

Inside Retina

Volume VIII

December 2011

News from the California Retina Research Foundation

CALIFORNIA RETINA CONSULTANTS' DR. ROBERT AVERY LECTURES AT PRESTIGIOUS INTERNATIONAL MEETINGS



Dr. Robert Avery and colleagues

Dr. Avery was invited to be one of three guest speakers at the Advanced Vitreous Surgery Course in Tokyo this past September. This meeting, held every other year, is the largest meeting of vitreoretinal specialists in Japan, attended by more than 90% of Japanese retina specialists. Dr. Avery had the unique honor of being a repeat guest speaker as he had been invited to lecture on Avastin uses four years ago. At the 2011 meeting, his topics included surgical techniques and success rates of

retinal detachment repair, new treatments of diabetic retinopathy and retinal vein occlusion, differences in anti-VEGF agents and systemic risks due to them, as well as advances in retinal drug delivery devices.

In September 2011, Dr. Avery was the guest speaker for a leading group of medical retinal specialists in the United Kingdom. He flew to London and spoke on advances in the treatment of diabetic macular edema, as well as the systemic differences between Avastin and Lucentis.

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CALIFORNIA RETINA TEAM RESTORES SIGHT IN HONDURAS

The armed guard stood outside the packed waiting room, which occupied the ground floor of a non-descript two-story building located on an unpaved dirt road, just minutes from the town center. Patients had arrived at 6:30 am, and one woman even slept outside the clinic the night before, awaiting the arrival of the American retina team. Dr. Dante Pieramici and Melvin Rabena, research director of California Retina Research Foundation (CRRF) had voluntarily traveled to El Progreso, Honduras over Thanksgiving on a humanitarian retina surgery mission to treat local patients, train resident physicians and establish early screening programs so that future patients could receive ongoing medical care.



“I’m fortunate to be trained and experienced in a field that enables me to save patients’ eyesight, hopefully improving their quality of life,” stated Dr. Pieramici. “The patients at Centro Cristiano de Servicios Humanitario de Honduras (CCSHH) health clinic have extremely limited resources and lack of access to knowledgeable retina care available so this is truly a valuable undertaking,” added Rabena. The two medical experts spent five days at CCSHH located in El Progreso, Honduras, examining many patients and performing retina surgeries.

Dr. Pieramici and Rabena traveled to Honduras on a mission with Surgical Eye Expeditions (SEE) International, a local nonprofit, humanitarian organization that provides medical, surgical, and educational services by volunteer ophthalmic surgeons with the primary objective of restoring sight to disadvantaged blind individuals worldwide. Doctors donate their professional services and cover their own travel expenses in an effort to help those most in need. Since being founded in Santa Barbara in 1974, SEE International has completed more than 400,000 sight-restoring surgeries worldwide.

“There are only two surgical retina doctors working in Honduras and they have limited time to assist the poor,” claimed Melvin Tejada, CCSHH Executive Director. He said patients traveled from all over the country to be examined by Dr. Pieramici, including the woman who drove four hours from Tegucigalpa, the country’s Capital and slept outside the clinic.



L to R: Carmen Toro, Melvin Rabena, Dr. Celeo Ramirez, Dr. Dante Pieramici, Melvin Tejada

While CCSHH is equipped to perform most ocular surgeries, including cataract, glaucoma and corneal



L to R: Dr. Dante Pieramici and Dr. Celeo Ramirez

transplant, having a retina specialist like Dr. Pieramici on hand is rare. Fifteen percent of the eight million Honduran people suffer from diabetes, making diabetic retinopathy widespread. Diabetic retinopathy is one of the most common eye diseases that may result as a complication of diabetes. Often detectable through baseline and early screening with appropriate technology and expertise, diabetic retinopathy can be treated. However, without treatment, all diabetic eye diseases can cause severe vision loss or blindness. Diabetes-related eye diseases accounted for the bulk of Dr. Pieramici's cases, along with advanced retina detachments and ocular injuries.

The California Retina Research Foundation helped fund the trip. CRRF is a non-profit, research-oriented division of the California Retina Consultants that offers clinical trial research to a variety of patients on the Central Coast. It is paid for by private donations. To find out more about CRRF or to make a donation, please visit www.californiaretina.com or complete the form below.



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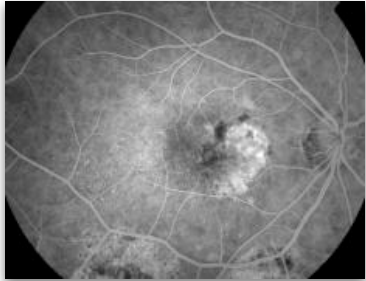
The California Retina Research Foundation (CRRF)

The California Retina Research Foundation is a non-profit organization based in Santa Barbara devoted to the prevention of blindness through the advancement of research in vitreoretinal diseases. The CRRF promotes collaborative and innovative research that demonstrates the potential for establishing effective new preventions, treatments and cures for many blinding retinal diseases. The CRRF is funded through the generosity of interested individuals. Phone: (805) 884-5185. email: crrf@californiaretina.com

RESEARCH REVIEW

The doctors and research staff of the California Retina Consultants and Research Foundation take pride in being at the forefront of retinal disease research. We are actively involved in prospective, national clinical studies and investigator-initiated trials and have enrolled hundreds of patients over the last several years.

Today, we are participating in over a dozen clinical trials in various locations along the central valley and coast. The information below summarizes a few of the new and ongoing studies at CRC.



Harbor Results for Wet AMD— 2.0 mg ranibizumab did not offer added benefit over 0.5 mg ranibizumab

Primary results for the HARBOR Trial were presented at

the American Academy of Ophthalmology's annual meeting this past October in Orlando, Florida. This study comparing 2.0 mg ranibizumab to the standard 0.5 mg ranibizumab dose in patients with wet macular degeneration showed similar gains in vision in both groups after 1 year, suggesting that the increased dosage offered no added benefit. Furthermore, vision improved similarly between patients receiving monthly injections of ranibizumab for 12 months compared with patients receiving ranibizumab injections on an as-needed basis following 3 initial monthly injections. The study also showed no difference in reported ocular or systemic adverse events between doses. Primary investigator, Dr. Ma'an Nasir led the oversight of this important study at CRC, and stated, "Although earlier trials hinted at a dose-dependent response, the results of this study provide evidence that the 0.5 mg dose is at or near the top of the dose-response curve and ultimately is a very safe and effective drug in the treatment of wet AMD."

The study, sponsored by Genentech, included 1,098 patients from clinical centers across the United States.

REACH Study for Wet AMD

In June 2011, California Retina Consultants was one of nine clinical centers in the United States invited to participate in a clinical trial studying the investigational medication, AGN-150998, which is injected into the eye in patients with wet age-related macular degeneration. The study, sponsored by Allergan, is designed to determine the safety and tolerability of AGN-

150998, as well as to determine how long the effects of the medication last. The study will also measure the amount of the medication that gets into the bloodstream and compare its effects to Lucentis, the FDA-approved treatment for wet AMD.

Phase 1 of the REACH trial was successfully completed this fall and Phase 2 of the trial is currently enrolling patients. Patients in Phase 2 of the study will randomly receive either 1 of the 2 planned doses of AGN-150998 or Lucentis. Approximately 200 patients will participate in this trial.

Anti-factor D Injections for Dry AMD

Approximately 80-90% of patients with macular degeneration have the dry form of the condition. Dry AMD is characterized by drusen (dots of yellow deposits that develop under the macula) and thinning of the retinal pigment epithelial cells that nourish the overlying photoreceptors critical for vision. While effective therapies are available for wet AMD, currently, there is no proven treatment for dry AMD.



Genentech is investigating the role of an antibody to factor-D in patients with geographic atrophy associated with dry AMD. Factor-D is an important activator of the complement system, which can cause tissue inflammation and cell death in the retina resulting in geographic atrophy leading to loss of central vision. By blocking factor-D drusen formation and enlargement of geographic atrophy may be prevented or reduced.

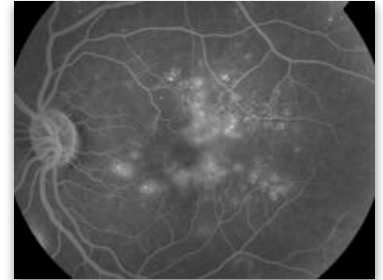
Enrollment was completed in October for a Phase 2 clinical trial (MAHALO Study) investigating the safety, tolerability, and evidence of effectiveness of anti-factor-D injections given monthly or every other month in patients with large areas of geographic atrophy associated with dry macular degeneration. The estimated completion date for the study is October 2013.

Diabetic Macular Edema

Diabetic macular edema (DME) is the leading cause of significant vision loss in patients under the age of 50 suffering from diabetes. Fluid leaking from blood vessels within the macula, the central portion of the retina, can cause blurring of the central visual field. Clinical trials are currently underway at California Retina Research Foundation (CRRF) to study the safety and efficacy of potential treatments for DME.

VEGF Trap-Eye for DME

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body that has been associated with the abnormal growth of new fragile blood vessels in the back of the eye, vascular permeability and the formation of edema. Regeneron and Bayer HealthCare are studying a compound known as VEGF Trap-Eye (aflibercept ophthalmic solution) in the treatment of diabetic macular edema. Trap-Eye is a VEGF receptor protein that binds all forms of VEGF-A. Clinical trials are underway at multiple centers across the United States including CRRF to assess the effectiveness of VEGF Trap-Eye for patients with DME.



DR. NATHAN STEINLE CONTRIBUTES TO RECENTLY PUBLISHED BOOK



Eye care professionals now have a new resource book available regarding the latest advancements in ocular ultrasound technology. *Ophthalmic Ultrasonography* (Singh and Hayden, Elsevier, 2012) is a 272- page reference manual that details all aspects of ocular ultrasonography from basic principles to breakthrough applications such as high-resolution anterior segment imaging.

Dr. Nathan Steinle of California Retina Consultants was asked to be one of the contributing authors for this project. Dr. Steinle notes, “This book provides comprehensive coverage of ultrasound applications across all sub-specialties in eye care including cornea, retina, glaucoma, pediatric, tumors, and trauma. I am excited that this reference book is now available to the eye care community. As a retina specialist at California Retina Consultants, we utilize this ultrasound technology on a daily basis to provide the highest level of care to our patients.”

2011 CRC ANNUAL EDUCATIONAL MEETING HIGHLIGHTS



Dr. Ma'an Nasir

The 10th annual California Retina Consultants' Educational Meeting held this past October at Fess Parker's Double Tree Resort, welcomed its largest audience ever with over 150 ophthalmologists, optometrists and eye care specialists from throughout the Central Coast, Central Valley and Southern California.

This year's meeting included two keynote speakers: Dr. Mark Humayun, Professor of Biomedical Engineering and Cell and Neurobiology, and Associate Director of Research, Doheny Retina Institute, University of Southern California; and Dr. Darius Moshfeghi, Associate Professor, Eye Institute at Stanford, and founder of the university's Network for Diagnosis of Retinopathy of Prematurity telemedicine screening.

Dr. Humayun described his work on an intraocular retinal prosthesis, a biomedical implant intended to partially restore vision to people who have lost their sight due to a degenerative retinal disease that severely damages the photoreceptors in the eye. The device is currently being studied in patients with severe vision loss due to retinitis pigmentosa.

Dr. Moshfeghi discussed findings of the BEAT-ROP study (Bevacizumab (Avastin) Eliminates the Angiogenic Threat of Retinopathy of Prematurity), a trial comparing Avastin to laser therapy in the management of retinopathy of prematurity (ROP). ROP is abnormal blood vessel development in the retina of premature infants.

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For the past decade, the California Retina Research Foundation (CRRF) has been able to bring leading vision researchers and geneticists to this annual event. Previous keynote speakers have included such local scientists as Dr. Dennis Clegg, Co-Director of the UCSB Center for Stem Cell Biology and Engineering, and Dr. Linc Johnson, Co-Director of the UCSB Center for Studies of Macular Degeneration. Dr. Daniel Martin, who designed and conducted the clinical trial comparing Avastin and Lucentis in the treatment of wet AMD was the keynote speaker in 2009. The CRRF collaborates with national clinical trials bringing the best research and treatments to local patients. Future plans include continuing and expanding conferences, seminars and other educational events devoted to furthering new treatment discoveries.

DR. PIERAMICI NAMED PRESIDENT SANTA BARBARA COUNTY MEDICAL SOCIETY



The Johns-Hopkins trained Dr. Dante Pieramici will become President of the Santa Barbara County Medical Society in January 2012. The Santa Barbara County Medical Society represents physicians practicing in Santa Barbara County and serves as the local branch of the California Medical Society. Dr. Pieramici has been working as a vitreoretinal specialist with California Retina Consultants, servicing patients throughout southern and central California for the past 11 years. He previously held academic positions at Yale University Eye Center and the Wilmer Eye Institute at the Johns Hopkins University in Baltimore.

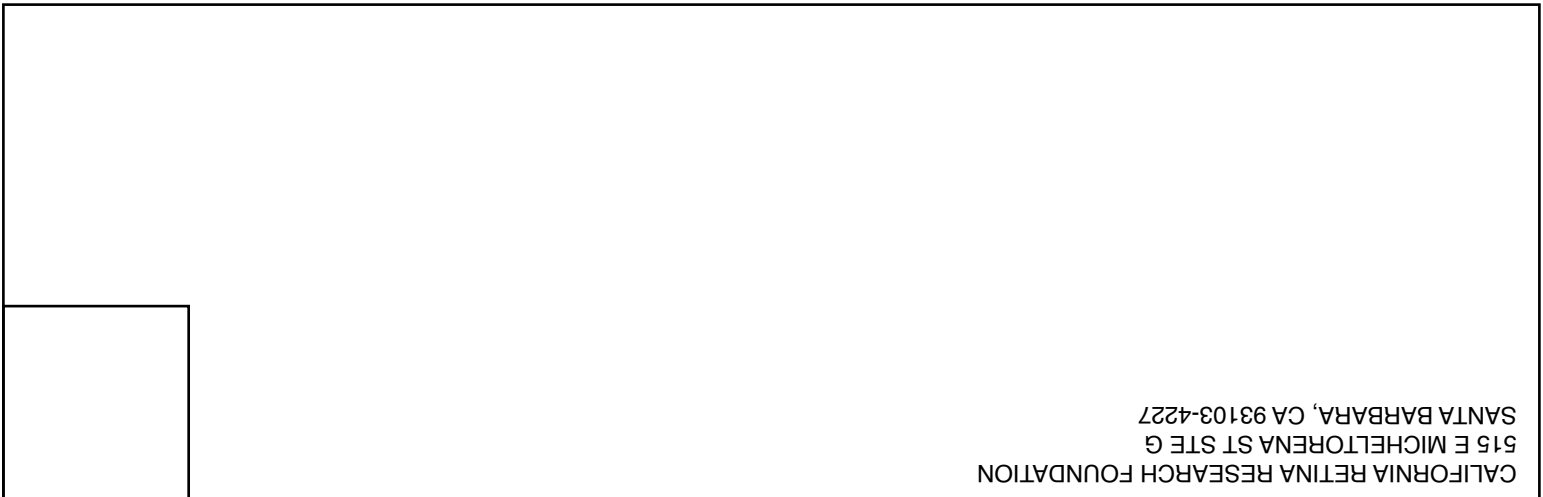
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