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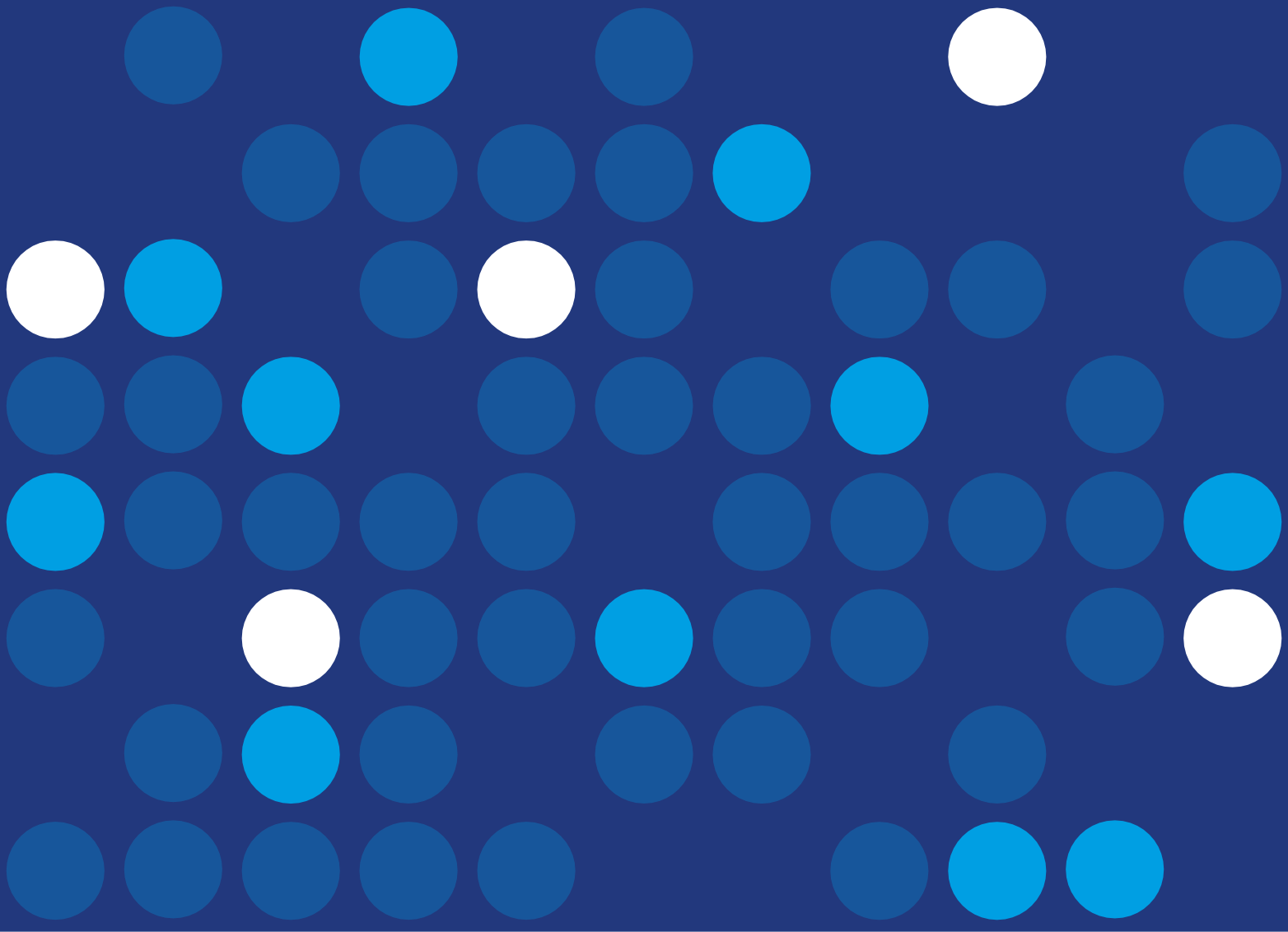

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AT-IOLs

Simulated mini-monovision using a non-diffractive extended vision intraocular lens – a systematic study of binocular defocus curves

First Author: *KG Gundersen, Norway*

Free Paper – Investigator Initiated Trial (#61478839)
18.02.2022 | 10:30h – 12:00h AM

Abstract Details

Purpose	To quantify the changes in the binocular defocus curve associated with the Vivity™ non-diffractive extended vision intraocular lens when the dominant eye was targeted for emmetropia and the non-dominant eye was artificially targeted for slight myopia using spectacles.
Setting	Private single surgeon clinic
Methods	This was a non-interventional research study of the corrected binocular defocus curve associated with binocular emmetropia (Setting A) and with emmetropia in the dominant eye and two different levels of myopia simulated in the non-dominant eye (− 0.50 D, Setting B and- 1.00 D, Setting C). Subjects were patients implanted with the AcrySof® IQ Vivity® intraocular lens in both eyes 3 to 12 months previously. Using the defocus data, the percentage of subjects with a continuous 2.5 D range of vision (distance to 40 cm) was calculated for various levels of minimum visual acuity (VA).
Results	Forty subjects were enrolled. The mean spherical equivalent refraction was- 0.06 D ± 0.36 D, with 0.37 D ± 0.29 D of refractive cylinder. There was no statistically significant difference in the mean VA at- 0.25 D or at- 0.50 D vergences between the test Settings, but there was a statistically significant difference at all other vergences. Differences were particularly noticeable at- 2.00 D,- 2.50 D and- 3.00 D, where higher myopia in the non-dominant eye yielded better binocular VA. A 2.5 D range of functional vision (20/25) was achieved by 38% of subjects at Setting A, 68% of subjects at Setting B and 85% of subjects at Setting C. At setting C, all but one subject (39/40, 97.5%) had a 2.5 D range of vision with a VA of 20/32 or better.
Conclusions	Significant gains in binocular near vision, with only a nominal effect on distance vision, can be achieved with the Vivity IOL by leaving the non-dominant eye of patients with 0.50 D or 1.00 D of myopia.

Tolerance to residual astigmatism and low spherical refractive errors on distance vision using a novel presbyopia-correcting intraocular lens

First Author: *L Álvarez-Rementería, Spain*

Poster – Investigator Initiated Trial (#66538975)
Available Online

Abstract Details

Purpose	To assess the impact of low residual refractive errors on distance vision in patients using a novel presbyopia-correcting extended vision intraocular lens (IOL).
Setting	Clínica Rementería, Madrid, Spain.
Methods	The study included patients with the Acrysof® VivityTM IOL. Distance vision was assessed three months after the surgery without distance correction VA (UDVA), with distance correction (CDVA) and with different refractive conditions: A) with a residual mixed astigmatism induced by adding a combination of -0.25 diopter (D) spherical and 0.50 D cylindrical lenses placed in vertical (against the rule - ATR), oblique and horizontal (with the rule – WTR) positions, B) with a positive (myopization) and a negative (hyperopization) defocus of 0.50D.
Results	A total of 15 eyes of 15 patients were included. UDVA was -0.04±0.06 logMAR while VA with the best distance correction (CDVA) was -0.05±0.05 logMAR. VA values for the ATR, oblique and WTR situations were 0.01±0.06, 0.00±0.06, 0.01±0.05 logMAR, respectively. The VA was better for the reference situation ($p<0.001$) and no differences were found among the three astigmatic situations ($p=0.19$). VA values with +0.50 D and -0.50D of defocus were 0.00±0.06 and 0.00±0.04 logMAR, respectively. Similarly, VA was better with distance correction ($p<0.001$) and no differences were found between the myopic and the hyperopic situations ($p=0.43$).
Conclusions	Low residual mixed astigmatisms, regardless their orientation, and low positive or negative spherical refractive errors, seem to be tolerated at distance vision in patients with the IOL under study. Despite VA was better for the emmetropic situation, none of the residual refractive errors showed a significant impact on distance VA.

A real world registry evaluation of satisfaction, spectacle independence and vision outcomes in German patients implanted with a novel wavefront-shaping presbyopia-correcting IOL

First Author: *D Breyer, 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 IQ Vivity and AcrySof IQ 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 AcrySof IQ 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	27 subjects were enrolled from four German sites. Mean UCDVA, UCIVA and UCNVA were -0.010±0.102, 0.088±0.117 and 0.212±0.150 logMAR, respectively. The need to wear glasses was 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% were satisfied with their sight, and 88.5% reported no difficulty seeing to engage in an activity/hobby of their interest. Visual disturbances rates were low – reported 'None' for halos 92.3%, glare 84.6% or starbursts 96.2%. There are no unanticipated AEs to date.
Conclusions	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 no visual disturbances.

Monofocal IOLs

Validation and clinical applications of Democritus Digital Acuity Reading Test DDART

First Author: *G Labiris, Greece*

Poster – Investigator Initiated Trial (#61417065)
Available Online

Abstract Details

Purpose	Primary objective of this study is the development and validation of the web-based Democritus Digital Acuity Reading Test – wDDART, which is based on the previously developed and validated Windows-based DDART.
Setting	The development of wDDART was carried out in the Department of Computer Science and Biomedical Informatics, University of Thessaly, Lamia, Greece, while the validation was conducted in the Department of Ophthalmology, University Hospital of Alexandroupolis, Alexandoupolis, Greece.
Methods	This is a prospective, comparative clinic-based trial. wDDART displays sentences with text sizes from 1.3 to -0.5 logMAR for different patient-screen distances and automatically calculates: reading acuity (RA), maximum reading speed (MRS), critical print size (CPS) and reading accessibility index (ACC). It provides advanced text calibration features and monitors examination distance using computer vision techniques. For the validation, normal and low vision patients responded to wDDART and the Windows-based version DDART on the same day, at 40cm distance. wDDART-derived reading parameters were compared with the corresponding ones from DDART. Test-retest reliability of wDDART was evaluated in a 15-day time-window.
Results	One hundred patients (normal vision group - NVG: 70 patients; low vision group - LVG: 30 patients) responded to DDART and wDDART. Non-significant differences between the two reading tests were found for all parameters in NVG and LVG. Intraclass correlation coefficients (ICCs) between the two tests demonstrated good or excellent correlation for RA, MRS, ACC and moderate correlation for CPS. Test-retest reliability was excellent for RA and ACC, while ICCs ranged between 0.715 and 0.895 for MRS and CPS.
Conclusions	To our knowledge, wDDART is the first validated ophthalmological reading assessment tool that is available as a web application with many novel features. Study outcomes suggest comparable validity to the DDART reading tool and high test-retest reliability, making it sufficient for clinical and research settings for the evaluation of reading acuity and reading performance in normal and low vision patients. The potential uses of wDDART as a web-based diagnostic tool are numerous, including support for screening initiatives and application to remote health facilities.

Pilot investigation into device deficiencies and corneal morphology with four IOL delivery systems

First Author: *M Nanavaty, UK*

Free Paper – Alcon Initiated Trial (#ILJ466-P003)
18.02.2022 | 8:30h – 10:00h AM

Abstract Details

Purpose	A pilot study to evaluate the performance of an automated preloaded intraocular lens (IOL) system (AutonoMe (A)), two non-automated preloaded (iTec (iT) and iSert (iS)) and a manual delivery system (Monarch III (MIII)) in terms of injector deficiencies, corneal morphology and clinical outcomes, at 2.5 hours and 1 month post cataract surgery.
Setting	University Hospitals Sussex NHS Foundation Trust, Brighton, United Kingdom & Univesity Clinic Frank Furt, Germany.
Methods	Prospective, multicenter, randomized, observer-masked pilot study of 24 subjects (N=48 eyes, 12/group). The 4 injectors were evaluated for deficiencies such as haptic trailing, nozzle tip splitting, IOL damage and sudden IOL injection. Anterior segment ocular coherence tomography (AS-OCT) was performed to evaluate corneal incision size, epithelial and endothelial gaping and misalignment, central corneal thickness (CTT), and corneal thickness at the incision site (CTIS). Specular microscopy was performed to assess endothelial cell counts (ECC). Clinical outcomes of best-corrected distance visual acuity (BCDVA) and surgically induced astigmatism (SIA) were also captured.
Results	Injectors A and MIII displayed 0 device deficiencies. iT and iS had 11 and 9 deficiencies respectively, the most common of which were nozzle tip splitting and sudden IOL ejection. At 2.5 hours, incision gaping was highest in iS (50.0%) due to epithelial gaping (iT: 16.7%, MIII: 8.3% and A: 8.3%). No epithelial misalignment was found in A or MIII versus 3 eyes with iS and iT each. At 1 month all but 1 eye (iT) were fully healed. CTT and CTIS were similar among injectors, and numerically greater in the A group. At 1 month, mean BCDVA ranged from -0.008 logMAR with Clareon IOLs (A) to 0.055 Tecnis ZCB00 (iT). ECC was similar between the systems. SIA magnitude was lowest with A and MIII.
Conclusions	This pilot study found that A and MIII have lower device deficiencies than iT and iS. Initial epithelial gaping and misalignment settles at 1 month. The AS-OCT is not the best tool to evaluate incision size and location at 2.5 hours post-operatively.

Lasers

Customized myopic LASIK treatments with the InnovEyes artificial intelligence software by Alcon: an observational single-arm consecutive case series

First Author: *AJ Kanellopoulos, Greece*

Poster – Investigator Initiated Trial (#63571029)
Available Online

Abstract Details

Purpose	To evaluate the safety and efficacy of a novel automated ray-tracing optimization in customization of excimer ablation in myopic LASIK.
Setting	Laservision.gr Clinical and Research Institute, Athens, Greece investigator initiated study 59917561 sponsored by Alcon Greece.
Methods	Observational consecutive case series; 20 consecutive myopic InnovEyes LASIK treatments (40 eyes). All qualifying cases were treated with LASIK and the InnovEyes suggested low order (refraction) and high order aberrations.The ablation profile is initially calculated based on a 3D model eye for each case. Optical coherence interferometry captures axial length data, and low and high order aberrations calculation is performed by ray-tracing based on wavefront and Scheimpflug tomography measurements, all from a single diagnostic device, InnovEyes sightmap. Visual Acuity, refractive error, keratometry, topography, high order aberrations and contrast sensitivity were evaluated, over six a month follow-up.
Results	TBA X % of eyes gained one line of vision (UDVA post compared with CDVA pre) and X % 2 lines. Attempted vs. achieved correction was X(TBA) Diopters sphere and Xc(TBA) Diopters Cylinder. Pre- to post-operative high order aberrations average: RMSh changed from X um to X um. Contrast sensitivity changed from X(TBA) pre- to X(TBA) post-operatively.
Conclusions	We report safety and effectiveness preliminary outcomes with a novel excimer laser customization by ray tracing optimization, for myopic LASIK treatments, employing axial length, wavefront and corneal tomography measurements captured from one single device to produce a customized eye model reference for each case. It bears the potential advantage through total eye aberration data and ray tracing refraction calculation to offer improved and more predictable visual outcomes.

Dry Eye and Ocular Health

Ocular discomfort following use of artificial tears in patients under treatment of intravitreal injections of Anti-VEGF agents.

First Author: *F Pastor-Pascual, Spain*

Poster - Investigator Initiated Trial (#63239827)
Available Online

Abstract Details

Purpose	The main objective of the present study is to evaluate the benefit of artificial tears instillation in patients under treatment with intravitreal injections of anti-vascular endothelial growth factor agents.
Setting	Oftalvist Valencia, Spain.
Methods	This was a randomized, prospective study considering 40 patients under treatment with intravitreal injections of anti-vascular endothelial growth factor agent (ranibizumab, 10mg/ml) for age-related macular degeneration. The study was approved by the Ethics Committee Hospital ClÍnico San Carlos, Madrid, Spain. Ocular discomfort symptoms were assessed by means of the ocular surface discomfort index (OSDI) and the Dry Eye Questionnaire-5 (DEQ-5), extensively used as an aid for dry eye diagnosis, one month after injections, and then after one month of artificial tears instillation, during a two-month follow-up period. Systane Hydration and Viscofresh 10 mg/ml artifical tears were used.
Results	There is a reduction in ocular discomfort symptoms assessed by means of OSDI and DEQ-5 questionnaires in patients under treatment of intravitreal injections of anti-vascular endothelial growth factor agents. Statistical tests will be shown at the time of the presentation with a larger dataset. Current standard of care after intraocular injections does not include artificial tear instillation of any kind, but the outcomes of the present study suggest it should be considered for inclusion in the post-injection protocol.
Conclusions	Artificial tears instillation reduces patient-reported symptoms of ocular discomfort in patients being treated with intravitreal injections for age-related macular degeneration.

Vision Care

Comparison of the tear film stability and comfort levels of a novel and two conventional daily disposable contact lenses in healthcare professionals who had to wear facial masks for prolonged period of time.

First Author: *A Penbe, Turkey*

Free Paper - Investigator Initiated Trial (#66288565)
19.02.2022 | 8:30h – 10:00h AM

Abstract Details

Purpose	Due to the Covid -19 pandemic, the need for switching glasses to contact lenses (CLs) was more common for healthcare professionals due to fogging and sterilization problems. We aimed to clarify the most appropriate daily disposable contact lens (DDCL) material in terms of tear film stabilization and ocular comfort levels for prolonged use.
Setting	A randomized, prospective and comparative study.
Methods	The healthcare professionals between 18-40 years old who wanted to wear CL as first-time users were randomly included to the 3 study groups (group 1: verofilcon A, Precision 1®, Alcon, group 2: nesofilcon A, Biotrue® Oneday, B&L, and group 3: senofilcon A, Acuvue Oasys®1-Day, J&J. The patients were evaluated initially and after 2 weeks of CL use with contact lens corrected visual acuity (CLCVA), keratometry, non-invasive tear break up time (NITBUT) scores at first, 4th, 8th, and 12th hours, high order aberrations (HoAs) scores obtained from Sirius Corneal Topography, and Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) scores for comparative analysis.
Results	Between August and September 2021, 65 eyes of 33 subjects included to the three study groups of the ongoing study completed the final visit. The initial CLCVA, keratometry, NITBUT and HoAs mean values were similar. After 2 weeks of CL use; the measurements were evaluated while the contact lenses were on the ocular surface. The mean values of CLCVA, keratometry, NITBUT and HoAs at first and 4th hours of wearing CLs were similar again. At the 8th hours of wearing CLs the mean NIBUT scores (Group1: 10.23 seconds (sec), Group 2: 9.74 sec, Group 3: 8.15 sec) were lower in group 3 (p= 0.027). However, at the 12th hours the mean scores of NITBUT scores were recorded as 8.72 sec in group 1, 5.91 sec in group 2 and 4.06 sec in group 3, and statistically meaningfully higher in group 1 according to the other two groups (p=0.016). The mean HoAs scores were similar at 8th hours but at 12th hours group 3 had the highest scores (p=0.036) and the group 1 had slightly lower scores than group 2 (p=0.067). The CLDEQ-8 scores were significantly lower in group 1 and group 2 (6.18, 7.23 and 9,82, respectively). (p=0.042).
Conclusions	The preliminary results of the ongoing study suggest superiority of the tear film stabilization capability of verofilcon A in prolonged use. The better scores of this lens at the 12th hours could be explained with a new and unique surface technology named SMARTSURFACE™ presenting a greater than 80% water content to maintain a stable pre-lens tear film. The higher CLDEQ-8 and HoAs scores of nesofilcon A could be depending on to the higher dehydration rates of the hydrogel CL materials compared to the silicon hydrogels CLs.

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Please refer to relevant product direction for use and operator manuals for list of indications, contraindications and warnings.
https://ifu.alcon.com/

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