

## InsideRetina Directory

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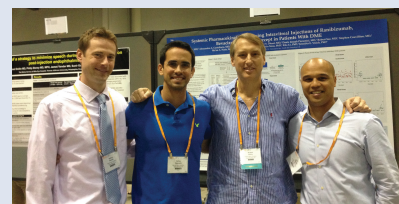
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## EYE SIGHTINGS AND ANNOUNCEMENTS

CRC congratulates clinical research coordinator **LISHA WAN** on her acceptance to the doctorate of optometry program at the Southern California College of Optometry in Fullerton, California

CRC welcomes **MICHELLE HANNA** as the new clinical research coordinator. Michelle recently graduated from UCSB with a degree in Biopsychology.



From left to right: Dr. Nathan Steinle, Dr. Carlos Quezada, Dr. Robert Avery and Melvin Rabena at 2014 ARVO annual research conference in Orlando, where they presented research studies.

**DR. STEPHEN COUVILLION** presented at meetings in Phoenix, Colorado (Aspen Retinal Detachment Society) and Las Vegas (Vitreous Buckle Society).

**DR. ROBERT AVERY** attended the Hawaii Eye Meeting, and was a guest speaker at the Bascom Palmer Angiogenesis Meeting in Miami. He also attended The Macula Society in Key Largo, ARVO in Orlando and Club Vit in Colorado.

**DR. NATHAN STEINLE** attended the West Coast Retina Update in Berkeley; he was a speaker at both the Vitreous Buckle Society in Las Vegas and the Cleveland Clinic Retina Symposium in Cleveland, and presented research at ARVO in Orlando.

**DR. ALESSANDRO CASTELLARIN** attended the Aspen Retinal Detachment Society and lectured on wet AMD, diabetic retinopathy and retinal vein occlusion in Newport Beach and San Diego.

**DR. DILSHER DHOOT** attended the West Coast Retina Update in Berkeley, the Vitreous Buckle Society in Las Vegas, and the Cleveland Clinic Retina Symposium. He also received the American Society of Retina Specialists 2014 Honor Award for his scientific presentations at the organization's annual meeting.

**DR. DANTE PIERAMICI** was recognized by the American Academy of Ophthalmology as a recipient of the 2014 Senior Achievement Award for his contributions to the Academy. Dr Pieramici was also a guest speaker at the Macula Society Annual Meeting in South Florida, the Wills Eye Hospital Management of Diabetic Retinopathy Roundtable in Santa Monica, and he delivered the Tom Aaberg Lecture at the 2014 Georgia Society of Ophthalmology.

**DR. ROBERT SEE** attended the Vitreous Buckle Society Meeting in Las Vegas.

**CALIFORNIA RETINA CONSULTANTS** was named "Site of the Month" in May for its outstanding performance in the Diabetic Retinopathy Clinical Research Network.

## CALIFORNIA RETINA RESEARCH FOUNDATION

515 E. Micheltorena St. Ste. G  
Santa Barbara, CA 93101-4427

## RESEARCH OVERVIEW CON'T.

therapies to treat ophthalmic genetic diseases. The first step in correcting a disease is to determine the specific gene and gene products that are abnormal. With this information a rational approach to therapy is possible.

### DIABETIC RETINA CLINICAL RESEARCH NETWORK STUDIES

Two new clinical research trials for diabetic macular edema are underway at California Retina Consultants. In Protocol U, patients with ongoing diabetic macular edema who currently receive eye injections of bevacizumab or ranibizumab will receive an additional drug—ranibizumab, dexamethasone—which is a combination therapy. The purpose of the study is to determine whether or not patients with diabetic macular edema can benefit from the addition of a second medication with a different mechanism of action.

Another DRCR clinical trial, Protocol V, will investigate the use of laser photocoagulation, anti-vegf injections or a combination of these therapies to determine best treatment practices.

### EARLY STAGE TRIALS FOR WET MACULAR DEGENERATION

California Retina Consultants are one of only three clinical centers in the world involved in this exciting new trial investigating the safety and efficacy of a new compound called DE-120 for patients suffering from advanced wet macular degeneration. DE-120 is a kinase receptor inhibitor which blocks vascular endothelial growth factor and platelet derived growth factor binding in cells involved in the formation of abnormal new blood vessels. The compound, DE-120, is injected into the eye. Data from this clinical trial will be submitted to the FDA for approval before continuing to next phase. This approach may allow for better visual outcomes and less treatments for our patients with neovascular AMD (wet AMD).

### SYSTEMIC VEGF LEVELS AND PHARMACOKINETICS FOLLOWING INTRAVITREAL ANTI-VEGF IN PATIENTS WITH MACULAR DEGENERATION

Dr. Robert Avery recently presented results of a study designed by CRC

researchers which measured drug levels and vascular endothelial growth factor (VEGF) levels present in the systemic circulation in patients who receive eye injections of ranibizumab (Lucentis), bevacizumab (Avastin) or aflibercept (Eylea). Blood samples were collected from patients at several intervals following their first and third eye injections. The results showed higher systemic levels of drug and concomitant lower levels of VEGF in the blood stream of patients receiving aflibercept and bevacizumab compared with those receiving ranibizumab. Further studies are needed to determine whether these results are associated with any serious adverse events, but this study is one of the first to show a potential systemic difference between the three drugs. The results of this groundbreaking clinical trial were published in the British Journal of Ophthalmology on July 7, 2014.



# InsideRetina



Dr. Nasir exams Mrs. Lois Abbott, who is being treated with Lucentis for wet Age-Related Macular Degeneration (AMD).

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## ANNUAL EDUCATIONAL MEETING SET FOR SEPTEMBER 27, 2014

Dr. Dan Martin, Chairman of the prestigious Cleveland Clinic's Cole Eye Institute, will be the keynote speaker at the California Retina Research Foundation's 13th Annual Educational Conference. Dr. Martin has been the principal investigator in dozens of clinical trials, including the well-known CATT trial for wet AMD. He has extensive experience in both medical and surgical treatments of the retina. Clinically, his specialty interests include age related macular degeneration, diabetic retinopathy, macular pucker, macular hole,

retinal detachment, and inflammatory and infectious diseases of the retina. The annual meeting is free to participate and takes place on Saturday, September 27, 2014 at the Fess Parker Doubletree Resort in Santa Barbara and is open to eye-care professionals and allied ophthalmic technicians.

Register online at [www.californiaretina.com](http://www.californiaretina.com) or call (805) 963-1648.



Above: The California Retina Research Foundation team taking steps to cure blindness. Below: iPad improves eyesight.

## TAKING STEPS TO RESTORE SIGHT

The fourth annual Santa Barbara VisionWalk took place on Saturday, April 26, at Chase Palm Park drawing a crowd of over 200 supporters who helped raise over \$44,000 for the Foundation Fighting Blindness and its efforts to find a cure for blinding retinal degenerative diseases. The California Retina Research Foundation was a contributing sponsor, forming a team of employees and their families who laced up their sneakers to support the 5K walk for vision.

“What was so exciting about this year’s walk was that the money raised remained in the Santa Barbara community,” said KC Wash, who co-chaired the VisionWalk with his wife, Rhonda, and their 15-year-old daughter, Lily, who suffers from retinitis pigmentosa (RP) and is a patient of the California Retina Consultants. Her doctor, Dr. Dante Pieramici, explains that RP is a rare genetic disease for which there is no effective treatment or cure, however he is optimistic about research currently underway. Much of that research is being conducted here on the Central

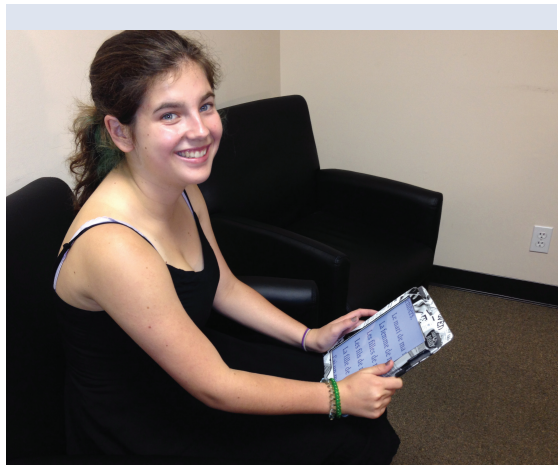
Coast by Dr. Dennis Clegg and his team at the UCSB lab.

Melvin Rabena, Research Director of the CRRF makes it clear that much of Clegg’s research could one day directly benefit the patients of California Retina Consultants and those around the world.

Dr. Clegg’s current emphasis is on retinal stem cell research, with a focus on developing therapies for blinding ocular diseases such as retinitis pigmentosa. Clegg and his team are in the process of developing a two-layered patch of cells to replace retinal tissue lost from conditions like RP and macular degeneration, making hopeful progress toward saving and perhaps restoring sight.

“The VisionWalks are important sources of funding for the Foundation Fighting Blindness which supports our research, allowing us to advance therapy from the lab to the clinic,” Dr. Clegg noted.

The VisionWalk takes place every April and is open to the public. [www.fightblindness.org](http://www.fightblindness.org)



### iPAD IMPROVES EYESIGHT

Sixteen-year-old patient Rachel Fields is seeing better thanks to her new iPad, a gift from the California Retina Research Foundation. Foundation Director, Dr. Dante Pieramici, credits iPads, laptops, kindles and other high tech devices with helping to improve vision that has been impaired due to blinding retinal diseases. Rachel, who suffers from retinitis pigmentosa, an inherited genetic condition, has started using the iPad to aid in her summer French classes, moving away from the oversized CCTV apparatus. She says it has changed her life!

## THE SUNSHINE ACT PASSES FEDERAL APPROVAL

The National Physician Payment Transparency Program, or the “Sunshine Act” takes effect in September 2014 and requires public reporting of payments to physicians and teaching hospitals from pharmaceutical and medical device companies.

The purpose of the new law is transparency. Information disclosed through this regulation will include: consulting fees, speaking fees, honoraria, research-related funding or grants, education or conference funding, physician ownership and investment interests, forms of equity, royalties or licenses, and charitable contributions paid by the pharmaceutical industry. The information in these reports will be made available to the public via a searchable website.

California Retina Consultants’ Research Director, Melvin Rabena, explains that research plays a critical role in the development of new drugs, medical devices and therapies. CRC physicians actively participate in clinical research, thereby receiving funding from pharmaceutical companies as well

as federal agencies and private organizations in order to effectively conduct important research trials. The financial support and grants received for these trials will be included in the Sunshine Act reports. Rabena says, “It’s important to understand that simply because the report discloses a large payment in the form of a research grant from a manufacturer to a principal investigator, it does not mean that the physician conducting the trial receives the payment for his or her personal use.” In fact, the vast majority of trials do not include compensation for the physicians’ time. Rabena continues, “We do these trials not to make money but to provide our patients with an opportunity to benefit from novel treatments and to further the field of ophthalmology.” The doctors of the CRC have all trained at academic programs that em-

phasized the development of clinician scientists. This dual role runs deep in the philosophy of the California Retina Research Foundation.

In order to comply with FDA regulations, clinical trial administration is complex and requires extensive training and documentation. In addition, the California Retina Research Foundation relies on outside support and grants to organize educational events for local community members and medical professionals on the Central Coast and Central Valley. CRRF also supports the training of local and international physicians through their fellowship and internship programs.

Public recording will reflect funds that CRC uses for research and education, helping advance the field of ophthalmology.



Dr. Couvillion is joined by CRC Clinic Manager Aimee Shook (left) and CRC Clinical Research Coordinator Michelle Hanna (right).

## RESEARCH OVERVIEW

The California Retina Research Foundation conducts ongoing research for patients suffering from blinding retinal diseases. The following provides a recap of current and ongoing clinical trials.

### LATE STAGE STUDY FOR DRY MACULAR DEGENERATION

The MAHALO study of lampalizumab (formerly FCFD4514S, Genentech) is a phase 2 study of a humanized monoclonal antibody fragment that binds factor D, which is a critical enzyme involved in the alternative complement pathway. The study proved successful, showing a reduction in slowing geographic atrophy over 18 months. This landmark clinical trial was the first to show efficacy of a therapeutic agent to slow the progression of geographic atrophy. Additionally, a subset of patients identified to be positive for exploratory biomarkers showed further reduction of geographic progression by 54% compared to the control group. The phase 2 trial enrolled 129 randomly assigned patients who received monthly or bi-monthly lampalizumab or sham injections. Lampalizumab selectively inhibits complement factor D. Increased activity in the alternative complement pathway (a part of our immune system) has been associated with the development of macular degeneration. Late stage trials to further study the efficacy and safety of lampalizumab in patients with dry macular degeneration are planned to begin in the U.S. later this fall. If these trials are likewise positive FDA approval will be expected sometime in the next few years.

### NEW MEDICATION FOR DIABETIC MACULAR EDEMA

In dual phase-three clinical trials, patients with diabetic macular edema treated with Eylea, a recombinant fusion protein, achieved significant improvements in visual acuity compared to patients treated with laser photocoagulation. Based on these positive results Regeneron Pharmaceuticals has submitted an application to the U.S. Food and Drug Administration for marketing approval of Eylea for treating diabetic macular edema. Eylea has been previously approved for the treatment of wet macular degeneration and central retinal vein occlusion. The physicians of the California Retina Consultants were early investigators in this groundbreaking trial and plan additional trials to determine in which patients this drug will be the most effective.

### GENETIC SEQUENCING FOR OCULAR DISEASES

California Retina Research Foundation is collaborating with the National Ophthalmic Genotyping and Phenotyping Network (EyeGene) study group as part of a multi-center effort to study the genetic components of inherited ocular conditions such as retinitis pigmentosa, Stargardt disease and Best disease. The EyeGene study group, with support from the National Eye Institute, facilitates translational eye research and provides patients with an opportunity to actively engage in developing gene-based

Continued on back

### California Retina Research Foundation

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Contributions are fully tax-deductible to the fullest extent allowed by law. Gifts may be arranged in memory or honor of a special person. Arrangements can be made to include the Foundation in a Last Will and Testament. CRRF is a 501(c)(3) non-profit.

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