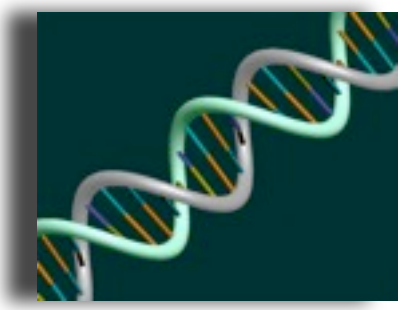
California Retina Research Foundation

Inside Retina

Volume V Fall 2009

News from the California Retina Research Foundation

NEW GENETIC TEST HELPS DETERMINE RISK OF MACULAR DEGENERATION



Residents with a family history of macular degeneration may want to consider a new genetic test that can help determine risk for developing the disease, the leading cause of vision loss and blindness among people age 50 and older.

The new genetic test involves a saliva sample which is sent to a lab for analysis with results returning within a few weeks. The test is not yet covered by most insurance plans but may be funded through a health savings program.

Dr. Couvillion is optimistic about this testing, "If a patient is at increased risk for developing age-related macular degeneration (AMD), they can make immediate lifestyle changes which could impact the occurrence or spread of the disease, including taking vitamins, reducing weight and most important, to quit smoking." He continues, "Early detection has the potential of reducing the development of visual complications of AMD."

California Retina Consultants has become a clinical site for the genetic test, called Macula Risk®, which has been developed by Toronto-based ArcticDX with some leading U.S. research laboratories involved. This is the first test to look at multiple genes that predispose someone to the disease. Seventy-five to eighty percent of all AMD has been traced to genes inherited from family members. Couvillion notes, "Macular degeneration has a very high inheritance pattern and this analysis is successful in testing for most of the genes, however there may be other, untested genes that play a part." In the future, treatments for AMD may be patient specific depending on the genetic defect that they manifest.

Over 15 million people in North America are currently affected by AMD and experts estimate that as the population ages the number of those afflicted will double in the next ten years.

AMD is a progressive disease associated with aging that causes damage to the macula-the light-sensitive cells at the center of the retina at the back of the eye. The macula is responsible for our ability to see with enough detail to read, drive, watch television and perform other activities that require focused, straight-ahead vision, as well as providing information that allows us to perceive colors. Once significant vision is lost, it cannot be restored and, if untreated, AMD can ultimately lead to blindness. The most effective treatment strategy will be to reduce the onset of the late visual threatening complications.

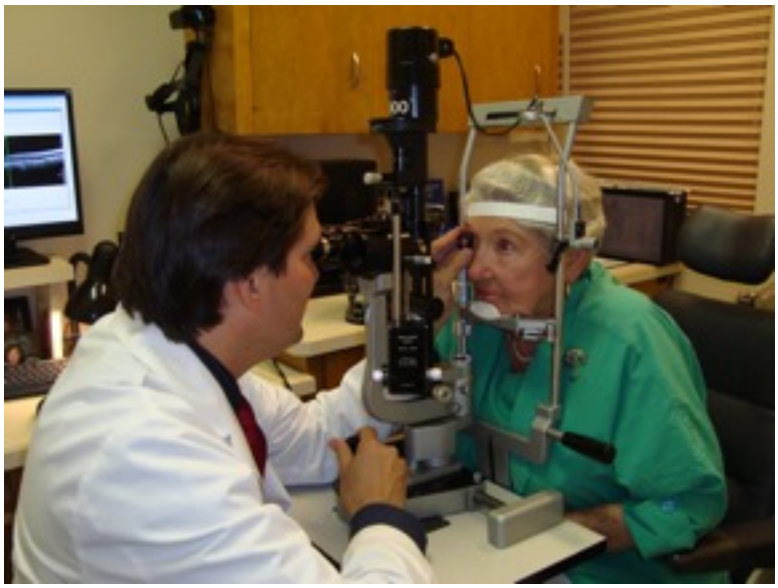
INSIDE THIS ISSUE

SO YOU WANT TO BE A RESEARCH SUBJECT?

Nearly 6 years ago Gloria Cloonan was losing vision in her "good" eye to age-related macular degeneration. The disease took a rapid turn for the worse with the onset of central blurring and distortion, tell-tale signs of wet or neovascular AMD. Gloria, a gregarious, retired nurse with an endless stash of optimism was now truly frightened. A few years prior, when she lost the central vision in her other eye, she seemed to chalk it up to the "aging process," a speed-bump in life. She quickly adapted to relying on the one "good" eye for reading and driving and appeared to move on with her life. Now the prospect of losing her "back-up" was devastating. The approved treatment options at that time were limited, offering at best a chance of slowing down the loss of vision. Gloria wanted a chance to regain some of what she had lost, and was therefore willing to take a chance on a treatment that had not been fully tested.

This new therapy might offer a better outcome but it came with the risk that it might prove less effective than the standard treatment options. She chose to become a research subject and took a gamble on the experimental therapy. Gloria's story has a happy ending: the drug that she received in the research trial was ranibizumab (Lucentis). By participating in the trial, Gloria had the opportunity to receive the drug prior to FDA approval. In fact, the study that she was part of helped facilitate the drug's FDA approval.

Lucentis and Avastin have now become standard care for the treatment of wet-AMD. Gloria's vision returned, enabling her to drive and read. Few research subjects experience such dramatic outcomes. However, even if the treatment proves ineffective in trial, it still advances understanding of the disease and potential therapies. In science, significant developments arrive on the shoulders of many small advances in our knowledge. Gloria acknowledges that being part of a clinical trial does mean more time in our office, but she felt that the time was well spent and appreciated the extra care, attention, and support that the research staff provided. In fact, she has been a research subject in two other trials. There are many reasons to consider participation in medical research if the opportunity arises, some are self-serving and some are altruistic. At a minimum we should all thank those like Gloria who have participated in the past. Their efforts are instrumental in creating effective therapies today.

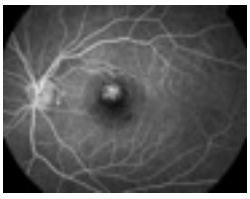


Dr. Pieramici and Gloria Cloonan

THE RESEARCH FRONT
OPEN ENROLLMENT FOR NEW AND ONGOING CLINICAL TRIALS

California Retina Research Foundation continues its mission to further research dedicated to combating vision loss associated with many retinal diseases. Participation in a study offers patients an opportunity to possibly benefit from new treatments, while providing a wealth of information that improves our knowledge base and benefits others suffering from the same disease.

Your generous donations make our research possible. Please contact our office if you are interested in donating to our foundation or participating in any of the following open trials.

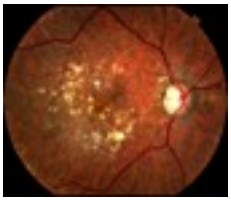


WET AMD

Data from a previous study comparing different doses of Lucentis suggest the possibility of achieving greater improvement in vision with higher doses of the drug. However, the affect of the higher dosage on the body is still relatively unknown. Ophthalmologists will investigate the effects of higher Lucentis doses by way of a two year clinical trial in which participants with newly diagnosed wet AMD will receive multiple eye injections

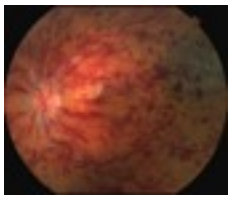
of different doses of Lucentis. The study will help doctors better understand the potential benefits and effects of increased doses of Lucentis and compare the results with the current formulation approved by the FDA.

The Comparison of Anti-VEGF Treatments Trial (CATT) is near the end of the second year of enrollment. Supported by the National Institute of Health, the CATT study is comparing two commonly used treatments for wet AMD: Avastin and Lucentis. Currently, there are 27 patients participating in this trial through California Retina Consultants and Research Foundation.



DRY AMD

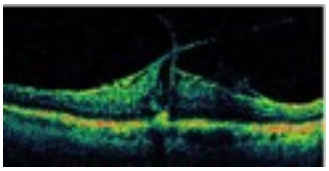
Approximately eighty-five to ninety percent of age-related macular degeneration (AMD) cases are of the dry form. Dry AMD is characterized by small yellow deposits called drusen, and by areas of thinning in the retina called geographic atrophy. No proven treatment exists for this type of AMD. However, recent developments in macular degeneration research have resulted in the design of experimental compounds that hold potential to prevent further vision loss from dry AMD. Earlier this summer five clinical centers across the nation, including California Retina Consultants, initiated a clinical trial to investigate the tolerability, safety and effects of a new drug in the eye and in the body. This is the primary application of the experimental compound in humans and the very first patient to receive the drug was treated at California Retina Consultants (Santa Barbara office).



CRVO

In the United States, retinal vein occlusion is the second most common condition to affect blood vessels in the retina (diabetic retinopathy is the first). In a central retinal vein occlusion (CRVO), a blood clot slows or stops circulation in a large vein within the eye's light-sensitive retinal tissue. In a branch retinal vein occlusion (BRVO) a smaller vein is affected. This may lead to new blood vessel growth and blood vessel leakage, which results in retinal tissue swelling – a common cause of vision loss from vein occlusion.

This fall California Retina Consultants and Research Foundation will begin separate clinical trials to test the efficacy of two new drugs in treating patients with CRVO.



VITREOMACULAR TRACTION

Vitreomacular traction (VMT) develops when the vitreous, the gel-like substance inside the eye, pulls forward and tugs the retina away from its normal position. The exact cause of VMT is unknown. Patients with VMT can experience occasional flashes of light, floaters, loss of contrast and increased vision distortion. Large holes and swelling in the retina can develop in advanced cases of VMT. Microsurgery to remove the vitreous can relieve the tension between the vitreous and retina, but there are inherent risks that may outweigh the benefits, such as infection and cataract formation. An experimental compound is currently being evaluated for its ability to separate the vitreous from the retina allowing the retina to return to its normal position. If this treatment proves effective, patients with VMT may be able to choose this less invasive treatment option.

RECENT CRC CLINICAL TRIAL STUDY RESULTS

A Randomized Trial Comparing Intravitreal Triamcinolone to Focal/Grid Photocoagulation for Diabetic Macular Edema (DRCR Protocol B)

A national, multi-center clinical trial organized by the Diabetic Retinopathy Clinical Research Network with support from the National Eye Institute, compared 1 mg and 4 mg doses of intravitreal triamcinolone to focal/grid photocoagulation in the treatment of patients with diabetic macular edema. The study enrolled 840 subjects and participants were monitored for three years. Results showed greater improvement in visual acuity and macular thickness within the first four months of treatment in eyes that received triamcinolone compared to focal/grid photocoagulation. However, continued examination and treatment up to three years in the study showed more efficacy and less

side-effects with focal/grid photocoagulation than 1 mg or 4 mg dosing of intravitreal triamcinolone. Side-effects noted in the triamcinolone group included increased intraocular pressure and increased rate of cataract formation. Clinical trials to evaluate combination treatment with intravitreal triamcinolone and focal/grid laser are ongoing.

Reference: Archives of Ophthalmology Vol 27 Mar 2009 1447-1449

A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Branch Retinal Vein Occlusion (BRAVO) and Central Retinal Vein Occlusion (CRUISE)

Genentech, Inc. announced the results of the phase III study, BRAVO and CRUISE in July 2009 press releases. BRAVO and CRUISE evaluated the use of Lucentis® (ranibizumab injection) for branch and central retinal vein occlusion. This trial compared the safety and efficacy of six monthly injections of Lucentis to monthly sham injections. Results showed early and sustained improvement over six months. Additional data will be presented later this year.

Reference: Genentech Inc. website www.gene.com

Phase III Clinical Trial Results - Standard Care vs. Corticosteroid for Retinal Vein Occlusion (SCORE) Study

The Standard Care vs. Corticosteroid for Retinal Vein Occlusion (SCORE) study, conducted at 84 clinical sites, including the California Retina Consultants, found that eye injections of a corticosteroid medication could reduce vision loss related to the blockage of major blood vessels within the eye, a condition known as central retinal vein occlusion (CRVO). This is the first long-term, effective treatment to improve vision and reduce vision loss associated with blockage of large veins in the eye. The study also demonstrated that laser therapy is equivalent to two different dosages of corticosteroid medications for treating vision loss from the blockage of small veins in the back of the eye, a condition known as branch retinal vein occlusion (BRVO). Furthermore, laser treatment was shown to have fewer complications for patients. This research was part of a multi-center, phase III clinical trial supported by the National Eye Institute (NEI) at the National Institutes of Health.

Source: NEI/NIH Press Release September 2009

Lucentis for CRVO

Data from a small clinical trial studying the effects of Lucentis in patients with CRVO were presented at the Association for Research in Vision and Ophthalmology 2009 annual meeting. Results showed that in this small sample of patients Lucentis was tolerated quite well and most participants experienced improvement in vision after treatment. This small clinical trial designed by Dr. Dante Pieramici and colleagues helped launch larger clinical trials involving multiple medical centers across the nation.

LANCASTER FACILITY OFFERS NEW EQUIPMENT

Clyde Hernandez, Jim Pandya, Dr. See, Jennifer Farnes

Over the last year, the Lancaster Community Hospital has invested in new ocular equipment, enabling Dr. See and his partners to perform vitreoretinal surgery at this location. Since the equipment has been installed, Dr. See has performed over 200 cases for patients from Antelope and Santa Clarita Valleys, as well as from Bakersfield and the central valley. California Retina Consultants owes a great deal of gratitude to Lancaster Community Hospital employees who make the surgical program possible, including Robert Troutman, CEO; Yolanda Douglas, RN; Clyde Hernandez, Jim Pandya and Jennifer Farnes.

NEW VALENCIA OFFICE OFFERS SHORTER WAIT TIMES AND LARGER WAITING ROOM

The Valencia office relocated to its current Tourney Road location in July 2009 and Dr. Robert See and Dr. Alessandro Castellarin couldn't be happier. During his three years with California Retina Consultants, Dr. See has spearheaded impressive growth in both the Valencia and Lancaster offices. See explains, "The Valencia practice has been steadily growing and our new office more than doubles the seating of our waiting room and offers two screening and exam rooms, which means shorter wait time for patients." Another benefit is the office location on the first floor, making it easily accessible for patients. The address is 27420 Tourney Road, Suite 170, on the southeast corner of Tourney Road and Wayne Mills Place.

ANNOUNCEMENTS AND APPOINTMENTS

Kang Zhang, M.D.,PhD

California Retina Research Foundation partners with Kang Zhang, M.D., PhD. Dr. Zhang is internationally known as a leader in the study of the genetics of eye diseases. He received his medical degree, magna cum laude, from Harvard Medical School in 1995 and his doctorate in genetics from Harvard in 1991. He completed his retina fellowship at the University of Utah and his ophthalmology residency at Johns Hopkins University's Wilmer Eye Institute. The Research Foundation has partnered with Dr. Zhang to study the genetics of diabetic retinopathy and age-related macular degeneration. Dr. Zhang is currently Professor of Ophthalmology and Genetics at the Shiley Eye Center.

Dr. Pieramici is appointed Treasurer of the Santa Barbara Medical Society, as well as Board Member of S.E.E. International (Surgical Eye Expeditions).

Dr. Avery and Dr. Pieramici have been recognized by The American Society of Retina Specialists as Senior Honor Award Winners due to their extensive participation at the society's annual meetings, including serving as senior authors, co-authors, moderators and film producers in the requisite number of educational elements.

Dr. Avery continues his work as Editor of *Retina Today*. He was also selected to be in both *Marquis Who's Who in America* and *Marquis Who's Who in Medicine and Healthcare.*

Dr. Castellarin, with wife Stephanie and daughter Francesca welcomed son, Luca born December 2008.

Dr. Couvillion and his wife Lisa welcomed their third son, Michael Easton, born September 2009.

Dr. Avery and wife Kelly welcomed the fifth addition to their family: a new Havanese puppy named Mozart.

The Santa Barbara Research Department welcomes new Study Coordinator Sarah Risard, who recently graduated from Westmont College with a degree in biology.

AMD Support Group continues to meet the first Tuesday of every month from 3:00 to 4:00 pm in the Santa Barbara office, upper level waiting room.

THE CRRF IS GRATEFUL FOR OUR GENEROUS DONORS

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DR. ANTHONY ARNOLD IS GUEST SPEAKER AT CALIFORNIA RETINA CONSULTANTS' ANNUAL EDUCATION MEETING

More than 100 eye care professionals attended the California Retina Research Foundation's Eighth Annual Education Meeting, held on September 19 at Fess Parker's Doubletree Resort in Santa Barbara.

Dr. Anthony C. Arnold, chief of the Neuro-Ophthalmology Division at UCLA's Jules Stein Eye Institute was the keynote speaker.

Dr. Arnold discussed diseases affecting the optic nerve, such as strokes (vascular disease), inflammations such as multiple sclerosis, and the most appropriate tests to image the nerve and detect ailments.

OUR MISSION IS YOUR VISION

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 and tax deductible donations can be submitted to California Retina Research Foundation at 515 E. Micheltorena Street, Suite G, Santa Barbara, CA 93103. Phone: (805) 884-5185. email: crrf@californiaretina.com

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EYE SIGHTINGS

California Retina Consultants physicians continue to share their knowledge and expertise with ophthalmologic colleagues around the world, while bringing the best practices from other locations back to California's central coast.

Here's a sampling of where our doctors have been in the past few months.

- Dr. Avery spoke at ARVO (Association for Research and Vision in Ophthalmology), Fort Lauderdale, Club Vit, Salt Lake City and ASRS, New York.
- Drs. Castellarin and Pieramici were guest speakers at the Danish Academy of Ophthalmology in Denmark.
- Dr. Pieramici spoke at the European Ophthalmology Society in Amsterdam, and presented at ARVO in Fort Lauderdale and ASRS in New York.
- Dr. Nasir spoke at the Retina in Cairo meeting in Egypt, ASRS (American Society of Retina Specialists) in New York and attended the Aegean Retina Symposium in Crete, Greece.
- Alison Ratliff, Practice Administrator, attended a Genentech Advisory Board Meeting in New York.

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