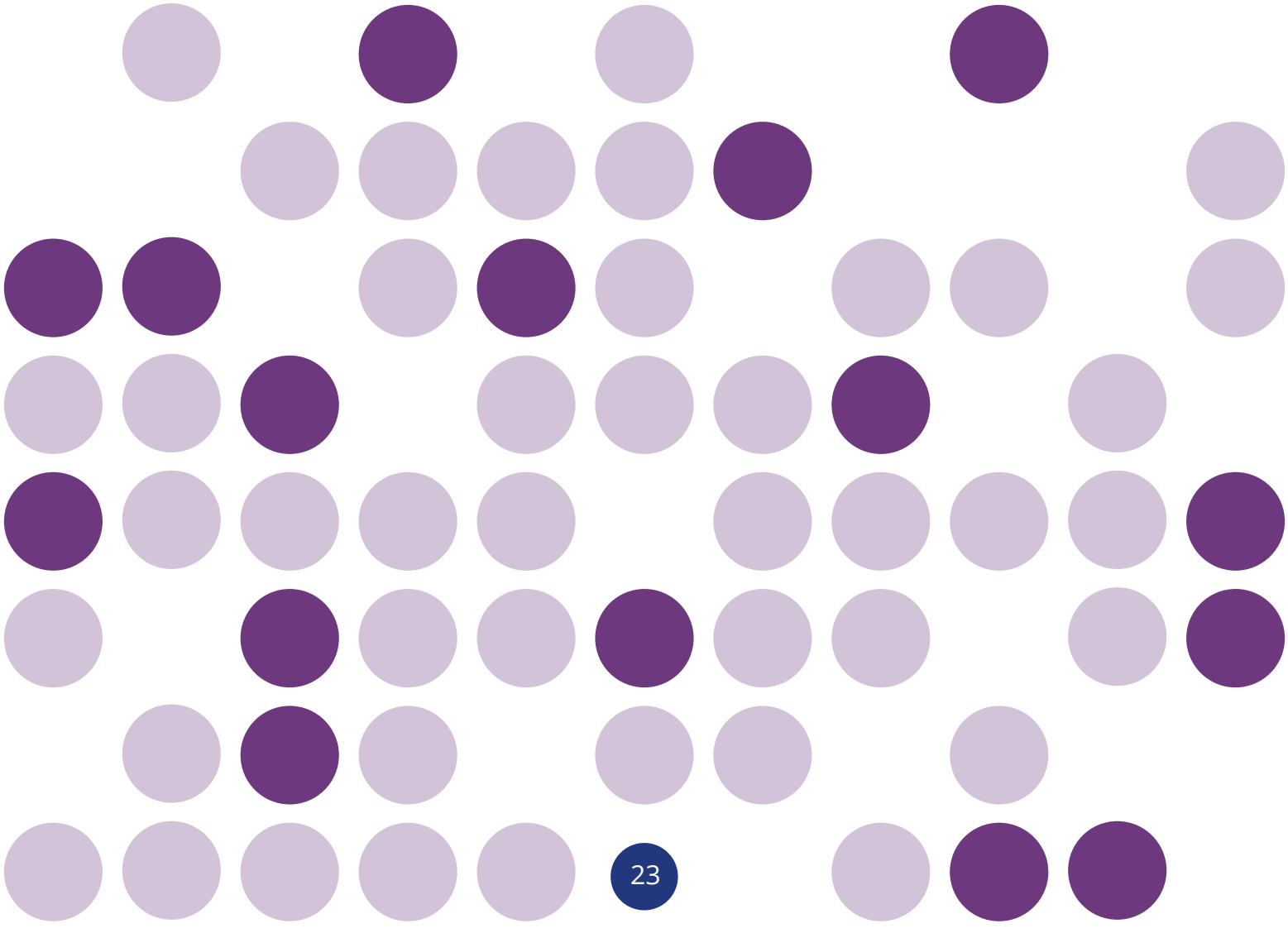
Alcon Initiated Trial

Poster

Abstract Details

Purpose	To evaluate spectacle independence following implantation of a new non-diffractive presbyopia-correcting intraocular lens (IOL), AcrySof® IQ Vivity IOL (model DFT015) versus an aspheric monofocal IOL (model SN60WF).
Setting	Nineteen investigational sites located in Australia (3 sites), Canada (6 sites), Spain (6 sites) and the United Kingdom (4 sites).
Methods	This prospective, multicentre, randomised, parallel-group, assessor- and patient-masked study assessed 156 and 120 patients undergoing cataract surgery targeting emmetropia, with bilateral implantation of DFT015 and SN60WF (aspheric monofocal control), respectively. At Month 6 postoperatively, a spectacle use questionnaire was implemented to ask patients the following questions: How often do you wear eyeglasses for: Any purpose? (Question 1); Near tasks (e.g. reading print)? (Q2); Intermediate tasks (e.g. computer)? (Q3); and Distance tasks (e.g. driving)? (Q4). The key effectiveness objective was to demonstrate superiority for DFT015 versus SN60WF in the proportion of patients 'never' requiring glasses for 'Any purpose' (Q1) and for 'Intermediate tasks' (Q3).
Results	A greater number of patients in the DFT015 group compared with the SN60WF group reported 'never' requiring spectacles for 'Any purpose' (Q1, 30.2% and 10.0%, respectively) and 'Intermediate tasks' (Q3, 75.5% and 53.8%, respectively). The observed 95% lower confidence limit (Q1, 8.77%; Q3, 7.92%) for the difference in proportions between the two groups was greater than the reference value of 0%. DFT015 also demonstrated increased spectacle independence for 'Near tasks' (Q2) compared with SN60WF (29.2% and 8.8%, respectively). Both DFT015 and SN60WF groups demonstrated similar, high frequencies of patients reporting 'never' requiring spectacles for 'Distance tasks' (Q4, 91.5% and 90.0%, respectively).
Conclusions	This large study demonstrates that the non-diffractive presbyopia-correcting IOL DFT015 provides an increased number of patients with spectacle independence compared with the aspheric monofocal control. When targeting emmetropia with DFT015, surgeons should set expectations that patients will likely need spectacles for some of their near tasks.
Financial Disclosure	The study was supported by Alcon.

Cataract equipment and diagnostics



Comparison of Post Occlusion Break Surge Volume in three Cataract Surgical Systems

First Author: *K. Miller, USA*
Co Author(s): *A. Aboughaida, S. Yalamanchili, D.W. Dyk, BS; O. S. Rohani*

Alcon Initiated Trial

Free paper

Abstract Details

Purpose	To characterize post occlusion break surge volume (SV) in the Centurion with Active Sentry peristaltic system (CAS), Whitestar Signature Pro peristaltic system (WSP), and Stellaris PC venturi system (SPC) under varying intraocular pressures (IOP), vacuum limits (Vac), and aspiration rates (Asp).
Setting	Stein Eye Institute, UCLA, Los Angeles, California, USA and Alcon Research, Lake Forest, California, USA.
Methods	A mechanical eye model that mimics the compliance of human eye was used to model the anterior chamber volume-pressure change behavior. Using this model, the SV of the systems were characterized at Vac of 300 to 600 mmHg, IOP of 30 to 80 mmHg, and Asp of 20 and 40 cc/min (the SPC does not have an Asp setting). Each operating setting was tested on six samples and the SV average and standard deviation (SD) for all the samples was calculated at all given settings [IOP, Vac, Asp].
Results	The CAS SV (SD) was 48.6 (3.1) µL at [50, 500, 20] and 61.8 (4.9) µL at [50, 600, 20]. The corresponding WSP SV (SD) was 70.3 (4.2) µL and 102.6 (5.5) µL while the corresponding SPC SV (SD) was >160 µL and >160 µL. The CAS SV (SD) was 50.9 (3.3) at [40, 500, 20] and 63.6 (5.1) at [40, 600, 20]. The corresponding WSP SV (SD) was 77.3 (6.2) µL and 112.5 (7.4) µL while the corresponding SPC SV (SD) was >160 µL and >160 µL. Wherever SV is reported as >160 µL, the mechanical eye model reached its limitations and therefore was not able to measure a surge volume that was greater than 160 µL.
Conclusions	SV is heavily dependent on the cataract system used and its surgical settings. CAS had a significantly lower surge volume in high Vac and low IOP when compared to WSP and SPC. CAS had a small SD which shows it can provide a higher level of case-to-case consistency. In CAS, surge is mainly a function of Vac and does not greatly vary with IOP.
Financial Disclosure	This study was supported by Alcon.

Prediction accuracy of the ORA intraoperative aberrometry device for the new Clareon® monofocal IOL

First Author: *L.S. Spekreijse, the Netherlands*
Co Author(s): *N.J.C. Bauer, F.J.H.M. van den Biggelaar, T.T.J.M. Berendschot, R.M.M.A. Nuijts*

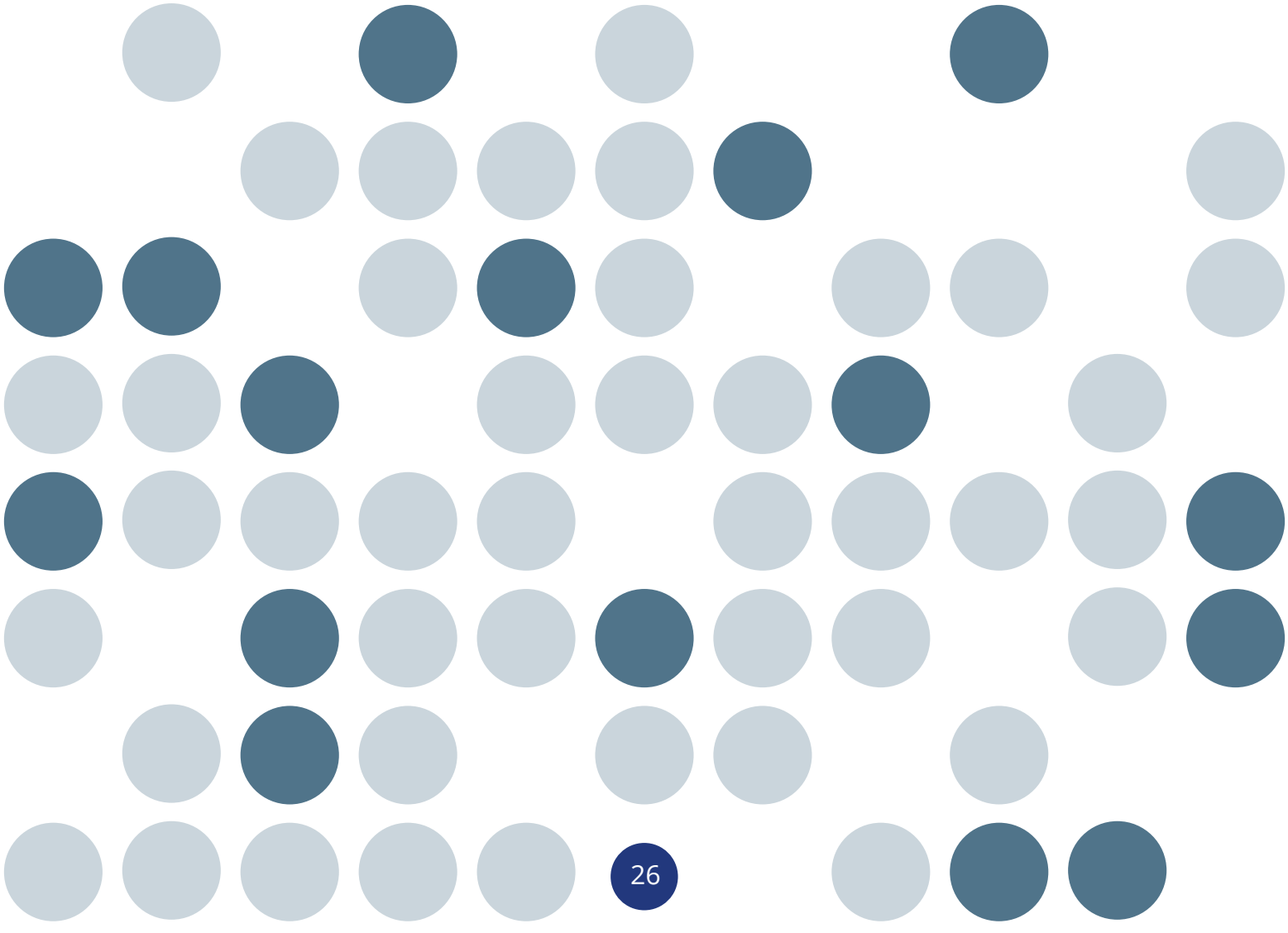
Alcon Investigator Initiated Trial #42147873

Free paper

Abstract Details

Purpose	To evaluate refractive outcomes for the new 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. Surgeries were performed by 2 surgeons (RN and NB) who were experienced in using the ORA system.
Methods	Patients with bilateral senile cataracts who underwent phacoemulsification in both eyes, either by delayed sequential surgery (2 weeks in-between) or on the same-day, were included in the study. Patients were excluded if they had an increased risk of refractive surprise (e.g. axial lengths <21mm or >27 mm, previous refractive surgery). The implanted IOL power was based on noncontact optical biometry data (IOLmaster®700, Carl Zeiss Meditec AG) using the Barrett Universal II formula for IOL calculation. Postoperative subjective refraction was measured 4-6 weeks after surgery.
Results	Eighty-two eyes (42 patients) were included in the study. Thirty-five patients underwent bilateral same-day surgery. Mean age (±SD) was 73±8 years and 36% of patients was male. For the ORA system, the percentage of eyes within 1.0D, 0.75D, 0.50D and 0.25D of target was 80.5%, 68.3%, 50.0% and 13.4%, respectively. For the preoperative biometry analysed by the Barrett Universal II formula these percentages were 96.3%, 86.6%, 74.4% and 47.6%, respectively. Mean absolute prediction error (±SD) was 0.62±0.37D for ORA and 0.35±0.28D for preoperative biometry (P<0.001).
Conclusions	According to the literature, a percentage of at least 90% of eyes that fall within 1.0D of target SE refraction is acceptable in current practice.[1] This study shows lower percentages of eyes within 1.0D, 0.75D, 0.50D and 0.25D for ORA compared to the Barrett universal II formula when using the Clareon® IOL. However, the ORA system uses postoperatively entered refractive data to fine-tune the intraoperative measurements and calculations. Since the Clareon® monofocal IOL is a new IOL, it is likely that more intraoperative measurements and postoperative data are needed to optimize the ORA system for this specific IOL.
Financial Disclosure	The study is an Investigator Initiated Study #42147873 supported by Alcon.

Lasers



Comparing Trans-Epithelial PRK to alcohol-assisted PRK using a 500Hz excimer laser

First Author: *A.Cummings, Ireland*
Co Author(s): *None*

Alcon Investigator Initiated Trial #44397877

Poster

Abstract Details

Purpose	The prospective study set out to compare the refractive outcomes, the corneal higher-order aberrations, the patient-reported outcomes in terms of early recovery and symptoms between a new transepithelial PRK (TE-PRK) on the WaveLight platform called StreamLight and manual PRK.
Setting	The Wellington Eye Clinic, Dublin, Ireland.
Methods	30 patients were prospectively randomised to one eye TE-PRK and the fellow eye PRK for the treatment of myopia and myopic astigmatism. The refractive target had to be emmetropia in both eyes and the refraction within 1.00D of one another.
Results	The results have not been completed yet as the study uses 6-month data for the refractive comparison. There is no significant difference regarding refractive outcomes for the 1- and 3-month intervals. The PRO data suggests that patients prefer the TE-PRK approach to manual PRK as they find it easier and less manipulation on the eye. The early recovery data has not been analysed yet and will only be available once all 30 patients have been enrolled.
Conclusions	TE-PRK (StreamLight on the WaveLight platform) is a safe and effective alternative treatment to manual PRK in patients with myopia and myopic astigmatism. Most patients prefer the TE-PRK approach as they find it more comfortable at the time of surgery than manual PRK.
Financial Disclosure	The study is an Investigator Initiated Study #44397877 supported by Alcon.

Topography-modified refraction (TMR): partial to total adjustment of treated cylinder amount and axis provided by topography data measured versus using the standard clinical refraction in myopic topography-guided LASIK

First Author: *J.A. Kanellopoulos*
Co Author(s): *None*

Alcon Investigator Initiated Trial #39176755

Free paper

Abstract Details

Purpose	To compare none vs. 50% vs. 100% adjustment of treated cylinder amount and axis (Topography-modified refraction) of the amount measured in manifest clinical refraction, in myopic topography-guided LASIK (Contoura® Vision).
Setting	LaserVision.gr
Methods	In this prospective contralateral eye study, 296 eyes of 148 patients were included: one eye of each patient was randomized to be treated with topography-modified refraction (TMR) either 50% TMR (group A) or 100% TMR (group B) while the contralateral-eye of each patient (group C) was randomized to be treated with the Standard Manifest Clinical Refraction (SMR). The 3 months peri-operative UDVA and CDVA, residual refractive and topographic cylinder, high order aberrations, and Contrast Sensitivity were compared between all three groups.
Results	3m results for 50% TMR group vs 100% TMR group vs SMR group: 63 vs.85 vs. 148 eyes. UDVA was respectively: 1.12, 1.17 and 1.02, residual refractive cylinder: – 0,07 D, – 0,02 D, and – 0,28 D; residual topographic cylinder: 0,59 D, 0,39 D, 0,78D; high order aberrations: 0,61um, 0,48um and 0,79 um. The differences in UDVA NOT statistically significant (P>.05). The differences between both TMR groups, compared to SMR were statistically significant for 2 lines of vision gained, residual refractive cylinder, residual topographic cylinder and total high order aberrations (P < .05 for both comparisons).
Conclusions	TMR appears to offer superior visual function outcomes in myopic topography-guided LASIK (Contoura® Vision) in terms of lines gained, and residual refractive and topographic astigmatism, and residual high order aberrations. In the parameters studied that revealed differences between these groups: both 50% and 100% TMR options appeared statistically significantly superior to the standard manifest clinical refraction, with no statistically significant difference between them, suggesting that 50% TMR only maybe sufficient for an effective improvement to when the standard manifest refraction was used.
Financial Disclosure	The study is an Investigator Initiated Study #39176755 supported by Alcon.

New polynomial decomposition to enhance the benefits of a nomogram using Q factor modulation

First Author: *N. Rahmania, France*
Co Author(s): *I. Salah Mabed, D. Gatinel*

Alcon Investigator Initiated Trial #39209869

Free paper

Abstract Details

Purpose	To introduce a new polynomial decomposition to depict high order aberrations changes for simulataneous correction of hyperopia and presbyopia using Q factor modulation.
Setting	Study led in Laser Vision Institute Noémie de Rothschild, Paris, France from November 2019 to April 2020.
Methods	In 28 hyperopes and presbyopic patients, multifocality was induced using Presbylasik with Q factor modulation aiming at myopic defocus in Non Dominant Eye whereas an emmetropic correction was targeted in Dominant Eye. We compared HOAs variations before and after surgery using standard polynomial decomposition (Zernike's) and new polynomial decomposition introduced by Gatinel and Malet.
Results	Changes in defocus and modified spherical aberration polynomials were better correlated with keratometric and asphericity changes respectively.
Conclusions	Our results suggest better accuracy of this new polynomial decomposition compared to Zernike's to reflect changes in High order aberrations variations when altering both target Q factor and defocus.
Financial Disclosure	The study is an Investigator Initiated Study #39209869 supported by Alcon.

Benefit assessment of corneal asphericity modulation for the correction of presbyopia in hyperopic patients: a prospective study over 14 months

First Author: *N. Rahmania, France*
Co Author(s): *I. Salah Mabed, R. Rampat, D. Gatinel*

Alcon Investigator Initiated Trial #39209869

Poster

Abstract Details

Purpose	To compare Distance Visual Acuity (DVA) in Non-Dominant Eye (NDE) achieved with monovision using contact lenses with post-operative bilateral PresbyLasik Custom Q and to confirm laser-induced multifocality in presbyopic and hyperopic patients.
Setting	Prospective intra-individually controlled superiority study including presbyopic hyperopic patients led between January 2018 and February 2019 Laser Vision Institute Noémie de Rothschild, Paris.
Methods	Classical monovision was simulated with contact lenses aiming at myopic defocus in NDE whereas an emmetropic correction was targeted in Dominant Eye (DE). We measured visual acuities first with contact lenses then 1, 3 and 6 months post-operatively. We targeted in NDE an aspheric profile by inducing a negative spherical aberration and myopic defocus and in DE a central emmetropia with positive spherical aberration. We measured corneal asphericity (Q-Factor), corneal spherical aberration c(4,0) and c(6,0), in all patients before and after surgery.
Results	28 patients (mean age: 56,03 ±4,31 years) were included. DVA in Log Mar was statistically different with contact lenses and 6 months after surgery in NDE (0,69± 0,09versus 0,04± 0,18; p<0,00001). Corneal asphericity was equal to 0,66± 0,24 and to -0,12± 0,37; (p< 0,00001), corneal Δc(4,0) to -0,07± 0,15 microns versus 0,01± 0,08 microns; p=0,013, corneal Δc(6,0) to -0,008± 0,02 microns versus -0,004± 0,03 microns; p=0,589 respectively for NDE and DE.
Conclusions	Our study shows significant improvement in visual scores by changing corneal asphericity with PresbyLasik Custom Q compared to monovision.
Financial Disclosure	The study is an Investigator Initiated Study #39209869 supported by Alcon.

Health Economics and Outcomes Research

Global prevalence, patient and economic burden of presbyopia: a systematic literature review

First Author: *C. Balachandran, Australia*
Co Author(s): *J. Berdahl, M. Dhariwal, J. Lemp-Hull, D. Thakker*

Alcon Initiated Trial

Free paper

Abstract Details

Purpose	Presbyopia is an impairment of near vision characterized by gradual loss of the ability of the eyes to focus on nearby objects. It is a common or nearly universal condition in older-aged adults (>65 years) and poses a burden on patients and healthcare systems. The objective of the present study was to collate and report published evidence on Presbyopia burden (prevalence, impact on patient quality of life and associated costs).
Setting	Systematic Literature Review of published evidence.
Methods	A systematic search was conducted in the MEDLINE®, Embase®, and Cochrane Library databases from the time of inception through October 2018. Studies published in the English language reporting the epidemiology and patient and economic burden of presbyopia were included. Overall, 64 studies were included for data extraction and reporting.
Results	Global presbyopia prevalence is predicted to increase from 1.1 billion in 2015 to 1.8 billion by 2050. In 2010, 43.8% of adults ≥40 years in Japan suffered from presbyopia. In rural China, functional presbyopia affected 67.3% of adults ≥40 years. Uncorrected presbyopia increases odds of difficulty in performing near-vision tasks and very demanding near-vision tasks by 2-fold and >8-fold, respectively. Uncorrected Presbyopia combined with uncorrected distance vision impairment significantly affects patients' quality of life. Globally, potential productivity loss due to uncorrected or under-corrected presbyopia in individuals aged <50 years is estimated at US $11 billion [0.02% of global GDP].
Conclusions	Presbyopia poses significant burden to societies, and requires timely and optimal correction to minimize impact on vision quality and productivity.
Financial Disclosure	The study was supported by Alcon.

Is Nd: YAG capsulotomy incidence influenced by IOL biomaterial? Real-word evidence from Spain at 3 & 5 years after cataract surgery

First Author: *J. Belda, Spain*
Co Author(s): *J. Placeres, J. Elvira, D. O'boyle, X. Puig, C. Perez Vives, M. Zou*

Alcon Initiated Trial

Free paper

Abstract Details

Purpose	Posterior Capsule Opacification (PCO) is the most common complication after cataract surgery and can result in reduced visual acuity, impaired contrast sensitivity and glare disability. Nd:YAG laser capsulotomies are performed to treat PCO, and can result in additional burden to patients and health care systems. Published evidence suggests that hydrophobic AcrySof® intraocular lenses (IOLs) have a demonstrated lower incidence of Nd:YAG capsulotomy compared to other hydrophobic and hydrophilic IOLs. However, there is a paucity of comparative evidence versus IOLs with a hydrophilic-with-hydrophobic surface. The aim of this research was therefore to generate robust real-world evidence to fill this gap.
Setting	This study is a retrospective analysis of anonymised electronic medical records of cataract patients from two large Spanish University 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 patients aged 65+ years who underwent cataract surgery during the period Jan 2007 – Dec 2017 were extracted from the two large Spanish regional hospitals, and analysed with SAS 9.4. Nd:YAG laser capsulotomy incidence proportions and 95% confidence intervals (CI) were reported for hydrophobic acrylic AcrySof® IOLs and non-AcrySof® IOLs (hydrophilic-with-hydrophobic surface Zeiss Asphina IOLs; hydrophilic acrylic AJL, IOL Tech, and Medicontur IOLs) at 3 years (n=8,478) and 5 years (n=4,011).
Results	At 3 and 5 years post-surgery, Nd:YAG incidence was significantly lower for AcrySof® compared to the other models. At 3-years the incidence of Nd:YAG capsulotomy for each IOL studied was as follows: 5.0% (CI 3.9%-6.1%) for AcrySof®, 21.2% (CI 19.9%-22.5%) for Zeiss Asphina, 23.1% (CI 21.0%-25.2%) for Medicontur IOLs, 23.2% (CI 14.7%-31.6%) for IOL Tech, and 31.1% (CI 28.6%-33.5%) for the AJL IOL. While at 5-years, the following Nd:YAG rates were observed: 8.8% (CI 6.0 %-11.6%) for AcrySof®, 44.3% (CI 42.4 %-46.2%) for Zeiss Asphina, 44.0% (CI 33.4 %-54.7%) for IOL Tech and 47.4% (CI 44.1 %-50.6%) for AJL.
Conclusions	This study generated robust real-world evidence on the relationship between IOL biomaterial and the incidence of Nd:YAG capsulotomy to treat PCO. The results indicate AcrySof® single-piece IOLs are protective against PCO and therefore reduce the requirement for Nd:YAG treatment compared to other single-piece hydrophilic-with-hydrophobic surface and hydrophilic acrylic IOLs 3 years after cataract surgery. For each comparison, the protective effect of AcrySof® IOLs with respect to PCO development became more pronounced when the follow-up period was extended to 5 years. Future research may be warranted to investigate consequence of lens choice for patient quality of life and overall healthcare costs.
Financial Disclosure	The study was supported by Alcon.

Comparative rotational stability of toric intraocular lenses: a systematic literature review and meta-analysis

First Author: *A. Dmitriew, Poland*
Co Author(s): *D. O'Boyle, C. Perez Vives, L. Saini, P. Cooney*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	Astigmatism is a refractive error typically resulting from anterior corneal asymmetry. Preoperative astigmatism ≥0.5 diopters is present in up to 77% of cataract eyes. Toric IOLs (TIOLs) are a safe and effective means of treating astigmatism. However, an issue sometimes experienced with TIOLs is postoperative rotational stability, which can impair astigmatic correction. Indeed, even small deviations in rotation of TIOLs from their intended axis can result in reducing astigmatic correction (3% power reduction per degree of rotation). The purpose of this research was to assess the literature with respect to rotational stability outcomes and compare across different types of TIOLs.
Setting	A systematic literature search was conducted on Embase®, MEDLINE®, MEDLINE® - In Process, and Cochrane databases to include studies from January 1974 through July 2019.
Methods	We performed a systematic literature search in the Embase®, MEDLINE®, MEDLINE®- In Process, and Cochrane databases from January 1974 through July 2019. We included randomized clinical trials (RCTs) and non-RCTs if they included rotational stability outcomes for Alcon AcrySof® TIOLs and other TIOLs, in patients with regular corneal astigmatism and age-related cataracts. A direct meta-analysis of overall mean absolute rotation was conducted using a random effects model, with AcrySof® TIOLs in one arm and the other available TIOLs grouped together in the other arm.
Results	Three RCTs and three non-RCTS met the inclusion criteria and were assessed. All six studies included the AcrySof® TIOL and Staar TIOL: 1 study; Tecnis TIOL: 4 studies; POD FT: 1 study, AT Torbi: 1 study. Reported absolute mean rotation, at 1 month post-operatively, varied from 2.05±2.56°–4.64±4.50° for AcrySof® TIOLs and 3.48±3.86°–9.45±7.0° for other TIOLs. At three months post-operatively, reported rotations were ≤ 5° in 73%-95.2% for AcrySof® TIOLs and 37%-76.19% for other TIOLs. AcrySof® TIOLs were associated with significantly better postoperative rotational stability compared to the group of other TIOLs (weighted mean difference: -0.94 CI: - 1.6, -0.28).
Conclusions	AcrySof® TIOLs are associated with excellent postoperative rotational stability and as demonstrated in this research, are likely to rotate less postoperatively, compared with a group of other available TIOLs. Factors that contribute to the performance of AcrySof® TIOLs in this respect are their single-piece design and biomaterial composition, which allows for binding with the lens capsule that stabilizes the lens in its desired position.
Financial Disclosure	The study was supported by Alcon.

Post-operative YAG capsulotomy rates with two trifocal intraocular lenses: review of evidence

First Author: *Y. Liu, China*
Co Author: *M. Dhariwal*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	To conduct a review of available evidence on post-operative YAG capsulotomy rates with two trifocal intra-ocular lenses.
Setting	ESCRS Congress Database review.
Methods	European Society of Cataract & Refractive Surgeons (ESCRS) congress database was queried using trifocal IOL specific search terms to identify relevant presentations (e-posters, videos and webcasts) from 2015-2019, reporting on post-operative YAG capsulotomy rates of two leading trifocal IOLs (PanOptix®, and AT LISA).
Results	Three comparative studies reported Nd:YAG rates for PanOptix® vs. AT LISA. A matched cohort study from Czech Republic reported Nd:YAG rates of 19.6% for AT LISA-tri (19.27 months) and 3.5% for PanOptix® (26.5 months). A matched prospective comparative study from Czech Republic reported Nd:YAG rates of 6% for AT LISA-tri and 0.5% for PanOptix® at 6 months. A matched prospective-cohort study from The Netherlands reported Nd:YAG rates of 10.7% for AT LISA-tri and 14.3% for PanOptix® at 12 months (P=0.11). Other non-comparative studies reported lower Nd:YAG rates with PanOptix® (studies duration, 3-9 months) vs. AT LISA-tri (studies duration, 3-24 months).
Conclusions	Published evidence indicates surgeons can experience favorable YAG capsulotomy outcomes with PanOptix® trifocal IOLs compared to AT LISA trifocal IOLs, both at short and long-term post-operative follow-up periods.
Financial Disclosure	The study was supported by Alcon.

Comparative safety, efficacy and efficiency of phacoemulsification systems for cataract surgery: a systematic literature review

First Author: *D. Lubeck, USA*
Co Author(s): *H. Cheng, M. Bourque, S. Kane, D. Son*

Alcon Initiated Trial

Poster

Abstract Details

Purpose	Phacoemulsification is the standard of care in cataract surgery. Advances in phacoemulsification technology aim to minimize iatrogenic effects, improve patient outcomes, and optimize procedural efficiencies. A systematic literature review (SLR) was conducted to evaluate recent clinical evidence comparing safety, efficacy, and efficiency of different phacoemulsification systems.
Setting	Not applicable.
Methods	PubMed and EMBASE/MEDLINE databases were searched in March 2019. Observational and randomized controlled trials comparing at minimum two phacoemulsification systems were included. Searches were not limited by language and articles published between 2009-2019 were included. Article screening was performed in duplicate. Exclusion criteria encompassed phacoemulsification studies involving femtosecond laser-assisted cataract surgery (FLACS), animal or laboratory studies, and non-comparative clinical studies. From all relevant comparative clinical studies, the study and patient characteristics, clinical efficacy, procedural efficiency, and safety outcomes (intraoperative and long-term) were extracted.
Results	A total of 5,895 articles were screened. Data was extracted from 27 relevant articles that included the following phacoemulsification systems: Whitestar Signature® PRO, Legacy®, Accurus®, Stellaris®, CENTURION®, and INFINITI®. A total of 6,099 eyes were studied in the 27 articles, the majority of which underwent phacoemulsification using CENTURION® (n=2,022 eyes) and INFINITI® (n=3,114 eyes). In the eight studies comparing CENTURION® and INFINITI®, safety outcomes were similar between the two systems; however, CENTURION® outperformed INFINITI® in the following procedural outcomes: cumulative dissipated energy (CDE, 8/8 studies), estimated fluid usage (EFU, 3/4 studies), and total aspiration time (TAT, 3/3 studies).
Conclusions	The CENTURION® and INFINITI® Vision Systems encompassed the majority of comparative clinical data identified in this SLR. The CENTURION® Vision System outperforms the INFINITI® Vision System in CDE, EFU, and TAT. Superiority in these efficiency measures may result in reduced ocular trauma, quicker patient recovery, and superior visual outcomes.
Financial Disclosure	The study was supported by Alcon.

An umbrella review comparing the safety of femtosecond laser-assisted cataract surgery with manual cataract surgery

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Poster

Abstract Details

Purpose	Femtosecond laser-assisted cataract surgery (FLACS) automates corneal incision, capsulotomy, and lens fragmentation steps of manual cataract surgery (MCS). Although this automation can provide improved accuracy and reproducibility, which may offer advantages in safety outcomes, primary literature remains inconclusive. A narrative umbrella review of systematic reviews and meta-analyses was conducted to summarize the totality of evidence available for safety outcomes.
Setting	Not applicable.
Methods	MEDLINE was searched using the terms "Femtosecond or femtolaser" and "cataract" from 2014-01-01 to 2019-11-01 for systematic reviews and meta-analyses comparing FLACS and MCS. No language restrictions were applied. Outcomes analyzed by more than one MA were extracted (corneal thickness [CT], effective phacoemulsification time [EPT] or power [EPP], endothelial cell loss [ECL], cumulative dissipated energy [CDE], anterior [ACT] or posterior capsular tears [PCT], edema, and intraocular pressure [IOP]).
Results	The search returned 7 meta-analyses. All reviews assessing CT (n=3 meta-analyses), EPT (3) and EPP (2), found significantly more favourable outcomes for FLACS compared with MCS. FLACS was reported to reduce ECL significantly (2) or trending to significance (1). Results were mixed for CDE, ACT, PCT, edema, and IOP. The majority of meta-analyses found no difference in the rate of complications for ACT, edema, and IOP, including the review with the lowest heterogeneity. Although one meta-analysis reported significantly lower PCT with MCS, a published re-analysis of this data along with one other review found no difference.
Conclusions	Conclusions generally favored FLACS, with good alignment between reviews. Significant heterogeneity was noted in analyses from larger reviews drawing on non-randomized trials. This research area would benefit from consistent reporting of outcomes to increase comparability within meta-analyses.
Financial Disclosure	The study was supported by Alcon.

Post-Nd:YAG laser complications in cataract patients treated for posterior capsular opacification: a systematic literature review

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Abstract Details

Purpose	Posterior capsular opacification (PCO) is the most common complication after cataract surgery and its development is associated with several factors, including lens material and design of implanted intraocular lens (IOL). Nd:YAG laser capsulotomy is the only effective treatment for PCO, however, the procedure can place a financial burden on health care systems and has been shown to be associated with a number of complications. A systematic literature review (SLR) was conducted to compile evidence on the complications associated with Nd:YAG capsulotomy for PCO after cataract surgery.
Setting	A systematic literature search was conducted on Embase®, MEDLINE®, MEDLINE®-In Process, and Cochrane databases to include studies from January 1996 through January 2019.
Methods	A systematic literature review was performed and post-Nd:YAG capsulotomy complications were identified in patients with age-related cataract, treated for PCO after IOL implantation. Randomized controlled trials (RCTs), and non-RCTs were included after independent screening by two reviewers, with conflicts resolved by a third reviewer.
Results	Overall, 70 studies (nine RCTs and 61 non-RCTs) were included. Retinal detachment (28 studies), IOP elevation (23 studies), cystoid macular edema (14 studies), and IOL pitting (14 studies) were most frequently reported post-Nd:YAG capsulotomy, with incidence rates ranging between 0.1% and 6.3%, 0.8% and 70%, 0.2% and 9.6%, and 0.5% and 19.2%, respectively. Other complications included uveitis, iritis vitreous prolapse, floaters, corneal injury, hyaloid phase rupture, hyphema, and posterior vitreous detachment. A limited number of studies reported other ocular changes, including effect of Nd:YAG capsulotomy on foveal and macular thickness and compared pre- and post-surgical values without any conclusive correlation.
Conclusions	The evidence suggests that a number of complications occur after Nd:YAG capsulotomy, potentially leading to adverse clinical consequences for patients and may place financial burden on healthcare systems. The observed rates of complications vary hugely among the published studies, potentially due to multiple risk-inducing factors, such as comorbidities, age, and eye structure. The optimal choice of IOL with PCO-inhibiting design may play a role in improving health outcomes in cataract patients and decreasing the economic burden on national healthcare systems by reducing the requirement for Nd:YAG capsulotomy.
Financial Disclosure	The study was supported by Alcon.

Cost benefit analysis of single- versus repeated-use of medical devices in cataract surgery

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Abstract Details

Purpose	To estimate the net cost effect (loss or benefit) associated with the real-world practice of repeated use of designated single-use medical devices (SUDs) versus the proper single use of such devices in cataract surgery in Greece.
Setting	Repeated use of SUDs is common practice despite the safety and legal concerns raised by the European Union directive 93/42/EEC. This practice stems from the assumption that the cost reduction associated with repeated use of SUDs outweighs the costs of secondary complications that may emerge from such use.
Methods	A cost benefit analysis model was constructed in the form of a decision tree. A digital expert panel was assembled in order to estimate the probabilities of intraoperative and postoperative complications associated with the single and the repeated use of SUDs. The unit costs for the management of each complication in the model were obtained from the official Greek bulletins. A Monte Carlo-type sensitivity analysis was performed to assess the robustness of the results.
Results	When SUDs are reused, the expected cost of each complication is higher. The total additional cost per cataract surgery when SUDs are used only once is estimated at 174.04€, while when they are used repeatedly it is as high as 356.33€. The net present value (NPV) per cataract surgery (benefit minus cost), is -1,418.24€ for single use, while for repeated use the NPV is -1,503.19€. Consequently, single use of the SUDs results in 84.95€ lower NPV per patient or 84,950€ per thousand patients compared to the repeated use of SUDs in cataract surgery.
Conclusions	Our study is the first to attach a monetary value to the common yet questionable practice of SUD reuse. Repeated use of SUDs in cataract surgery is unethical, it jeopardizes patient safety and it carries a legal liability for the reuser. This study also shows that it is not cost beneficial. We, thus, expect that our results will have implications in policy formulations to improve the delivery of cataract healthcare.
Financial Disclosure	The study was supported by Alcon.

Burden of blindness in China – a systematic literature review

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Alcon Initiated Trial

Poster

Abstract Details

Purpose	To collate and review published evidence in order to assess burden of blindness in China.
Setting	Systematic Literature Review of published evidence.
Methods	A systematic literature search was conducted in PubMed (period: January 2006 – May 2019) to collate and synthesize published evidence on burden of blindness in China.
Results	Prevalence of blindness in China ranged between 0.3% (adults greater than 40 years) to 1.7% (adults greater than 50 years). Cataract remained the most frequent (36.7%-52.6%) cause for blindness in Chinese adults followed by myopic retinopathy (24.8%-36.4%), myopic macular degeneration (7.7%-10.9%), glaucoma (6.25%-9.1%) and corneal opacity (6.2%-16.2%). In 2015, 11.7 million of the 111.7 million cataract cases in China suffered from blindness (BCVA less than 0.05). Chinese Ministry of Health reported that 45% of China's county hospitals do not offer cataract surgery services and most rural residents are unable to afford surgery in urban centers.
Conclusions	Chinese population is progressively ageing, resulting in an increasing burden of preventable blindness. There is a rural urban divide in access to surgery in China; lack of disease awareness and concerns about the quality of local services appear being the principal barriers in rural Chinese population.
Financial Disclosure	The study was supported by Alcon.

Effect of intraocular lens biomaterial on posterior capsule opacification: long-term real-world clinical practice evidence from large population based studies

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Alcon Initiated Trial

Poster

Abstract Details

Purpose	Posterior Capsular Opacification (PCO) involves lens epithelial cell proliferation and capsular fibrosis, resulting in visual obstruction. Nd:YAG laser capsulotomy treats PCO but leads to additional healthcare resource utilization. Longitudinal real world evidence (RWE) studies can provide long-term outcomes for large cohorts of patients and reflect routine clinical practice.
Setting	Literature Review of published evidence.
Methods	The present study is an overview of recently available RWE studies (N=3) on long-term PCO/Nd:YAG outcomes due to different IOLs.
Results	In Finland, a retrospective-cohort study (Lindholm 2019) estimated cumulative Nd:YAG incidence (2007-2016,N=10,044) and showed that AcrySof® IOLs had 38% reduced Nd:YAG risk vs Tecnis ZCB00 (P less than 0.001). In UK, a retrospective-cohort study (Ursell 2018) using NHS cataract-clinics data (2010-2016, N=52,162) showed significantly-lower 3-years Nd:YAG incidence for single-piece hydrophobic AcrySof® IOL vs. other hydrophobic and hydrophilic IOLs (P less than 0.001). A healthcare-claims data analysis (Kossack 2017) conducted in Region Bavaria (Germany) assessed impact of different IOLs on PCO (2010-2014, N=3,025). Findings indicated statistically significantly lower Nd:YAG risk in hydrophobic vs. hydrophilic IOLs (P less than 0.0001) up to 4-years post-cataract surgery.
Conclusions	Three robust RWE studies show that Hydrophobic IOLs are associated with a significantly lower risk of PCO requiring Nd:YAG capsulotomy vs. hydrophilic IOLs. In two studies, AcrySof® IOLs were associated with significantly lower YAG capsulotomy incidence vs. Tecnis ZCB00.
Financial Disclosure	The study was supported by Alcon.

Work productivity losses due to blindness in working Chinese adults aged ≥50 years and their caregivers

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Alcon Initiated Trial

Poster

Abstract Details

Purpose	To estimate the patient and caregiver burden resulting from productivity losses in working Chinese adults aged ≥50 years suffering from blindness.
Setting	Decision analytic modelling from China's perspective.
Methods	A productivity loss estimator model was developed in Microsoft Excel. Input parameters: prevalence of blindness in the working Chinese adults aged ≥50 years was sourced from Zhao et al. epidemiology study. On average 50% loss of remaining working-age years per blind person was assumed after considering state retirement age-limit (5 and 2.5 years respectively men and women). World Bank data on Chinese Gross National Income per capita ($8,690) was used. Assuming one caregiver per blind person, caregiver productivity loss was set at 10% and number of years of lost productivity for caregivers were assumed at 3.75 years.
Results	An estimated 1.66 million Chinese men and 0.96 million Chinese women aged ≥50 years in the working age population suffered from blindness. Productivity loss due to blindness in working Chinese adults aged ≥50 years and their caregivers was estimated to be $102.4 billion ($72.1 billion for men, $21.6 billion for women, and $8.6 billion for their caregivers). Productivity losses in cataract related blindness, the cumulative burden for men, women and their caregivers was estimated at $53.9 billion (due to cataract) and $25.4 billion (due to retinal diseases).
Conclusions	Blindness affects 1.7% of China's population ≥50 years and it poses significant burden on society due to losses in work productivity. Health policy makers should aim to further improve access to vision care and reduce the incidence and prevalence of preventable blindness in China.
Financial Disclosure	The study was supported by Alcon.

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