

Johnson & Johnson VISION

Clinical Research & Innovations

A GUIDE TO OUR

American Academy of Optometry
2018 Posters and Presentations







Dear Colleague,

On behalf of Johnson & Johnson Vision, welcome to San Antonio for the 97th meeting of the American Academy of Optometry. We are delighted to join you for an exciting, educational meeting, and we are proud to once again be a Visionary Sponsor for Academy 2018 San Antonio.

Johnson & Johnson Vision is proud to thank our colleagues and their collaborators around the world for their hard work to compile the comprehensive data contributing to 11 papers and posters being presented at Academy 2018.

We hope you will have an opportunity to attend these poster sessions and presentations, summarized in this guide.

During your time in San Antonio, we also hope you will stop by the Johnson & Johnson Vision booth (#1742) to talk with our team, try our portfolio of ACUVUE® Brand Contact Lenses, learn more about our LipiScan™ and LipiFlow® technologies and check out the Blink® Family of Products for yourself. This year, we are excited to showcase our newest innovation, ACUVUE® OASYS with Transitions™ Light Intelligent Technology™, through interactive experiences in our booth.

We thank you for your partnership and look forward to our continued work together.

Warm regards,

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PAPERS

AND

POSTERS

A Contralateral Comparison of the Visual Effects of Clear vs. Photochromic Contact Lenses

Billy Hammond PhD

Professor, Brain and Behavioral Sciences

Renzi-Hammond L, Buch J, Cannon J, Toubouti Y

Significance: A first-in-class photochromic soft contact lens has recently been approved by the Food and Drug Administration (FDA) that darken when a wearer is exposed to bright outdoor conditions that would, presumably, otherwise impair vision. This study was designed to assess whether this soft contact lens with photochromic additive could improve visual function when subjects were exposed to simulated sunlight conditions.

Purpose: To compare the visual effects of a photochromic contact lens to a non-photochromic contact lens under simulated sunlight conditions.

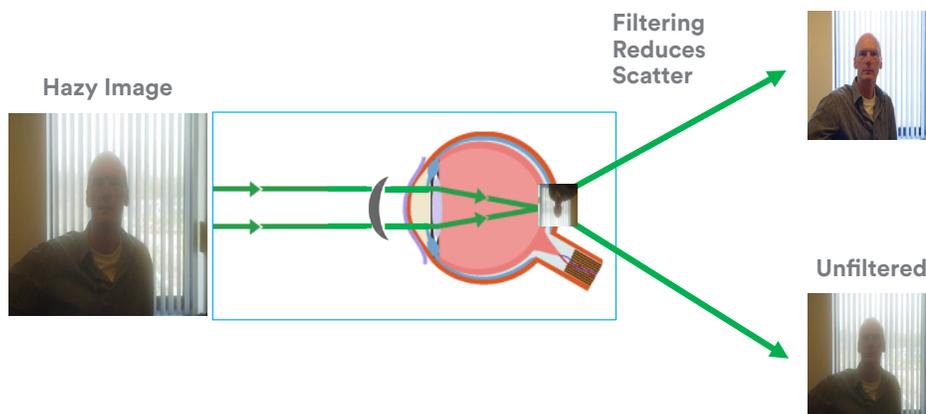
Methods: A subject-masked, age-stratified, contralateral design was used. A total of 61 subjects were enrolled (40 subjects of age 18 to 39, and 21 of age 40 to 65) and randomized to wear a senofilcon A-based contact lens with photochromic additive (Test) in either the left or right eye and a senofilcon A based contact lens without photochromic additive (Control) in the other eye. The photochromic was partially activated during testing with a steady state transmittance of approximately 62%. The primary endpoint was visual outcome and this was based on measuring photostress recovery (PSR), glare disability (GD), glare discomfort (GDC) and chromatic contrast (CC). Iris color and macular pigment density were assessed as control variables. PSR was quantified by measuring the time needed to recover visual acquisition of a grating target after five seconds of an intense xenon white flash exposure (matched to the spectrum of sunlight); GD was evaluated as the energy in a surrounding xenon white annulus necessary to veil a central grating target; GDC was assessed using bio-imaging of the squint response. CC was measured as thresholds for a yellow grating target superimposed on a 460-nm background (matched to sky light).

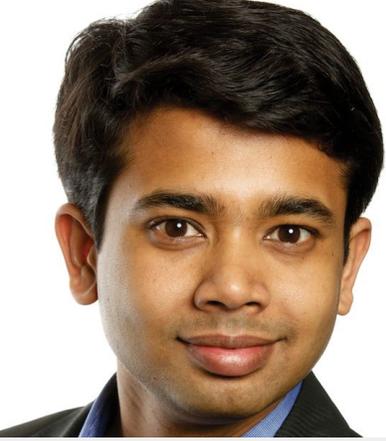
Results: PSR was 44% faster using the tinted photochromic compared to the control and the eye wearing the photochromic had 39% less squint (GDC) compared to the control. GD was improved by 36% in the photochromic vs. control (less GD) and CC was enhanced by 33% in the photochromic (all p values <0.05).

Conclusions: There was a clear benefit to visual function when comparing the activated photochromic contact lens with a transparent contact lens on the same individual. This significant benefit was seen specifically with respect to photostress recovery time, glare discomfort and glare disability when using light stress matched to daylight sun. Chromatic contrast thresholds were also improved when using wavelengths simulating the blue of skylight.



Dr. Hammond is a full Professor in the Brain and Behavioral Sciences program at the University of Georgia (UGA) and the Principal Investigator of the Visual Sciences Laboratory. His Bachelor of Science was obtained at the University of Oregon and his PhD was received at the University of New Hampshire. He was a postdoctoral fellow at Harvard Medical School and a professor for several years at Arizona State University before coming to UGA in 1999. He has published over 100 empirical papers and numerous chapters, reviews, and theoretical papers on the biology (e.g., retinal carotenoids) and optics of the visual system and brain.





Contact Lens-Induced Corneal Infiltrative Events During Extended Melimine Antimicrobial Contact Lens (MACL) Wear Clinical Trial

Debarun Dutta BOptom, PhD, FAAO
Research Fellow

Investigator Initiated Study

Kalaiselvan P, Konda N, Sharma S, Vaddavalli PK, Stapleton F, Willcox M

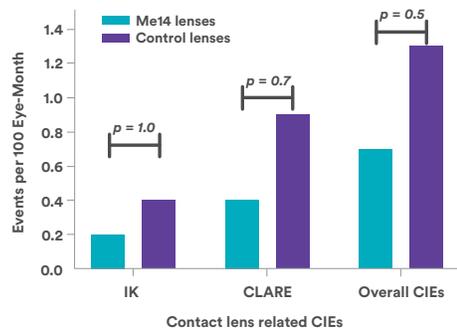
Dr. Debarun Dutta is a research fellow at the School of Optometry and Vision Science University of New South Wales, Australia. He completed his Bachelor of Optometry training in India, followed by clinical fellowship at the LV Prasad Eye Institute, India. Dutta worked as a contact lens practitioner at the LV Prasad Eye Institute for two years prior to his PhD at the Brien Holden Vision Institute and University of New South Wales, Australia in 2014. Dutta has been involved with clinical trials of novel contact lenses and contact lens coatings investigating their efficacy in reducing corneal infiltrative events. Dutta has presented his work in various scientific meetings and published results in peer review journals.

Purpose: Contact lens-induced corneal infiltrative events (CIEs) occur with soft contact lens wear. Preventing and reducing these events remains a challenge for practitioners and industry. The aim of this study was to evaluate the incidence and type of CIEs seen with bi-weekly disposable hydrogel antimicrobial contact lens wear compared with a control lens wear over three months of extended wear.

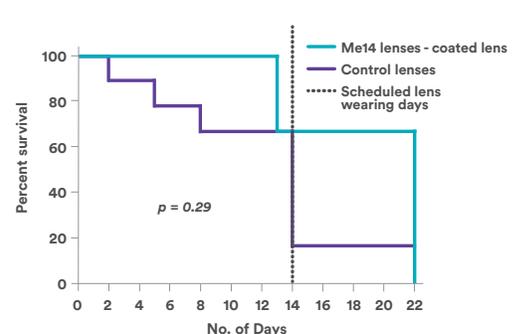
Methods: A prospective, randomised, double-masked, contralateral, extended contact lens wear clinical trial was conducted with 176 subjects. The study received ethics approval (HREC#15436) and was registered with Australia and New Zealand Clinical Trial Registry (ACTRN1261500072556). Antimicrobial contact lenses were produced by coating with Mel4 (Melimine) peptide as reported earlier. Subjects were 18 to 42 years of age (22.6 ± 4.2) and had refractive errors ranging from a -0.75 dioptre (D) sphere to a -6.50 D sphere with a cylinder ≤ -1.50 D. The contact lenses were removed and replaced at 14-day intervals over a period of three months. Follow-up visits were conducted after one night, two weeks, one month and three months of lens wear, including a non-lens wear follow-up after one month of discontinuing the lens wear. The main outcome measures were the incidences of CIEs per 100 eye-months and rate of discontinuations.

Results: A total of 135 subjects completed the study; 73% were neophytes. Microbial keratitis did not occur. Nine CIEs were seen, three with Mel4-coated lens wear (0.7 events per 100 eyes per month) and six with control lens wear (1.3 events per 100 eyes per month; $p = 0.508$). With the Mel4-coated lens, the incidence of contact lens-induced acute red eye (CLARE) and infiltrative keratitis (IK) was 0.4 and 0.2 events per 100 eyes per month respectively, while with the control lens wear, the incidence rates were 0.9 and 0.4 for the same CIEs respectively. A total of 14.2% participants dropped out from the study; 5.1% due to general health issues such as fever, chickenpox and hypothyroidism, 5.1% were not interested in continuing in the study, 2.8% had bilateral ocular discomfort with contact lens wear and 2.3% relocated to other cities.

Conclusions: Mel4-coated (Melimine peptide) antimicrobial contact lenses reduced the incidence of CIEs by 50% during two weeks extended hydrogel contact lens wear, but this did not reach statistical significance due to the low rate of CIEs generally in this population.



Incidence of corneal infiltrative events per 100 eye-month



Survival analysis for corneal infiltrative events

Does Extended Melimine Antimicrobial Contact Lens (MACL) Wear Effect the Ocular Microbiota?

Parthasarathi Kalaiselvan BOptom, MOptom, PhD Candidate

Investigator Initiated Study

Willcox M, Konda N, Sharma S, Vaddavalli PK, Stapleton F, Dutta D



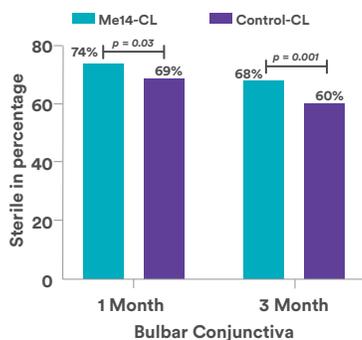
Purpose: Long-term extended wear of hydrogel lenses does not alter the conjunctival microbiota. However, it is not clear whether antimicrobial lenses alter this microbiota. The aim of this study was to investigate the effect of Mel4-coated antimicrobial contact lenses on the conjunctival microbiota during three months of extended wear.

Methods: A prospective, randomised, double-masked, contralateral, extended contact lens wear clinical trial was conducted. The study received ethics approval (HREC#15436) and was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN1261500072556). The antimicrobial peptide Mel4 was covalently attached to etafilcon A contact lenses. A total of 176 subjects wore test and control lenses on a contralateral basis for three months of 14 nights extended wear. The conjunctival microbiota was sampled using sterile cotton swabs moistened with sterile distilled water during asymptomatic lens wear at one and three months of wear. The microbiota from the worn contact lenses were cultured after one and three months of wear. Standard techniques were performed to culture the microbiota.

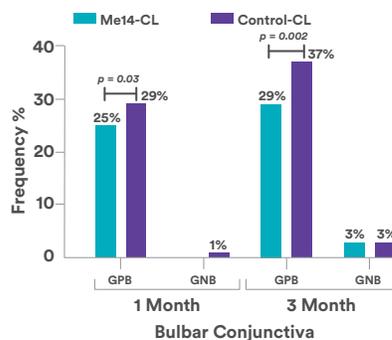
Results: The microorganisms most frequently isolated from both the test and control lenses and the conjunctiva were the Gram-positive bacteria *Staphylococcus epidermidis* (6-20% isolation rate). There was no evidence of overgrowth by fungi; *Candida albicans* was the only fungus isolated from the conjunctiva or contact lenses (1% isolation rate) after one month of wear from both eyes. The conjunctiva exposed to Mel4-coated contact lenses were significantly more sterile ($p = 0.031$, $p = 0.001$) and Gram-positive bacteria were recovered less frequently ($p = 0.031$, $p = 0.002$) at one month and three months. There was no significant difference in Gram-negative bacteria (0-7% isolation rate). There was no significant difference in the number of Gram-positive ($p = 0.500$) or Gram-negative bacteria ($p = 0.250$) recovered from either lens type.

Conclusions: MACL wear reduced the microbiota colonising the conjunctiva during extended wear, but did not significantly alter the microbiota from lenses. There was no evidence of overgrowth by microbiota that is not usually present on the ocular surface, particularly scenarios involving low contrast. This information can help practitioners understand the potential wearer benefits of MFCL designs in real-world conditions.

Parthasarathi Kalaiselvan is a PhD Scholar at School of Optometry and Vision Science, University of New South Wales (UNSW) in Sydney, Australia. He completed his Bachelors (2007) and a Masters (2014) in Optometry training in India, followed by a post-graduate clinical fellowship in Optometry (2008) at LV Prasad Eye Institute, Hyderabad, India. Further, he completed his Clinical Research Fellowship in Vision Cooperative Research Centre (CRC) at Brien Holden Vision Institute, Sydney, Australia (2011) and joined the contact lens department at LV Prasad Eye Institute, Hyderabad in 2011 and finally took up teaching responsibilities within the Institute, along with a number of other roles including consultant and research optometry. His area of interest is contact lenses, antimicrobial peptide, ocular microbiome and contact lens adverse events, tear film and ocular surface. His current PhD thesis aims to evaluate the ability of antimicrobial contact lenses to reduce the incidence of corneal infiltrative events during extended wear.



Percentage of sterile bulbar conjunctiva at 1 & 3 months of extended contact lens wear



Bacteria recovered from bulbar conjunctiva at 1 & 3 months of extended contact lens wear



Investigating the Role of UV-blocker as an Antioxidant to Prevent Oxidation of Tear Film Component Deposition in Commercial Contact Lens Hydrogels

Noelle Rabiah, BSE, MS
PhD Candidate

Scales C, Fuller G, Cegelski L

Noelle Rabiah is a fifth-year PhD candidate in Chemical Engineering at Stanford University and is co-advised by Prof. Gerald Fuller and Prof. Lynette Cegelski. Throughout her PhD research, Noelle has studied contact lens materials, often in the context of tear-film component deposition. She has conducted contact lens research both on the molecular scale, using solid-state NMR, and on the macromolecular scale, investigating the stability of the tear film in the presence of contact lens materials.

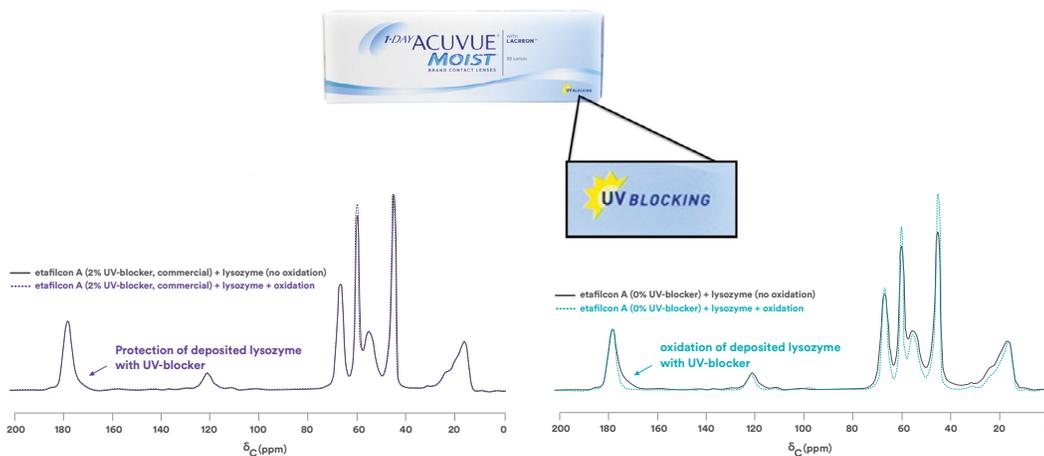
Significance: In addition to its UV-blocking abilities, we have found evidence that UV-blocker (2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl]ethyl methacrylate) also acts as an antioxidant within the contact lens, protecting tear-film components (i.e. lysozyme) that integrate into the lens during wear from oxidative damage.

Purpose: In certain commercial hydrogel contact lens materials, UV-blocker is used to provide UV-blocking capabilities to prevent UV-damage to the cornea. Recently, there has been evidence that this molecule functions as an antioxidant and protects the oxidation of deposited lipids within the contact lens. The aim of this study was to investigate if this UV-blocker also could protect deposited lysozyme from oxidative damage.

Methods: Etafilcon A was prepared with specific levels of UV-blocker (i.e. 0, 0.95, and 1.8 wt%) in addition to commercially available etafilcon A (2 wt%) and each composition was subjected to a 72-hour incubation with lysozyme in phosphate-buffered saline (2 mg/mL) followed by exposure to controlled in vitro oxidative conditions (i.e. 3% hydrogen peroxide in deionized water (pH 7) under 24 hours of ultraviolet light ($\lambda=365$ nm) at 1.9 mW/cm²). Cross-polarization magic angle spinning ¹³C NMR was used to quantify the amount of lysozyme integrated within the contact lens and detect changes to deposits after oxidation

Results: The presence of UV-blocker (0.95, 1.8, and 2 wt%) in etafilcon A protects lysozyme from oxidative damage. We demonstrate that lenses that contain any amount of UV-blocker (as low as 0.95 wt%) retain similar amounts of lysozyme within their matrices (i.e. approx. 10-14 wt% within the dried hydrogel material) after exposure to oxidative conditions, while lenses without UV-blocker show complete dissociation of lysozyme from the material under oxidative conditions, likely due to oxidative cleavage of lysozyme within hydrogel lens. We confirmed that when lysozyme is subjected to oxidation conditions prior to incubation with commercial etafilcon A (2 wt% UV-blocker), lysozyme is not taken up by the contact lens.

Conclusions: Our findings support the importance of UV-blocker as a protectant from tear-film component oxidative damage and suggest a potential benefit to contact lens patients.



Meta-Analysis of Axial Elongation in Myopic Children

Noel Brennan, BOptom, MSCOptom, PhD, FAAO
Clinical Research Fellow

Cheng X, Toubouti Y, Bullimore M

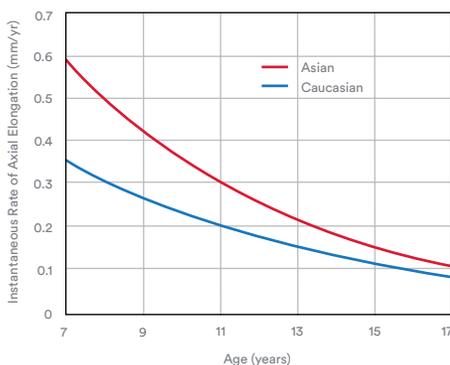
Purpose: In evidence-based medicine, well-conducted meta-analyses are regarded as providing the highest level quality of scientific evidence. Donovan et al have published results of a meta-analysis of refractive progression rates among myopes.¹ However, axial length may be preferred to refractive error as a metric for assessing myopia as (i) it is significantly associated with retinal disease, (ii) its measurement is relatively more repeatable than refractive error and (iii) it can be obtained without cycloplegia. We conducted a meta-analysis to model axial elongation in myopic children.

Methods: A search of PubMed and Embase was conducted based on the following search terms ["myopi* AND ((axial AND (length OR elongation)) OR biometr*) AND (progression OR shift OR longitudinal) NOT (animal OR surgery OR surgical OR adult)]. The search yielded 260 results. After excluding those studies which did not present isolated data for myopes, those with redundant information, those outside the age range of 7 to 18 years, those with sundry other issues, and adding in additional studies cross-referenced in the papers surveyed, a total of 45 useful references remained. To account for varying ages of the sample populations and different periods of follow-up, axial elongation (AE) was modeled using the integral of the exponential decay function based on the following equation:

$AE = (e^{\lambda t_2} - e^{\lambda t_1}) * \alpha / \lambda$, where AE is measured at ages t_1 and t_2 and α and λ are fitted constants. Populations were separated into Asians and Caucasians depending on the predominant race in different studies.

Results: The figure plots the modeled fitted instantaneous rate of axial elongation (mm/yr) versus age for both Asians and Caucasians ($R^2 = 0.92$). A 9-year-old Asian child is predicted to have instantaneous progression of 0.43mm/yr while a Caucasian child of the same age has a rate of 0.27mm/yr. Predicted rates of axial elongation are consistent when compared to refractive progression curves of Donovan et al¹ by applying age-related ratios of axial length/refractive error, although the difference between Asian and White children is higher than expected.

Conclusions: Our model presents the first meta-analysis of axial elongation in myopic children, to our knowledge. Axial length measurement is expected to become an increasing part of clinical practice as myopia control becomes more widely accepted. As such, our data should provide a useful referent for practitioners when assessing myopic progression in children and may assist in setting efficacy criteria for myopia control products. Future work will model other risk and associated factors, the change in the axial length/refractive error ratio and progression rates during various forms of myopia control treatment.



1. Donovan et al, Optom Vis Sci 2012; 89: 27.



Dr. Noel A. Brennan is Global Platform Lead for Myopia Control and a Clinical Research Fellow at Johnson & Johnson Vision Care Inc., where he has been since 2011. For 16 years prior to that he co-directed a privately-owned research consulting company and, before that, was an academic faculty member at the University of Melbourne, reaching the level of Reader. He is a Senior Fulbright Alumnus, a Max Schapero Memorial Lecture Awardee of the American Academy of Optometry and a councilor of the International Society for Contact Lens Research. He was recently named one of the 30 most influential people in the contact lens field in the global trade journal, Contact Lens Spectrum. He has over 500 publications, including over 100 peer-reviewed papers as well as educational articles, peer-reviewed conference abstracts, industry reports and patents, and has presented more than 400 lectures internationally, including paid invited lectures in over 30 countries. He is best known for his work in measurement and interpretation of contact lens oxygen transmissibility, identification of lens friction/eyelid interaction as the paradigm-shifting mechanism of contact lens discomfort, the unique optics of the Medmont topographer and the celebrated Liou-Brennan model eye.



The Impact of Photochromic Contact Lenses on Daytime and Nighttime Driving Performance

John Buch OD, FAAO
Senior Principal Research Optometrist
Cannon J, Toubouti Y

Dr. John Buch is a Senior Principal Research Optometrist for Johnson & Johnson Vision Care and a Fellow of the American Academy of Optometry. John received his OD degree from The Ohio State University College of Optometry and his MS degree from the Indiana University School of Optometry. His thesis investigated the effect that contact lens designs have on ocular surface physiology. Since joining Johnson & Johnson in 1998, Dr. Buch has been the clinical project lead on multiple products including ACUVUE OASYS® 1-Day and ACUVUE OASYS® with Transitions. He has a research interest in the psychophysical and neurobiological basis of visual perception and the clinical evaluation of contact lens performance.

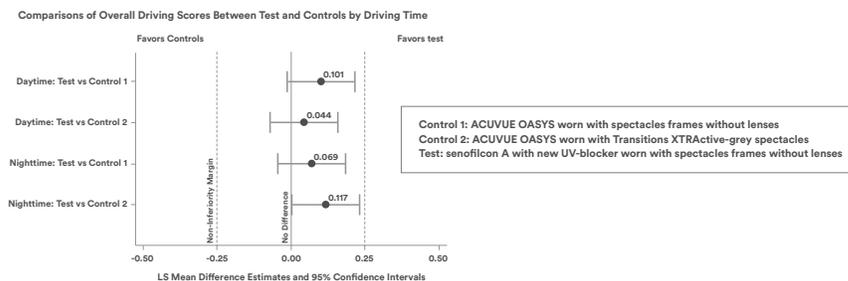
Significance: The U.S. Food and Drug Administration (FDA) has recently cleared the first contact lens to incorporate a photochromic additive that automatically darkens the lens in the presence of ultraviolet (UV) and high energy visible (HEV) light and lightens in its absence. Since any ophthalmic lens that absorbs visible wavelengths will reduce retinal illuminance, it is important to understand the impact of this new ophthalmic lenses on both daytime and nighttime driving performance.

Purpose: Evaluating the performance of the first-in-class photochromic soft contact lens on vision and driving performance in both daytime and nighttime lighting under real-world driving conditions.

Methods: In a four-visit bilateral 3x3 crossover study, 24 subjects were randomized to assess the performance of the photochromic soft contact lens (Test) on vision and driving performance by comparison to the non-photochromic soft contact lens worn without and with plano photochromic spectacles (Control 1 and Control 2, respectively). The subjects drove an actual car on a closed-circuit driving track, with three different routes administered in random order and under a range of challenging controlled conditions. Overall driving performance was a composite Z-score based on six objective metrics: average sign recognition distance (in meters), percentage of signs correctly identified (42 signs), percentage of hazard avoidance/detection (nine hazards), average pedestrian recognition distance (in meters), percentage of time inside the driving lane, and the inverse driving lap time (in seconds). Other vision measures included logMAR visual acuity (ETDRS charts) under various luminance and chart contrasts, as well as contrast sensitivity under high luminance (Pelli-Robson charts) and low luminance (Mesotest II) conditions.

Results: Out of the 24 participants, 58% were female with Mean (SD) age of 29.8 (7.71) [Range: 21-46 years old]. For nighttime driving, the adjusted mean difference in Z-score (95% CI) between Test and Control 1 and between Test and Control 2 were 0.069 (-0.045, 0.183) and 0.117 (0.003, 0.231), respectively. For daytime driving, the differences were 0.101 (-0.013, 0.216) between Test and Control 1, and 0.044 (-0.070, 0.158) between Test and Control 2. The results demonstrated the non-inferiority of Test relative to the control lenses with respect to both nighttime and daytime driving performance using a non-inferiority margin of -0.25 Z-score. Non-inferiority (margin 0.1 logMAR), or no statistical difference (proportion of letters correctly identified), of the Test to Control 1 and Control 2 was also demonstrated on all logMAR and contrast threshold testing.

Conclusions: Subjects wearing the photochromic soft contact lens during daytime driving, nighttime driving, logMAR and contrast sensitivity testing performed equal or better than when they wore a non-photochromic contact lens by itself and when worn in conjunction with plano photochromic spectacles.



Evidence-Based Efficacy of Myopia Control Interventions

Noel Brennan, BOptom, MSCOptom, PhD, FAAO
Clinical Research Fellow

Cheng X, Toubouti Y, Bullimore M

Purpose: Decision-making in modern clinical practice is increasingly dependent on evidence-based medicine. Here, we apply these principles to the question of efficacy of myopia control interventions.

Methods: We systematically reviewed the literature to categorize studies based on adherence to evidence-based principles and the outcomes of such studies (we included details from as yet unpublished conference presentations). Previous analyses of the efficacy of myopia control interventions have delivered results as percentage or absolute reduction in myopia progression over a given time frame. Estimates of longer-term efficacy have been constructed around these estimates but fail to account for two important recent observations: (i) myopia control efficacy tends to an absolute effect rather than a relative effect across the progression range, and (ii) efficacy may decrease over time on both an absolute and relative basis. The only indisputable metric that can be used is data-driven estimates of absolute reduction in progression rather than annual or relative rates. The primary variable should be reduction in axial elongation because of its relevance to disease development but refractive error also serves as an important secondary endpoint.

Results: The table shows the classification of studies of current interventions of interest according to levels of evidence. Study designs to the left of the table represent more rigorous levels of evidence. Despite the popularity of low-dose (0.01%) atropine, there is no evidence of a statistically significant reduction in axial elongation with this intervention. Orthokeratology (in a cohort study) and spectacles (in a controlled, randomized study) have provided the largest recorded treatment effects. Soft, multizone lenses have the greatest weight of evidence but do not demonstrate superior performance possibly because of insufficient study periods. Increased time outdoors alone does not provide a large treatment effect but may be a useful adjunct therapy. It should be noted that rebound was not examined in any of studies except for one cohort study with low-dose atropine.

Conclusions: This analysis presents a basis for evidence-based reporting of myopia control interventions. The maximum treatment effect that can be currently supported is 0.43mm for axial elongation and 1.05D for refractive error (although absence of rebound cannot be guaranteed). Any reports of greater potential efficacy are speculative and not evidence-based.

Intervention	Regulatory Clearance (globally)	Metric	Study design			Maximum efficacy (D)
			Controlled Randomized Masked	Controlled Randomized	Cohort	
0.01% Atropine	—	Refractive	2	—	2	0.79D
	—	Axial	1	—	—	-0.02mm
Orthokeratology	—	Refractive	—	—	—	—
Soft Multizone Lens	2	Axial	—	2	7	0.43mm
		Refractive	4	4	3	0.57D
Spectacles	—	Axial	4	4	3	0.19mm
		Refractive	—	2	—	1.05D
Outdoors	NA	Axial	—	2	—	0.28mm
		Refractive	—	4	—	0.22D
		Axial	—	4	—	0.15mm



Dr. Noel A. Brennan is Global Platform Lead for Myopia Control and a Clinical Research Fellow at Johnson & Johnson Vision Care Inc., where he has been since 2011. For 16 years prior to that he co-directed a privately-owned research consulting company and, before that, was an academic faculty member at the University of Melbourne, reaching the level of Reader. He is a Senior Fulbright Alumnus, a Max Schapero Memorial Lecture Awardee of the American Academy of Optometry and a councilor of the International Society for Contact Lens Research. He was recently named one of the 30 most influential people in the contact lens field in the global trade journal, Contact Lens Spectrum. He has over 500 publications, including over 100 peer-reviewed papers as well as educational articles, peer-reviewed conference abstracts, industry reports and patents, and has presented more than 400 lectures internationally, including paid invited lectures in over 30 countries. He is best known for his work in measurement and interpretation of contact lens oxygen transmissibility, identification of lens friction/eyelid interaction as the paradigm-shifting mechanism of contact lens discomfort, the unique optics of the Medmont topographer and the celebrated Liou-Brennan model eye.



Comparison of a Neuro-Optical Model With Vision Performance in Multifocal Contact Lenses

Derek Nankivil, BSc, MSc, PhD
Staff Engineer

Lau C, Xu J, Schnider C

Dr. Derek Nankivil's primary research aims to relate visual perception and retinal optical stimuli and to develop novel contact lenses. Nankivil received his BSc in Aerospace Engineering, his MSc in Biomedical Engineering, and his PhD in Biomedical Engineering and Photonics. His research interests include nanomechanics, laser surgery, liquid crystal optical phased arrays, ocular growth and senescence, optomechanics of accommodation, corneal transplantation, accommodation restoration, intraocular lenses, tear film, ophthalmic imaging, virtual reality and art conservation. Nankivil is a member of the OSA, the Commercial Relations Committee of ARVO and the Ophthalmic Technologies Program Committee of SPIE. He is a reviewer for various optics and ophthalmic journals.

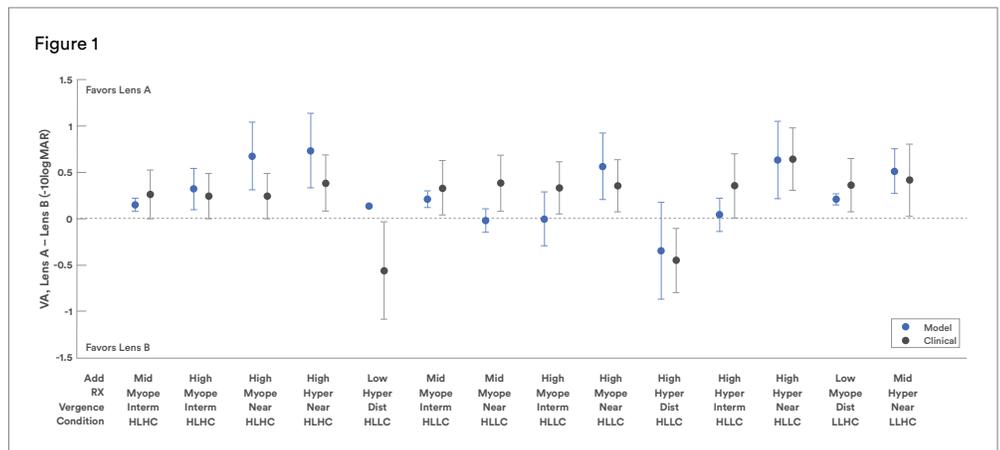
Purpose: To simulate visual performance across a range of environmental conditions and subject qualities that influence a wearer's vision experience with multifocal contact lenses (MFCLs) using our neuro-optical model (ARVO 2017, Nankivil & Wooley), and to compare the model output to clinical performance data.

Methods: Visual acuity (VA, $-10\log\text{MAR}$) was estimated using a model that includes age, refraction (Rx) and accommodation dependence of spherical aberration, the luminance, age and Rx dependence of the pupil, age-dependent accommodative loss, accommodative gain and binocular summation. Visual performance was modelled across adds +0.75 to +2.50D, Rx -9.00 to +6.00D, vergence demands up to 2.5D and luminance levels up to 7,000 cd/m². Visual performance prediction of two MFCL designs (A: pupil optimized center-near aspheric 3-add system, B: fixed optic center-near aspheric 3-add system) were compared with VA data from a clinical study. Presbyopes (n = 275, mean age: 50 ± 6.3 sd) participated in a randomized, bilateral, cross-over, 10-day dispensing, multi-center study. Subject cohort consisted of 181 myopes and 94 hyperopes with 28%, 32%, and 40% subjects in low, mid and high add, respectively. Visual performance was assessed in high luminance high contrast (HLHC), high luminance low contrast (HLLC), and low luminance high contrast conditions (LLHC), at distance, intermediate and near.

Results: Lens A exhibited superior performance in four, six and two conditions for HLHC, HLLC and LLHC respectively, primarily at intermediate and near. Lens B exhibited superior performance in two conditions for HLLC only at distance. Modelling results matched VA in the majority of conditions: 11/14 neutral and 3/4 superior for HLHC; 7/10 neutral, 3/6 superior, and 0/2 inferior for HLLC; 7/16 neutral and 1/2 superior for LLHC (Figure 1).

Conclusions: The neuro-optical model shows promise for estimating clinical performance and differences in performance with multifocal contact lens designs. Results indicate that, with high add lenses, the benefits predicted by the model are in general agreement with clinical results. But the conditions under which benefits were predicted are not those typically measured in a clinical setting. These results underscore the need for a period of real world experience before making judgements on suitability of a given design, and the need to better explore perceived visual performance under challenging viewing conditions, particularly scenarios involving low contrast. This information can help practitioners understand the potential wearer benefits of MFCL designs in real-world conditions.

Figure 1: Modelled and measured difference in VA (Lens A - Lens B, $-10\log\text{MAR}$) for all conditions where a measured difference was observed. Error bars give the model standard deviation and the clinical upper and lower 95% confidence interval.



Prevalence of Astigmatism in Presbyopes

Tom Karkkainen OD, FAAO
Senior Principal Research Optometrist

Young G, Hunt C, Clark R



Purpose: To determine the proportion of presbyopic patients suitable for toric multifocal contact lenses (CLs) of various parameter ranges.

Methods: Twenty optical practices in the US took part in a chart review of presbyopic and pre-presbyopic patients (age: 40 to 70 years) attending for a routine eye test or contact lens aftercare visit. The study protocol was approved by a research ethics committee and subjects gave informed consent for their data to be reviewed. The eye exam took place within two weeks prior to giving informed consent or the four weeks after obtaining consent. The data collected included age, gender refraction and CL history.

Results: The records from 1001 patients were reviewed. The number of patients per site ranged from 10 to 60, with a median of 52. Of the 1,001 subjects, 634 (63.3%) were female and 367 (36.7%) were male. Mean age was 54 ±8 years (range: 40 to 70 years). The mean refractive sphere power was -1.03D (range: -15.00 to +10.25D); 60% of subjects were classified as myopes, compared with 28% hyperopes, 8% emmetropes and 4% anisometropes. The proportion of myopes ranged between sites from 39% to 83%. Mean cylinder power was -0.73D (max: 4.00D).

A high proportion (95.0%) of the sample were presbyopic (add: ≥0.75D) and, of these, a majority (57%, 546/950) had significant astigmatism (≥0.75DC) in at least one eye; 33% had significant astigmatism in both eyes. Using a higher astigmatism threshold of 1.00DC, 39% (370/950) of presbyopes had this level of astigmatism in at least one eye; 19% had this level of astigmatism in both eyes.

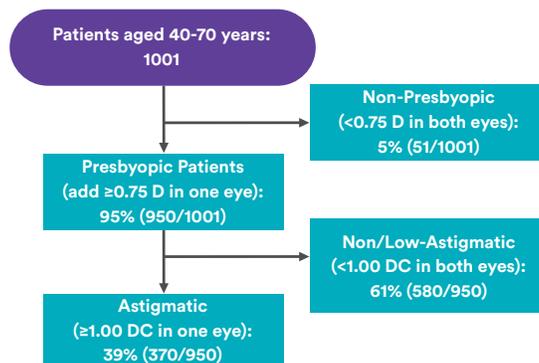
Approximately half of patients (49.8%, 498/1001) were existing (41.8%) or previous (8.0%) contact lens wearers. The most common reason for CL discontinuation was vision problems (33.8%) followed by discomfort (25.0%). The proportion of astigmatic presbyopes was similar for current CL wearers and non-wearers; 56% (219/392) of CL wearers had significant astigmatism in at least one eye, while 57% (273/481) had this this level of astigmatism in both eyes.

Conclusions: A high proportion of presbyopic patients are in the prescription range that might benefit from toric multifocal contact lenses.

Tom Karkkainen, OD, MS, FAAO obtained his Doctor of Optometry degree from the Illinois College of Optometry. He completed a Fellowship in Corneal and Contact Lens Research and obtained a Master's Degree in Vision Science from the University of Alabama at Birmingham. Prior to joining Johnson & Johnson Vision Care, Inc. he was an Associate Professor at the Southern College of Optometry. He has numerous publications in the ophthalmic literature including a book chapter in Borish's Clinical Refraction.

Dr. Karkkainen joined Johnson & Johnson Vision in 2004 as a Senior Research Optometrist. He became the Clinical Manager of the Applied Optical Products group and was the clinical lead in the development of ACUVUE OASYS® Brand Contact Lenses for presbyopia and 1-DAY ACUVUE® MOIST Brand MULTIFOCAL Contact Lenses. He is currently a Senior Principal Research Optometrist working on the Presbyopia Platform and manages the Advanced Optics group within the Clinical Sciences department.

Breakdown of presbyopic patients with refractive astigmatism of ≥1.00 D in at least one eye.





Prelens Tear Film Measurements Using Twyman-Green Interferometr

Greg Hofmann MS BS
Principal Engineer

Coles-Brennan C, Hoyt K, Cheng X

Greg Hofmann has worked in contact lens research and development for nearly 20 years. He has been involved in a variety of activities ranging from process development to in vitro tribology. His current focus is in clinical metrology and finding connections between in vivo objective measures and subjective responses using machine learning methods. He has a BS in Physics from the University of Illinois and a MS in Materials Science from the University of Wisconsin.

Table 1: Observed means and standard deviations for bare eye and prelens tear films

Purpose: Most (~70%) of the refraction correction for a contact lens occurs at the air-prelens tear film interface. The tear-air interface defines a surface, which, ideally, would be smooth and free of undulations. An in vivo tear surface interferometer (IVV) has been fabricated to measure the dynamic tear surface shape, in order to investigate how the tear shape may affect visual performance.

Methods: Tear surface quality was measured with the IVV in 42 subjects at baseline (over bare eye) and with subjects wearing ACUVUE OASYS® 1-Day with HydraLuxe lenses (AO1D) and habitual lenses over three visits. The tear surface shape quality was defined by converting the dynamic tear shapes to a weighted modulation transfer function (WMTF) and subsequently averaging the WMTF over the measurement period (10 seconds). The resultant tear shape quality metric is referred to as the mean weighted modulation transfer function (MWMTF). Any missing MWMTF data were imputed using the Monte Carlo Markov Chain method. Paired differences between the native and prelens MWMTF along with the corresponding 95% confidence intervals were calculated to determine significance.

Results: The observed mean (over subjects) MWMTF values are shown in Table 1.

Table 1		
Condition	Mean MWMTF (arb)	Standard Deviation MWMTF (arb)
Bare Eye	4486	629
AO1D	3767	587
Habitual	3301	697

Differences in the MWMTF between the bare eye and either lens were significant ($p < 0.05$). The difference between bare eye and AO1D MWMTF was smaller as compared to the difference between bare eye and habitual MWMTF ($p < 0.05$).

Conclusions: These results show that the IVV may be capable of measuring subtle differences in the tear quality between bare eye and prelens tear film and between prelens tear film of different lenses.

Comfort and Biocompatibility During Extended Melimine Antimicrobial Contact Lens (MACL) Wear Clinical Trial

Parthasarathi Kalaiselvan BOptom, MOptom, PhD Candidate

Investigator Initiated Study

Dutta D, Konda N, Sharma S, Vaddavalli PK, Stapleton F, Willcox M



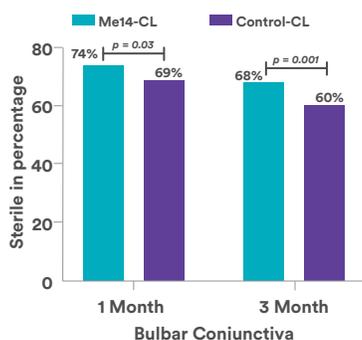
Purpose: The effect of long term contact lens wear on the ocular surface has been studied previously. However, the comfort and biocompatibility of antimicrobial-coated contact lenses have not been studied. The purpose of this study was to investigate the clinical performance of Melimine Antimicrobial Contact Lenses (MACL) during extended wear.

Methods: A prospective, randomized, double-masked, contralateral human clinical trial was conducted to evaluate the ocular clinical signs and symptoms during three-month extended contralateral wear of MACL and untreated control lenses. The study received ethics approval (HREC#15436) and was registered with the Australia and New Zealand Clinical Trial Registry (ACTRN1261500072556). MACL were produced by covalently coating lenses (Acuvue® 2) with the Mel4 peptide. A total of 176 participants with a mean age of 22.6 ± 4.2 years were recruited, 74% of which were neophytes. The wearing modality was 14-day extended lens wear for a period of three months. After consent, the participants were assessed at baseline, contact lens dispensing, after one night, two weeks, one month and three months of extended wear, as well as one month after study completion. Assessment included detailed slit lamp examination for bulbar and limbal redness, palpebral redness and roughness, conjunctival and corneal staining, front surface wetting, front and back surface deposits, and the presence of mucin balls, using CCLRU grading scales. Ocular comfort and dryness was measured using a 1–100 score for comfort and the CLDEQ-8 questionnaire modified for monocular lens wear, as well as assessing lens and edge awareness.

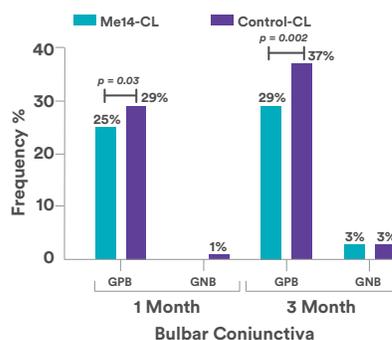
Results: A total of 137 participants completed the study. No statistically significant differences were observed in bulbar or limbal redness, palpebral redness and roughness in any quadrant between MACL and control lenses ($p > 0.05$). There were no statistically significant differences in conjunctival ($p = 0.46$) or corneal staining ($p = 0.50$) between the two lens types. No statistically significant ($p > 0.05$) differences were found for the front surface wetting, front surface deposits and back surface debris. Mucin balls were not seen. No statistical significant difference ($p > 0.05$) was found in comfort, dryness, CLDEQ-8 scores, lens and edge awareness. There was no evidence for delayed reactions on the ocular surface one month after cessation of antimicrobial lens wear.

Conclusions: The novel antimicrobial contact lenses showed similar comfort to control lenses and were highly biocompatible during extended wear. There were also no delayed reactions from wearing the antimicrobial lenses. Thus, these lenses were compatible with the ocular surface.

Parthasarathi Kalaiselvan is a PhD Scholar at School of Optometry and Vision Science, University of New South Wales (UNSW) in Sydney, Australia. He completed his Bachelors (2007) and a Masters (2014) in Optometry training in India, followed by a post-graduate clinical fellowship in Optometry (2008) at LV Prasad Eye Institute, Hyderabad, India. Further, he completed his Clinical Research Fellowship in Vision Cooperative Research Centre (CRC) at Brien Holden Vision Institute, Sydney, Australia (2011) and joined the contact lens department at LV Prasad Eye Institute, Hyderabad in 2011 and finally took up teaching responsibilities within the Institute, along with a number of other roles including consultant and research optometry. His area of interest is contact lenses, antimicrobial peptide, ocular microbiome and contact lens adverse events, tear film and ocular surface. His current PhD thesis aims to evaluate the ability of antimicrobial contact lenses to reduce the incidence of corneal infiltrative events during extended wear.



Percentage of sterile bulbar conjunctiva at 1 & 3 months of extended contact lens wear



Bacteria recovered from bulbar conjunctiva at 1 & 3 months of extended contact lens wear



THE
AGENDA

Papers – November 7

Room 303 | 1:15 PM – 1:30 PM

A Contralateral Comparison of the Visual Effects of Clear vs. Photochromic Contact Lenses

Hammond B, Renzi-Hammond L, Buch J, Cannon J, Toubouti Y

Room 303 | 2:30 PM – 2:45 PM

Contact Lens Induced Corneal Infiltrative Events During Extended Melimine Antimicrobial Contact Lens (MACL) Wear Clinical Trial

Dutta D, Kalaiselvan P, Konda N, Sharma S, Vaddavalli PK, Stapleton F, Willcox M

Investigator Initiated Study

Room 303 | 2:45 PM – 3:00 PM

Does Extended Melimine Antimicrobial Contact Lens (MACL) Wear Effect the Ocular Microbiota?

Kalaiselvan P, Willcox M, Konda N, Sharma S, Vaddavalli PK, Stapleton F, Dutta D

Investigator Initiated Study

Room 303 | 3:00 PM – 3:15 PM

Investigating the Role of UV-blocker as an Antioxidant to Prevent Oxidation of Tear Film Component Deposition in Commercial Contact Lens Hydrogels

Rabiah N, Scales C, Fuller G, Cegelski L

Papers – November 8

Hemisfair Ballroom C1 | 8:30 AM – 8:45 AM

The Impact of Photochromic Contact Lenses on Daytime and Nighttime Driving Performance

Buch J, Cannon J, Toubouti Y

Room 304 | 1:00 PM

Meta-Analysis of Axial Elongation in Myopic Children

Brennan N, Cheng X, Toubouti Y, Bullimore M

Posters – November 9

Poster #84 | Exhibit Hall 3 | 10:00 AM – 12:00 PM

Evidence-Based Efficacy of Myopia Control Interventions

Brennan N, Cheng X, Toubouti Y, Bullimore M

Poster #156 | Exhibit Hall 3 | 10:00 AM – 12:00 PM

Comparison of a Neuro-Optical Model With Vision Performance in Multifocal Contact Lenses

Nankivil D, Lau C, Xu J, Schnider C

Poster #141 | Exhibit Hall 3 | 1:00 PM – 3:00 PM

Prevalence of Astigmatism in Presbyopes

Karkkainen T, Young G, Hunt C, Clark R

Poster #159 | Exhibit Hall 3 | 1:00 PM – 3:00 PM

Prelens Tear Film Measurements Using Twyman-Green Interferometry

Hofmann G, Coles-Brennan C, Hoyt K, Cheng X

Poster #151 | Exhibit Hall 3 | 1:00 PM – 3:00 PM

Comfort and Biocompatibility During Extended Melimine Antimicrobial Contact Lens (MACL) Wear Clinical Trial

Kalaiselvan P, Dutta D, Konda N, Sharma S, Vaddavalli PK, Stapleton F, Willcox M

Investigator Initiated Study

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