Clinical Evaluation of the FIN C2 Lens in Slowing Myopia Progression (The Essilor Study)

Investigators: Yi Pang, OD, PhD, Megan Allen, OD, Alaina Bandstra, OD, Denise Skiadopoulos, OD, Elyse Nylin, Study Coordinator

The purpose of this study is to test the effectiveness of the FIN C2 spectacle lens on myopia progression. In this study, performance of the FIN C2 spectacles will be compared to single vision spectacle lenses. Participants will be evaluated over a 3 year period.

MiSight 1 Day Post-Approval Study for Effectiveness of Visual Symptoms

Investigators: Yi Pang, OD, PhD, Megan Allen, OD, Denise Skiadopoulos, OD, William Skoog, OD

The purpose of the study is to confirm in the U.S. population that there are clinically meaningful differences (super-superiority margin of 0.50D) in the mean change of cycloplegic spherical equivalent refractive error (SERE) and axial length change from baseline after three years of using MiSight 1 Day lenses among intended patient population compared to the mean changes in a control group using conventional daily disposable lenses. In addition, the study will estimate the effects of race, baseline cycloplegic spherical equivalent refractive error, and baseline age on the treatment effect.

Amblyopia Treatment Study 23

Investigators: Yi Pang, OD, PhD, Megan Allen, OD, Christine Allison, OD, Alaina Bandstra, OD, Aubrey Breithaupt, OD, Denise Skiadopoulos, OD

The purpose of the study is to determine if watching dichoptic movies wearing the Luminopia headset (1 hour per day, 6 days per week) is non-inferior to 2 hours of patching per day 7 days per week, with respect to change in amblyopic eye distance VA from randomization to 26 weeks. Children 4-7 years old will be enrolled. This is a Pediatric Eye Disease Investigator Group (PEDIG) study.

Amblyopia Treatment Study 24

Investigators: Yi Pang, OD, PhD, Megan Allen, OD, Christine Allison, OD, Alaina Bandstra, OD, Aubrey Breithaupt, OD, Denise Skiadopoulos, OD

The purpose of the study is to formally compare the effectiveness of the Luminopia headset (1 hour per day, 6 days per week) while wearing optical correction if needed versus continued optical correction alone (if needed), as a superiority test. The study will also formally compare the effectiveness of Vivid Vision (25 minutes per day, 6 days per week) while wearing optical correction if needed versus continued optical correction alone (if needed), as a superiority comparison. Children 8-12 years of age will be enrolled. This is a Pediatric Eye Disease Investigator Group (PEDIG) study.

Myopia Treatment Study 2

Investigators: Yi Pang, OD, PhD, Megan Allen, OD, Christine Allison, OD, Alaina Bandstra, OD, Denise Skiadopoulos, OD

The purpose of this study is to compare the treatment effectiveness of a) 0.05% atropine vs. placebo and b) highly aspherical lenslet (HAL) vs. single vision lenses for slowing myopia progression. The effectiveness of combined therapy vs. Placebo, HAL alone, and atropine alone will also be studied. This is a Pediatric Eye Disease Investigator Group (PEDIG) study.

Hoya Vision Care Study: DG1 spectacle lens for myopia progression control in children: A three year multicenter, prospective, randomized, double-masked, controlled clinical trial to evaluate the efficacy and safety followed by a one-year rebound evaluation

Investigators: Yi Pang, OD, PhD, Megan Allen, OD, Alaina Bandstra, OD, Kathryn Hohs, OD, Courtney Luce, OD, Denise Skiadopoulos, OD

This study aims to assess if the DG1 lens will slow the progression of myopia compared to single-vision spectacles based on both spherical equivalent refractive error and axial length.

Funded by: HOYA

Efficacy in Controlling Myopia in Younger Children using DOT 0.2 Spectacle Lenses (The Eucalyptus Study)

Investigators: Yi Pang, OD, PhD, Alaina Bandstra, OD, Denise Skiadopoulos, OD

This study aims to assess the efficacy of the SightGlass Vision DOT 0.2 Spectacles in reducing the progression of juvenile myopia in a young age group (6-8 years).

Satisfaction of Wearing Precision1 Sphere and Impact on Dry Eye Symptoms and Signs in Teens

Investigators: Yi Pang, OD, PhD, Alaina Bandstra, OD Shannon Carmo, OD, Jannis Doan, OD

The purpose of this study is to assess the perception and comfort of Precision1 Sphere on teens who are new contact lens wearers. The impact of contact lens on dry eye symptoms and clinical measurements will be determined.

Funded by: Alcon

Clinical performance of IDEAL silicone hydrogel contact lens in individuals with myopia

Investigators: Yi Pang, OD, PhD, Jennifer Harthan, OD, William Skoog, OD

The purpose of this study is to assess the perception and comfort of the IDEAL spherical contact lens compared to an already approved contact lens (MyDay, Precision 1, Infuse).

Funded by: VizionFocus, Inc.

Performance Evaluation of Swept Source OCT: A & P Study
Investigators: Michael Chaglasian OD, Anne Rozwat OD, Ashley Speilburg OD, Patty Salazar OD

The goal of this study is to evaluate the clinical performance of a new swept-source OCT imaging device and to evaluate substantial equivalence with a predicate device, the Cirrus 5000. Clinical performance will be assessed through an agreement and precision analysis of OCT measurement parameters and through a visualization comparison of OCTA images. Evidence for substantial equivalence will be through establishing similar precision results between devices, establishing similar visualization evaluation results, and also meeting pre-determined performance goals for precision and agreement results for a majority of parameters.

Data Collection Study on Swept Source OCT
Investigators: Michael Chaglasian OD, Anne Rozwat OD, Ashley Speilburg OD, Patty Salazar OD

The goal of this study is to collect swept source and spectral domain OCT images on patients with ocular pathology and normals. Images will be used by the Sponsor to support development and validation of image analysis methods of swept source scans and to allow comparisons between different devices. Measurement repeatability and agreement between devices will also be assessed.

MyKidneyAI: PILOT STUDY
Investigators: Michael Chaglasian OD, Erica Ittner OD, Kathryn Hohs, OD, Alyssa Lancaster, OD, Navjit Sanghera, OD

This sponsor-initiated study evaluates MyKidneyAI, an investigational software tool that analyzes retinal images to estimate Chronic Kidney Disease (CKD) risk in Type 2 Diabetics. One hundred adult patients with diabetes will be recruited. Fundus photographs will be obtained on two different camera systems. A blood draw and urine sample will be collected for lab testing. Additional background medical information will obtained also. The AI software prediction results from photographs will be compared to established risk calculations for CKD.

CLAiR Pivotal Study
Investigators: Michael Chaglasian OD, Erica Ittner OD, Kathryn Hohs, OD, Alyssa Lancaster, OD, Anne Rozwat, OD, Patricia Salazar, OD, Navjit Sanghera, OD, Ashley Speilburg, OD

This research is being done to investigate artificial intelligence (AI) software called CLAiR, which is used to analyze a type of eye photograph (retinal image) and determine the future risk for heart disease. Retinal images are photos that are taken of your retinas. In this study, CLAiR software will be used to look at retinal images from each of your eyes and help to determine if a person between the ages of 40-75 is at higher risk for developing Atherosclerotic Cardiovascular Disease.

CLAiR Precision Study
Investigators: Michael Chaglasian OD, Erica Ittner OD, Brittney Brady OD, Kashifa Ansari OD

The CLAiR AI software has been developed to identify patients at elevated risk of atherosclerotic cardiovascular disease (ASCVD) using non-mydriatic fundus photographs. This is a single-visit, data-collection study designed to evaluate: Inter-operator reproducibility, inter-camera-unit reproducibility and repeatability on two different camera systems. All outcomes are generated by the CLAiR AI software using retinal photographs.

Visual Field Data Collection Study
Investigators: Michael Chaglasian OD, Brittney Brady OD, Reneta Simeon OD

This study aims to compare the clinical performance, test time, and patient experience between the three different visual field testing devices: 1) Humphrey Field Analyzer (bowl based testing), 2) Topcon Tempo (video, tabletop perimeter), and the 3) Topcon Inspire (a headset perimeter). This study will evaluate several aspects of the test results for each device including: mean deviation dB sensitivity, test time, test reliability and repeatability, pattern of visual field defect identified. Approximately 100 patients will be tested during a single visit.

Scleral Lenses in Current Ophthalmic Practice: an Evaluation (SCOPE)

Investigators: Principal Investigator: Muriel Schornack, OD, Consultant: Joe Barr OD, Co-Investigator for communication: Jennifer Harthan, OD, Co-Investigator for study design: Cherie Nau, OD, Co-Investigator for funding: Amy Nau, OD, Co-Investigator for communication: Ellen Shorter, OD

Our initial project was to conduct a survey of domestic and international eye care providers self-identified as fitting scleral lenses to assess current global scleral lens practice patterns.
The second arm of the study is to execute a multi-center prospective study that will define patient centered outcomes, changes in visual acuity and impact of scleral lens wear on anterior segment structures. Primary purpose or goals: To determine if patients using scleral lenses report improved vision-related quality of life, ocular comfort, and refractive quality of life and to determine visual acuity and ocular surface outcomes for patients wearing scleral lenses.

The SCOPE (Scleral Lenses in Current Ophthalmic Practice: an Evaluation) study group was established in 2014 under the auspices of the American Academy of Optometry Fellows Doing Research Special Interest Group. The group comprises national experts in the clinical fitting of scleral lenses who also have academic research interests. Because scleral lenses have only recently become part of mainstream clinical practice, there are significant gaps in our understanding of practice patterns, fitting philosophies and the biological effects of these devices. The goal of our collaboration is to spearhead clinical research in scleral lenses, and to engage clinicians and basic scientists on a global scale. Included in our mission the dissemination of our findings to clinician, industry and patient stakeholders.

The Executive Committee members are: Jennifer Fogt, Jennifer Harthan, Amy Nau, Cherie B. Nau, Muriel Schornack and Ellen Shorter. We engage with a vetted network of other experienced scleral fitters interested in assisting with clinical and research projects on an ad hoc basis. The following link shows all presentations published by the SCOPE study group:

https://chicago.medicine.uic.edu/departments/academic-departments/ophthalmology-visual-sciences/make-a-gift/scope/

Neurosensory Abnormalities in SymptomAtic Ocular Surface Patients (NASA)

PI ICO: Jennifer Harthan, OD

Recent evidence suggests that up to 10% of patients with ocular surface symptoms can be characterized as having NCP [8]. The TFOS DEWS II characterization of this diagnosis acknowledges the importance of neurosensory abnormalities in ocular surface disease, but the prevalence of the neuropathic component of dry eye remains unknown. VERSION 2.0: March 4, 2021 Page 7 of 41 Corneal nerves have been shown to respond to topical hyperosmolar saline [12-15], and more recent evidence suggests that 5% hyperosmolar saline causes a larger response in patients with NCP [16]. Assessing the pain levels of patients before and after 5% hyperosmolar saline and topical proparacaine, as described previously, will allow for the identification of the neuropathic component of dry eye and its subtypes. A large, multicenter study will provide prevalence statistics and characterize the demographics for each group.

Efficacy and Tolerability of Systane PRO on Signs and Symptoms of Dry Eye Disease in Digital Device Users

PI: Jennifer Harthan, OD

Subinvestigators: Elyse Chaglasian, OD, Diana Masolak, OD, William Skoog, OD
Dry Eye Disease (DED) is a common condition encountered by eye care professionals and is characterized by a multifactorial disease process affecting the tears and ocular surface. DED results in a broad range of symptoms and signs that, if left untreated, can have potentially damaging effects on eye health and quality of life. Meibomian Gland Dysfunction (MGD) has been identified as the most prevalent cause of evaporative DED, which occurs when the meibomian glands are unable to secrete an adequate lipid layer for the tear film. This disruption in the tear film can lead to the common symptom of “dry eyes,” causing discomfort and visual disturbances. There are many treatments for DED including over-the-counter therapies. However, few target meibomian gland dysfunction in digital device users. This study aims to address patient-reported and clinician-graded efficacy of an over-the-counter artificial tear (Systane PRO PF) for this patient population.

Delaying the Onset of Nearsightedness Until Treatment Study (DONUT) (The Ohio State University College of Optometry, University of Houston College of Optometry and NIH)

Site PI: Jennifer Harthan, OD

Subinvestigators: Brittney Brady, OD, Kathryn Hohs, OD, Valerie Kattouf, OD, Yi Pang, OD, Denise Skiadopoulos, OD, William Skoog, OD

The **Delaying the Onset of Nearsightedness Until Treatment (DONUT)** study is a large, multi-center clinical trial conducted across 14 U.S. sites. It aims to determine whether low-dose atropine eye drops can delay the onset of myopia (nearsightedness) in children aged 6 to 11 who are at high risk of developing the condition. Over a two-year period, participants will use either nightly 0.05% atropine drops or a placebo. The goal is to assess whether early treatment can lessen the degree of nearsightedness later in life and reduce the risk of vision-threatening complications.

Randomized Controlled Multicenter Clinical Trial of Multi-Periscopic Prism Glasses for Homonymous Hemianopia

Overall PI: Eli Peli

Relying Site Investigator: Tracy Matchinski, OD

We will conduct a multi-center randomized crossover clinical trial to evaluate the efficacy of Multi-Periscopic Prisms (MPP) compared to conventional Fresnel peripheral prisms (FPP) as a mobility device for patients with HH. MPPs provided 45° (100Δ) of lateral field expansion for patients with HH while FPP provide 33° (57Δ). We will evaluate the ability of the prismatic devices to improve detection of moving hazards on the side of the field loss. We hypothesize that performance will be better with the MPPs than the FPPs as evidenced by higher detection rates in the pedestrian detection and collision judgment task in our virtual reality (VR) walking simulator. In particular, we predict that the MPP will enable detection of pedestrians at much higher bearing angles on the side of the field loss and thereby protect against the higher risk for such collisions.

Funded by: NIH

Macro- and micro-vascular function and related cognitive effects in response to dietary exchanges in pre-diabetes

Investigators: Stephanie Adams, OD PhD, Darren Koenig, OD, Rebecca Zoltoski PhD, Britt Burton-Freeman PhD, Indika Edirisinghe PhD, Rachael Ellison PhD.

This nutritional study examines the effects of an 8 week high avocado and mango content diet on pre-diabetic subjects including their vascular function and cognitive performance. A diet rich in fruits and vegetables provides antioxidants and has long been associated with potential positive effects in the setting of chronic diseases, such as heart disease and diabetes. Antioxidants protect cells from being damaged by substances that are found in our environment. In collaboration with the Illinois Institute of Technology, ICO investigators are conducting a quantitative examination of micro-vascular retinal health using Optical Coherence Tomography Angiography (OCTA). Retinal micro-vascular abnormalities are detected in subjects with diabetes even in the absence of diabetic retinopathy as determined by dilated eye exam. We hypothesize that the OCTA will

detect micro-vascular abnormalities in pre-diabetic subjects compared to control subjects, and that these abnormalities may improve with the intervention diet. The results may support the impact of diet on ocular and brain health even in the pre-diabetic stage.

Funded by: Hass Avocado Board, National Mango Board, Research Resource Committee (ICO)

A Randomized, Masked, Sham-Controlled Phase 2 Trial of the Safety of a Single Intravitreal Injection of jCell (Famzeretcel) for the Treatment of Retinitis Pigmentosa (RP) — Pre-Screening and Referral

Principal Investigator: Mathew W. MacCumber, MD, PhD

Site PI: Raman Bhakhri, OD

This study involves a retrospective chart review at the Illinois Eye Institute to identify patients who may qualify for the Phase 2 multicenter clinical trial sponsored by jCyte, Inc. (Protocol JC02-88). The trial evaluates the safety and potential efficacy of a single intravitreal injection of human retinal progenitor cells (jCell; famzeretcel) in individuals with retinitis pigmentosa. Eligible patients identified through this review will be contacted and potentially referred to the Illinois clinical site at Illinois Retina Associates (Oak Park location) for possible enrollment.

Funded by: jCyte, Inc.