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Keynote Forum

Day 1

Ronaldo Toyos, Optom Open Access 2017, 2:1 (Suppl)
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Ronaldo Toyos

Toyos Clinic, USA

Trans-scleral cyclophotocoagulation for the treatment of glaucoma

Introduction: This project was undertaken to assess the clinical value of using a new transscleral cyclophotocoagulation device in patients with mild to severe glaucoma including those who have unsuccessfully undergone other procedures. This is a one year update of earlier reported data.

Method: This is a single site review of 26 eyes of 20 patients, 4 eyes were classified as mild glaucoma, 5 as moderate and 18 as severe or end stage glaucoma. Two eyes of one patient were lost to follow up. All eyes but 3 had previously undergone phacoemulsification and SLT or MLT. 4 eyes had previously undergone trabeculectomy.

Results: Patients undergoing the procedure had an average IOP of 25.6 and were on an average of 3 IOP lowering meds. After the procedure, patients were started on difluprednate hourly for the first day then tapered over 3 weeks. Average IOP drop at POD 1 was 20% and 34% at pod7 (using an average 1.3 IOP lowering meds). At POD14, average IOP from baseline was 8% using one IOP lowering medication. At one month, IOP was down by 20% and average number of IOP reducing medications was 1.2. At 6-12 months, the average IOP lowering was 30% compared with baseline IOP on and average of 1.8 medications. There were no serious adverse events.

Conclusion: Patients with glaucoma of varying severities are able to safely undergo transscleral cyclophotocoagulation. On average, IOPs were reduced by 30% over one year's time and number of IOP lowering medications was reduced by 60%. Further study is required to determine ideal treatment guideliness.

Biography

Rolando Toyos is an American Physician and Medical Director who specializes in Ophthalmology. He developed the use of intense pulsed light for the treatment of dry eye conditions such as meibomian gland dysfunction.

rostar80@gmail.com

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Hugo Quiroz-Mercado, Optom Open Access 2017, 2:1 (Suppl)
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Hugo Quiroz-Mercado

University of Colorado, Mexico

Integrin peptide therapy for treating Vitreoretinal Disorders

Researchers have long known that integrins serve as "bridges" between cells and regulate how cells interact with each other and with the extracellular matrix. There are 27 known integrins, each named for a specific alpha-beta combination. Integrins have been associated with angiogenesis, inflammation, and thrombosis, so it makes sense to investigate them as potential treatments for ocular disorders. However, finding agents that can inhibit integrins has been challenging. One integrin antagonist, lifitegrast (Xiidra, Shire), recently received US Food and Drug Administration approval for the treatment of dry eye. ALG-1001 (Luminate, Allegro Ophthalmics) has the potential to target four different integrin sites. This agent has two mechanisms of action. First, it inhibits three integrins considered to be angiogenic; angiogenesis is a key factor in AMD, DME, and RVO. Integrins are known to work both upstream and downstream of the VEGF pathway. Second, ALG-1001 inhibits an integrin-mediated pathway of the vitreoretinal interface, making it capable of inducing posterior vitreous detachment (PVD).

Anti-edematous Effect: ALG-1001 seems to have clear anti-edematous and antiproliferative effects. Its mechanism is quite different from that of anti-VEGF agents; therefore, this compound has potential as both adjunctive and standalone therapy. It addresses the goal of using multiple therapeutic approaches with different mechanisms of action that target different aspects of disease. Because ALG-1001 inhibits multiple integrins, including αvβ3, αvβ5, and α5β1, it may be able to prevent new blood vessel formation while concurrently stopping leakage from existing blood vessels. Early study results have suggested that this combination of integrin inhibition may be potent enough to be used as monotherapy for DME and AMD. What is particularly interesting, however, is that these early data also suggest that anti-integrin therapy may be effective for patients who have not been successfully managed with anti-VEGF treatments alone. A phase 1 study of ALG-1001 in DME enrolled 15 patients with poor vision and substantial intraretinal fluid who had undergone more than 10 anti-VEGF injections. In this trial, eight of the 15 (53%) patients improved by 3 to 5 lines in visual acuity testing; four (50%) of these patients improved from legal blindness to functional vision in the range of 20/40 to 20/60. Additionally, more than half the patients in this phase 1 trial experienced a 30% to 80% reduction in central macular thickness. The substantial improvement seen in these patients has driven the ongoing investigation of ALG-1001 for treatment of DME.

Vitreolysis Effect: Vitreomacular traction (VMT) is a pathology associated with the vitreoretinal interface. In a normally aging eye, the vitreoretinal interface gradually releases. In eyes with VMT, although the rest of the vitreous is released from the retina, a residual area of adhesion remains. It is extremely difficult to effect that release without causing damage to the retina. From a pharmacologic standpoint, it has recently become possible to use an enzyme to achieve vitreomacular detachment, although surgical removal of the adhesion remains the standard of care. Inducing a posterior vitreous detachment (PVD) in a patient with a normal vitreoretinal interface can be viewed as assisting part of the spectrum of normal vitreous aging. There are numerous hypotheses about how the vitreous releases, and some suggest that overstimulating VEGF could create a depot of sorts at the vitreoretinal interface, possibly causing disease to progress. There is a significant body of evidence that suggests that inducing a PVD may inhibit the progression of retinal disease, particularly DR. We know that, in proliferative DR (PDR), blood vessels grow onto the vitreous scaffolding. But if the vitreous has undergone a PVD and elevated itself, there would be no scaffolding for vessels to grow onto. In theory, this could stop the proliferation from occurring. Or it might cause the growth to behave more like coral branching out from the seabed, doing little damage because it is not causing traction. In the phase 1 study of ALG-1001 in DME, researchers noted a high rate of PVD. Evidence suggests that ALG-1001 inhibits a fourth

integrin—α3β1—and, by doing so, aids in the breakdown of vitreous and its separation from the retina. This separation should move the hypothesized VEGF depot away from the retina, which would, in theory, prevent further damage.

Phase 2 Studies: ALG-1001 is being evaluated in several ongoing studies. DEL MAR is a phase 2b study evaluating ALG-1001 as monotherapy, as well as in combination therapy with anti-VEGF agents, and as a treat-and-maintain therapy. According to the manufacturer, results are anticipated as early as Q4 2016. DEL MAR has enrolled almost 120 patients. Efficacy endpoints include mean change in visual acuity and central retinal thickness (as measured by optical coherence tomography) at weeks 16 and 20. The study is evaluating 1.0, 2.0, and 3.0 mg of ALG-1001 in comparison with bevacizumab (Avastin, Genentech). A second arm of the study is evaluating ALG-1001 as an adjunctive therapy after treatment with any anti-VEGF agent, and a third arm is evaluating ALG-1001 in combination with bevacizumab. The last two arms are enrolling an additional 75 patients. The PACIFIC study is another phase 2b trial, enrolling about 100 subjects with nonproliferative DR without PVD to evaluate ALG-1001 as a standalone therapy. The trial will assess whether induction of PVD can inhibit progression to PDR. The PACIFIC trial will evaluate four doses of ALG-1001: 1.0, 2.0, 3.0, and 4.0 mg, with balanced saline solution as a placebo. Results from PACIFIC are expected in the first half of 2017, according to the manufacturer. The main endpoint is PVD induction based on optical coherence tomography and/or B-scan ultrasound. Another prospective, randomized, double-masked phase 2b study evaluated ALG-1001 in patients with vitreomacular adhesion (VMA) and VMT. Topline results indicate that this study met its endpoint, with 50% of patients who received the highest dose of ALG-1001 achieving release of VMT or VMA by day 90, compared with 9.7% of those receiving saline solution as placebo (P =.0129). The study randomly assigned 106 patients to receive ALG-1001 2.0, 2.5 mg, 3.2 mg, or placebo. The drug was well tolerated, with no drug-related toxicity or inflammation noted with repeated injections.

Conclusions: It is hoped that the reporting of the full datasets of these studies will reinforce the concept that, although these are small studies, ALG-1001 appears to be effective in a significant subset of patients with AMD or DME. The larger VMT study seems to suggest that ALG-1001 can effect vitreous release in a significant subset of patients. ALG-1001 shows promising efficacy, with mechanisms of action that are distinct from those of anti-VEGF therapy. This gives hope that the compound may become a new weapon in our armamentarium that may be complementary or additive to anti-VEGF therapy. If the results from DEL MAR, PACIFIC, and other future studies confirm early findings, ALG-1001 may become a viable alternative approach to both pharmacologic vitreolysis and treatment of AMD, DME, and DR.

Biography

Hugo Quiroz-Mercado is an Ophthalmologist specializing in Diabetic Retinopathy and Retinopathy Prematurity as the Director of Ophthalmology Service at Hugo Quiroz-Mercado. With over 25 years of practice experience, he has held previous appointments as the Director of the Retina Department and Chief of the Experimental Surgery Laboratory at Luis Sanchez Hospital for the Prevention of Blindness, as well as Professor of Ophthalmology at the Facultad de Medicine Universidad Autonoma de Mexico..

Hugo.Quiroz-Mercado@apec.com.mx

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Day 2

Christine Allison, Optom Open Access 2017, 2:1 (Suppl)
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Christine Allison

Illinois College of Optometry, USA

The long term progression of eye-movements in relationship to birth order in children

Purpose: The purpose of this longitudinal study was to analyze eye movement data related to birth order in a group of children upon entering Kindergarten, and then again upon entering 3rd grade. We have previously reported on a significant difference in eye movements among the pre-Kindergarten groups of children with no siblings, first born with siblings, and children who are not first born and have siblings. The findings have led to the theory that first born children and children with no siblings may exhibit better saccades and fixation control prior to entering Kindergarten due to differences in the type of activities they pursue. Once children are in school, their activities are more regulated, thus we theorized that the same children prior to entering 3rd grade would not show a significant difference in eye movements.

Methods: 112 children with similar academic/socioeconomic backgrounds were examined in the summer prior to Kindergarten. 33 of the same children have been examined again upon entering 3rd grade. The children were given comprehensive exams including tests of accommodation and vergence. The children also received eye-movement analysis with the Visagraph protocol. The caregivers completed a survey regarding the number/ages of siblings, prior school history, and amount of time spent on tasks like reading, using computers, and playing outdoors.

Results: Children in the pre-Kindergarten group who were first born exhibited better fixation control with fewer off-target drifts (F 6.09, $p \leq 0.05$) and more efficient horizontal saccades (F 5.96, $p < 0.05$). The Bland-Altman analysis of the 3rd grade group indicated good agreement among all groups for saccadic accuracy, saccadic speed, fluency, and fixation accuracy.

Conclusions: The activities that first born children are encouraged to perform regularly prior to Kindergarten may lead to better eye movement skills at that age. However, by 3rd grade, a child is using eye-movements to learn, and uses visual tracking, saccadic sequencing and reading fluency to read at a higher level. Our data suggests that the first born group continues to have moderately improved eye-movement performance compared with the others, but not significantly better. The children in this study will be re-evaluated prior to 6th grade to determine if any new trends with eye movements or binocular stability develop.

Biography

Christine Allison is a Fellow of the American Academy of Optometry, a Fellow of the College of Optometrists in Vision Development (COVD), and an American Academy of Optometry Diplomate in Binocular Vision, Perception and Pediatric Optometry, and a Distinguished Scholar and Fellow in the National Academies of Practice. She is the Clinical Director for the Illinois Special Olympics Lions Club International Opening Eyes Program, as well as a Regional Clinical Advisor for this program. She is the President-elect for COVD as well as the Illinois Optometric Association. She has published numerous articles, and given many presentations and lectures both nationally and internationally.

callison@ico.edu

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Jose Luis Monroy

La Salle University, Colombia

Scleral lenses: Mexican experience

Statement of the Problem: Keratoconus is a progressive and idiopathic disease in which the cornea develops into an irregular and conic shape. The clinical signs include thinning of the cornea in its central or paracentral region, an apical protrusion that results an irregular astigmatism, and this condition can progress. Keratoconus is the most common form of dystrophy or corneal ectasia, with an incidence of 50–230 per 100,000 persons. In Mexico, the research on keratoconus is scarce; the articles published show statistics that are similar to those in international literature, which indicates a higher prevalence in male patients with a mean age of 24.5 years. The incidence is about 1/2000 people in the general population in Mexico. Medical management with scleral lenses is a viable treatment for vision rehabilitation.

Methodology & Theoretical Orientation: Retrospective, cross-sectional, observational, descriptive study of 66 patients with diagnosis of keratoconus and other secondary ectasias post refractive surgery was done; and for those who were followed from 2014, we are fitting them with scleral contact lenses.

Findings: We have found two particular situations in patients fitted with scleral lenses in Mexico: in 80% of cases a significant impingement occurs in the scleral area with lens diameter of 15.8 mm and above, and due to this, peripheral areas need proper for better alignment of the edge with the sclera or smaller diameters. The other situation is that in 34% of cases the adjustments to the front surface due to the presence of residual astigmatism resolving this situation with toric designs have been made.

Conclusion & Significance: Scleral lenses provide excellent vision correction and superior comfort compared to traditional contact lens options for the management of keratoconus and other ectasias post refractive surgery. In most of cases scleral lenses provide a really visual rehabilitation. Scleral lens should be considered before surgical intervention. However, lens designs should be improved especially in the landing zone.

Biography

José Luis Monroy is an Optometrist and graduate of La Salle University in Colombia (1987). He is experienced in eye-care business and professional in Optical/Ophthalmologic and Optometry industry channels in Latin-America with 29 years of clinical, academic and business experience. He is actually a Senior Clinical Optometrist and Researcher at Unidad Oftalmológica del Valle in México City. He is the Commercial Director of Yolia Health and the Academic Director of the Institute of Continuing Education in Optometry in Mexico. He is the Professor of Graduate Contact Lens Fitting Post Refractive Surgery at Universidad Nacional Autonoma de México (UNAM). He is the President and Founder of the Latin-American Association of Contact Lens and Cornea.

jlmonroy_99@yahoo.com

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