### CALIFORNIA RETINA RESEARCH FOUNDATION

# InsideRetina

#### **VOLUME 1, 2017**

# CENTRAL VALLEY OFFICE RELOCATES TO EXPANSIVE, NEW FACILITY

One of California Retina Consultants' busiest offices recently moved to a new space to meet its growing needs. The new Bakersfield office is expansive, with 7,500 square feet, an impressive facility given CRC's humble beginnings in a shared space nearly 25 years ago. At that time, Bakersfield was a satellite location served solely by Dr. Robert Avery, who saw patients



to be facilitated. With the impending arrival of Dr. Learned this summer, the Bakersfield practice realized it was once again time to move.

While the new office remains centrally located between highways 99 and 58, it has expanded its research department with 2nd floor workspace for CRC's Central Valley study coordinators, utilizing two vision testing lanes and laboratory space. There's also a dedicated space for billing, insurance authorizations and an information technology office. The entire first floor encompasses the main clinical operations including seven screening rooms, a separate

waiting area for dilated patients, four imaging suites for diagnostic testing, and eight exam rooms. "As the clinical practice evolved it needed more space as it began adding more doctors and a dedicated research staff. I don't view Bakersfield as a satellite office; it is consistently one of the busiest offices in the CRC network and now has the space it needs to better serve this city and the surrounding areas," stated Dr. Pieramici.

CRC is proud of a new office in the High Desert as well. Palmdale has moved to a spacious suite with over

#### **CRC's new Bakersfield office**

just once per month. When Dr. Pieramici joined the practice in 2001, he and Matt Giust established an independent CRC office which was only 1,000 square feet, containing one screening and one exam room. With Dr. Castellarin's arrival, the office moved to the original Office Center Court location, a virtual paradise, doubling the screening and exam space.

In the time between 2004 and 2012, the practice's operations in Bakersfield continued to grow with the additions of Drs. See in 2004, Steinle in 2011, and Dhoot in 2012. With full time staff, California Retina had officially outgrown its original space and moved to a larger location within the same building. Two doctors were finally able to work side by side and clinical trials were able 3,000 square feet comprised of three work-up and four exam rooms, in addition to FA and OCT spaces for a smoother clinic flow and less waiting time – though the new office has two new waiting rooms making the visit more comfortable.



CRC's new Palmdale office

### **STAFF UPDATES**





**Tammy Lauinger** 

John McDermott

The research department is delighted to announce the appointment of two new coordinators: Tammy Lauinger and John McDermott. Tammy joins the Santa Maria clinic with 31 years of experience in ophthalmology. She graduated from Cuesta College with an LVN license and is a certified phlebotomist and medical assistant. She was born and raised in San Luis Obispo County and has two daughters with her husband. John graduated from UCSB in 2014 with a degree in pharmacology and has spent the last three years working at a local biotech startup. John's grandfather and his father were both ophthalmologists. While the medical gene runs in his family, John says he also enjoys crocheting — by candlelight — in his spare time!





Sarah Fishbein

Polina Erokhina Larissa Halsell

California Retina Consultants is sad to say farewell to Sarah Fishbein, Polina Erokhina, and Larissa Halsell. Sarah Fishbein was a clinical research coordinator at CRC for five years and is moving to Portland, Oregon to pursue a Nurse Practitioner degree. Polina Erokhina was with CRC for two years and plans to go back to school; she also just got married this spring. Larissa Halsell was a clinical research coordinator at CRC over the past year and is leaving to help her husband with his growing business and to prepare for her growing family, as Larissa recently announced her pregnancy! We wish them all the best of luck.

# CRC RESEARCHERS TRAIN FOR UPCOMING TRIALS

California Retina Research Foundation is excited to help CRC begin some groundbreaking new clinical research trials at several of our locations. We are especially happy that these trials will cover many conditions for which CRC patients are treated. Our clinical research coordinators have been traveling to train and prepare to get these trials activated at our CRC locations.

Research coordinators Jack Giust and James Cazares traveled to New Orleans in March to train for an exciting trial that will be offered at our Bakersfield location. The trial will combine a new experimental treatment with an approved drug to treat patients with the central and branch retinal vein occlusion (RVO). This same combination of therapies will also be tested in patients suffering from diabetic macular edema.

James also attended training in New York City for a novel trial seeking to treat patients who have severe non-proliferative diabetic retinopathy with a treatment that is already approved for other conditions of the retina. This trial will run at our Bakersfield and Santa Maria locations.



In the area of age-related macular degeneration (AMD), Santa Barbara senior research coordinator Gina Hong trained in Austin, TX recently for a trial comparing injections of Lucentis with a surgically implanted treatment for wet AMD.

Gina Hong attends a study meeting in Austin, Texas with other coordinators from across the country.

This promising trial is already in progress in Santa Barbara, and will soon be active in Bakersfield.

Each of our main research offices is preparing to take part in a groundbreaking trial for the treatment of geographic atrophy. And an exciting new trial for DME will give patients great flexibility through a home-administered treatment conducted by the patient. This trial is starting up in Bakersfield and CRC and CRRF are working to bring this to other offices as well.

Our Bakersfield site is still enrolling patients with non-infectious uveitis accompanied by macular edema, and all of our research locations are enrolling patients with persistent DME who qualify to participate.

If you are a patient interested in participating in a clinical trial, please call your California Retina Consultants location or consult with your physician during your next visit to see if you might qualify.

# LUCENTIS NOW APPROVED FOR MYOPIC CHOROIDAL NEOVASCULARIZATION

For all of our nearsighted readers, especially those of you that are holding this newsletter really close, there is good news to share. Genentech announced recently that Lucentis (ranibizumab) was approved by the Food and Drug Administration for the treatment of myopic choroidal neovascularization (MCNV). MCNV is a vision-threatening complication of high myopia (nearsightedness). MCNV affects more than 41,000 people in the United States (especially in eyes with a refractive error of -6 D or greater).

In patients with high myopia (nearsightedness), the eye progressively lengthens to the point where cracks in the retina can form and atypical blood vessels then develop and bleed (neovascularization). The condition is most prevalent in people ages 45 to 64, but can affect younger and older people. Women are more commonly affected than men. Symptoms of MCNV include sudden onset of central blurred or distorted vision, worsening of central vision or difficulty distinguishing colors in the affected eye.

"MCVM can afflict nearsighted patients in the prime of their careers, and can lead to severe vision loss," states Nathan Steinle, M.D. "With Lucentis, people with this condition now have a new FDA-approved treatment option that has been shown to offer significant improvements in vision. The study data reveal earlier treatment leads to better vision gains, so nearsighted patients should report any new symptoms affecting their central vision without delay."

Lucentis inhibits MCNV by binding to vascular endothelial growth factor (VEGF), the protein implicated in the formation of atypical blood vessels. MCNV is the fifth FDA-approved indication for Lucentis since its launch in 2006 (Lucentis is also used in other retina conditions such as diabetes, wet macular degeneration, and retinal vein occlusions).

Dr. Nathan Steinle was asked to present the pivotal RADIANCE trial results that led to FDA approval of Lucentis for MCVM at several national meetings in February 2017, including retina meetings in Fort Lauderdale, Florida, Lake Tahoe, California, and Lexington, Kentucky. He also recently presented findings from RADIANCE in Baltimore at the ARVO international meeting in early May.

The findings of the RADIANCE study formed the basis of the Lucentis approval. This Phase III year-long study enrolled MCNV patients from 76 centers worldwide. The study demonstrated that treatment with Lucentis provided superior visual acuity gains in people with MCNV compared to verteporfin photodynamic therapy (vPDT). At three months, average visual acuity gains for patients treated with Lucentis were more than 12 letters, compared to 1.4 letters for those treated with vPDT.

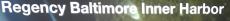
Dr. Steinle notes, "This landmark RADIANCE trial will guide our treatment of CNVM for decades, so it was truly an honor to be asked to present these trial results at several national retina meetings this year, and the honor speaks highly of our cutting-edge research department we have at the California Retina Research Foundation."



Dr. Dante Pieramici (right) poses with Dr. Andrew Moshfeghi, Director Clinical Trials Unit and Associate Professor of Ophthalmology at USC Roski Eye Center after his grand rounds presentation at the medical school.

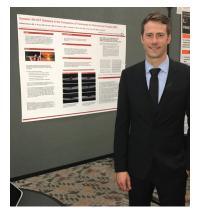


Vit-Buckle Meeting in Las Vegas where both Drs. Avery and Dhoot were invited guest speakers.





Doctors John Pitcher, Sunil Srivastava, Caroline Baumal, Nathan Steinle, Dante Pieramici, and Peter Kaiser after Drs. Pieramici and Steinle hosted "Retina Believe it or Not" case conference at the ARVO annual meeting in Baltimore.



Dr. Nathan Steinle presents dynamic OCT study results in patients with vitreomacular traction at the annual 2017 ARVO international meeting in Baltimore. He has developed a new assessment technique he coined the "California Quake."

# **EYE SIGHTINGS**



Dr. Robert Avery participating in a panel discussion at the Vit-Buckle Society Meeting in Las Vegas.

**DR. ROBERT AVERY** presented original research on the safety of anti-VEGF agents at the Retinal World Congress in Fort Lauderdale, FL; he attended the Hawaiian Eye Meeting in Kauai, the Aspen Retinal Detachment Society, and the Vitrectomy Buckle Society in Las Vegas where he contributed on expert panels. He presented a review of prior and ongoing collaborative research that

CRC has done with UCSB and Cottage Hospital at the 2017 Cottage Hospital Collaborative Research Symposium; he was selected to be on an expert panel discussing treatment of diabetic retinopathy at the All-Star Retina Festival at the Johns Hopkins Hospital's Wilmer Eye Institute. He also presented original research and was selected to be on an expert panel discussing current treatment of diabetes, macular degeneration and vein occlusion at the largest research meeting of the year, the Association for Research in Vision and Ophthalmology (ARVO), in Baltimore.

**DR. DILSHER DHOOT** attended the Vit-Buckle Society in Las Vegas and the Hawaiian Eye Meeting in Kauai, Hawaii. He was an invited guest speaker at regional meetings in Salem, OR and Huntington Beach, CA.

**DR. GABRIEL GORDON** presented research conducted at the California Retina Research Foundation at ARVO in Baltimore.

**DR. DANTE PIERAMICI** presented new CRC research for the 2017 Cottage Hospital Collaborative Research Symposium in January; facilitated an advisory board of thought leaders for Genentech in San Francisco in March; was visiting professor at USC department of ophthalmology in April where he presented Grand Rounds on Management of Neovascular AMD: A Hindsight View to the Future and also lectured to USC residents on the Management of Severe Ocular Injuries. Dr. Pieramici also presented and participated as faculty for the Cleveland Clinic Cole Eye Hospital Retina Summit in Baltimore, Maryland in May and was a presenter and faculty representative for All-Star Retina Festival at the Johns Hopkins Hospital Wilmer Eye Institute. Lastly, Dr. Pieramici helped organize Retina Believe it or Not Case Presentations in Retinal Diseases at the ARVO meeting in Baltimore.

**DR. NATHAN STEINLE** has presented at several national and international meetings in 2017 including the Retina World Congress in Florida, the ARVO annual meeting in Baltimore, and the Squaw Valley Retina Symposium at Lake Tahoe. He also gave educational lectures at the University of Kentucky, as well as in Evansville, Indiana, Memphis, Tennessee, and Rapid City, South Dakota. He also was invited to provide insight at national retina advisory board meetings in Kauai, Hawaii, Las Vegas, Nevada, Huntington Beach, California, and New York City, New York.

#### California Retina Research Foundation

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#### For more information, visit us online at www.californiaretina.com and www.californiaretinaresearch.org.

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# SAFEGUARD AGAINST FALSE, UNREGULATED STEM CELL TRIALS

On March 15, 2017 *The New York Times* published an article bringing attention to the dangers of unlicensed, or "quack" stem cell procedures in the eye as described in a *New England Journal of Medicine* publication. The publication focused on three Florida women who attended a clinic called Bioheart (the company has since changed their name to US Stem Cell) where they had fat cells sucked out via liposuction; these cells were then "purified" to select for only the stem cells present, and injected in the eyes of the same patients in an attempt to ameliorate their age-related macular degeneration. Unfortunately, all cases ended in complete blindness in both eyes for the patients. As the cells came from the patients themselves, what is called an autograft (as opposed to an allograft which is cells from another person), the procedure was NOT regulated by the FDA.

While we understand that patients with failing vision want to try anything to help their condition, grasping at "snake oil" therapies may often do more harm than good. There were many warning signs that should have set off red flags such as the fact that the clinic was charging thousands of dollars for an experimental trial, and they had no follow-up or post-operation exams to determine the safety and/or benefit of the procedure. Also, as it turns out, none of the people providing the procedures were licensed medical doctors, despite their claims to be licensed.

There are several important lessons that patients should take away from this experience:

1. It is important to know the difference between a regulated clinical trial and a fake trial.

2. There are regulated trials underway where doctors do inject stem cells into a patient's eye; do not be tricked into thinking all trials are scams. California Retina Consultants is currently participating in such a trial in collaboration with USC and UCSB, and is hoping to bring on a second stem cell trial later this year in collaboration with Janssen Pharmaceutical.

3. Real clinical trials will never ask for payment for the treatment. If a "clinic" offers stem cell procedures for your eye, make sure they are not asking for money — that is a big red flag!

4. Be wary of getting an experimental procedure done in both eyes at the same time. There is no rush so consider taking it one eye at a time.

5. Just because a trial is registered with clinicaltrials.gov, does NOT mean it's endorsed by the NIH or FDA. If you are unsure, ask a trusted doctor.

This is an extremely troubling trend in the medical community and it's difficult to keep tabs on unregulated "clinics". CRC is a well-established practice and our physicians, or the director of research is happy to discuss this article with you. Please feel free to call or email Gabriel Gordon, at 805-963-1648 with any questions or concerns or speak with your physician at your next appointment. A link to the *New York Times* article can be found at: https://mobile.nytimes.com/2017/03/15/health/eyes-stem-cells-injections. html?\_r=1&referer=.

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### **NEW NORTHERN REGION OFFICES**



We are pleased to announce that California Retina Consultants has opened two new offices to serve our patients in the northern region. Our San Luis Obispo office is located at 835 Aerovista Place, Suite 110 and our Paso Robles office is conveniently located off the 101 in Gateway Center. Both of these offices offer devoted staff, three large exam rooms, three patient screening rooms, two diagnostic imaging rooms and dedicated research suites. In addition, the new offices maintain CRC's cutting edge diagnostic testing and treatment principles. Research studies are underway to better serve our North County patients offering them office options closer to home.

In addition to the new and improved offices in the northern region, CRC has also moved to a new facility in Oxnard to

serve California's South/Central coast area. This office is located at 2901 North Ventura Road, Suite 250 Oxnard, CA 93036 and has a newly dedicated area specifically for studies and CRC hopes to expand our recruitment capabilities in that area especially in the treatment of diabetic eye disease and age-related macular degeneration. Please continue to contact the study department in Santa Barbara at 805-963-1648 regarding any interest in participating in studies out of the new Oxnard location!





Pictures of the new CRC offices in Oxnard (top left), San Luis Obispo (top), and Paso Robles (bottom)