

Inside Retina

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News from the California Retina Research Foundation



DR. STEPHEN COUVILLON JOINS CALIFORNIA RETINA CONSULTANTS

Dr. Stephen Couvillon joined California Retina Consultants in September 2007 and has been seeing patients in our central coast & Lancaster offices. Dr. Couvillon received his medical degree from Tulane University and completed residency training and vitreoretinal fellowship at the prestigious Bascom Palmer Eye Institute, where he also served as Chief Resident and Co-Director of Ocular Trauma.

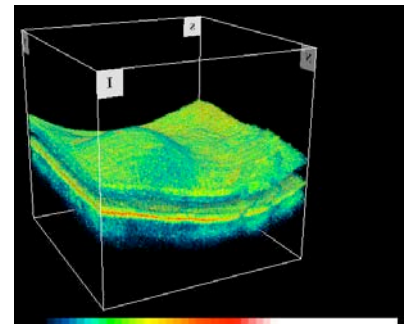
Dr. Couvillon is an active member of the Association for Research in Vision and Ophthalmology and the American Academy of Ophthalmology. He has been an investigator in numerous trials for the treatment of macular degeneration and diabetic retinopathy and results of his research have been published in numerous medical journals.

Dr. Couvillon enhances our practice with his expertise in macular degeneration, diabetic retinopathy, ocular trauma and vacular diseases of the retina. His father, Dr. Glynne C. Couvillon was one of the first practicing vitreoretinal specialist on California's central coast. His son now follows in his footsteps. Dr. Stephen Couvillon resides in Montecito with his wife and two sons.

NEW HIGH RESOLUTION OCT IN SANTA MARIA OFFICE

New OCT (Optical Coherent Tomography) technology, known as Fourier domain OCT or Spectral domain OCT is now available in our Santa Maria office. The new technology captures extensive data more efficiently and at a higher resolution than the traditional time-domain OCT. Traditional OCT provides the physician with a cross sectional view of the retina. Usually several slices of an area are scanned, viewed and measured to give the physician valuable information about the retinal thickness as it correlates to different retinal findings, particularly retina swelling due to wet AMD and diabetic retinopathy. The new technology is fifty times faster in acquiring scans, giving the patient less time for their eye to wander and lose fixation, which was a difficulty with the time-domain OCT.

The greater speed means less movement and artifact in the images.



The increase in the amount of data collected enables improved, three-dimensional views that help doctors and researchers evaluate treatment options. The new technology also allows the physician to more accurately pinpoint the exact location of the retina problem and monitor its progression from visit to visit.

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AVASTIN AND LUCENTIS CRC ON THE FRONT LINES OF CONTROVERSY

California Retina Consultants remain in the center of cutting edge developments in the treatment of age related macular degeneration (AMD). During the spring of 2005 there were not any effective approved drugs to improve vision for neovascular AMD on the market. Early studies with Genentech's Lucentis looked promising, but out of reach to patients not in the initial clinical trials. Landmark work at the Bascom Palmer Eye Institute introduced the retina community to the possibility of an alternative in July, 2005. Retina specialists injected Genentech's Avastin for the treatment of neovascular AMD with remarkable results. California Retina Consultants were the first ophthalmologists in the nation to follow suit. They realized that both drugs worked by blocking Vascular Endothelial Growth Factor (VEGF), an important factor both in anti-cancer treatments and neovascular AMD.

The Wall Street Journal estimates that restricting Avastin access could cost Medicare (and taxpayers) 1 to 3 billion dollars each year.

As excitement over this new vision saving treatment was still sweeping the world, California Retina Consultants continued to move ahead. We were the first practice to publish a comprehensive series of articles demonstrating the efficacy of Avastin in patients with AMD, diabetic retinopathy and retinal vein occlusions. We continue to enroll patients in on-going clinical trials of anit-VEGF and other new treatments.

Unfortunately, access to this exciting treatment has recently become an issue. Genentech, the manufacturer of both Avastin and Lucentis, plans to limit the supply of Avastin to ophthalmologists beginning January 1, 2008. Like many ocular treatments, the use of Avastin for AMD, diabetic retinopathy and vein occlusions has not been approved by the FDA. Treatments other than for colon and lung cancer remain off-label for Avastin. Intraocular Avastin is packaged for off-label use in state approved compounding pharmacies. Under sterile conditions, small amounts of medicine are removed from glass vials of Avastin at a fraction of the cost of a similar dose of Lucentis. The cost of the Avastin drug, preparation and storage is roughly \$50 to \$100 per dose. The monthly dose of Lucentis is \$2200. The Wall Street Journal estimates that restricting Avastin access could cost Medicare (and taxpayers) 1 to 3 billion dollars each year. Genentech claims that despite the proven, widespread use of intraocular Avastin, it must stop providing Avastin to compounding pharmacies because of something the FDA told them during a site visit to their manufacturing plant. The FDA has publicly stated that they have not told Genentech to stop providing Avastin to compounding pharmacies, but the records of the FDA site visit in question have not been made public.

In order to avert a shortage of Avastin, the American Society of Retina Specialists has formed an Avastin Access Work Group, and has appointed Dr. Robert Avery as one of its eight members. This group had face to face meetings with Genentech to try and change their decision, but this effort was unsuccessful. The task force has met with government agencies and representatives of the compounding pharmacy associations, and is exploring different legal ways of maintaining access to Avastin after Jan.

1, 2008. On the legislative front, they have been in communication with Senator Herb Kohl, Chairman of the US Senate Special Committee on Aging. He has decided to investigate the decision of Genentech to limit ophthalmologist's access to Avastin.

In his letter to the commissioner of the FDA, he notes:

Through review of public documents and interviews with FDA staff, my staff has determined the FDA has not indicated to Genentech, in any way,

shape or form, that it must limit its supply of Avastin to compounding pharmacists.

However, officials from Genentech continue to state that the FDA is opposed to Genentech supplying Avastin to compounding pharmacists (please see, "Genentech President Defends Company's Decision to Embargo Avastin Sales to Compounding Pharmacies";

http://www.aao.org/advocacy/genentech_recap.efm).

His committee has subpoenaed all of the FDA and Genentech's records in relation to the site visit and the decision to restrict access to Avastin. Details of his committee's investigation can be found its website: http://www.aging.senate.gov/hearing_detail.cfm?id=288003&

We hope to be able to find a way to provide Avastin after the January embargo, especially for those patients with diseases other than AMD, such as vein occlusion or diabetic retinopathy, where Lucentis is off-label and prohibitively expensive if not covered by insurance.

In an effort to further our understanding of Avastin and Lucentis, California Retina, along with 45 universities and research groups, has been selected to participate in a National Eye Institute funded study. This trial will compare the efficacy of these two drugs head to head and examine the optimal dosing strategy. The results will give us better understanding in their use for the treatment of neovascular AMD. Should the as-needed dosing schedule of Avastin be as effective as the every-month dosing of Lucentis, the savings to Medicare could amount to over \$2 billion annually.

IN THE NEWS

Dr. Robert Avery Named Associate Chief Medical Editor Of *RETINA TODAY*



Robert Avery, MD has been named Associate Chief Medical Editor of Retina Today, where he currently serves as an editorial board member.

Dr. Robert Avery received the American Society of Retina Specialist's Honor Award for his significant contributions to the Society's annual meetings.

Dr. Avery has also been named to "Best Doctors in America" and to "Who's Who in America."

Dr. Ma'an Nasir Lectures At The American Indian Health Services Clinic



Dr. Nasir recently lectured at the American Indian Health Services Clinic, presenting information on ocular trauma and diabetic eye disease, as well as informing AIHS physicians and staff about the California Retina Research Foundation and current clinical trials.

Dr. Dante Pieramici Named To Medical Society Board Of Directors



Dr. Pieramici was recently nominated to the Santa Barbara Medical Society Board of Directors.

At the American Society of Retinal Specialists (ASRS) Annual Meeting, Dr. Pieramici presented original research on new treatments for retinal vein occlusions.

Dr. Stephen Couvillion Guest Lectures At SEE International

Dr. Couvillion discussed retinal complications at a special course attended by SEE (Surgical Eye Expedition) International volunteer eye surgeons from across the country, Romania and India.



GIVE THE GIFT OF SIGHT THIS HOLIDAY SEASON

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 research, both laboratory and clinical, that demonstrates the potential for establishing new treatments intended for our patients with blinding retinal diseases. To date, research supported by the foundation has helped to establish effective, safe new treatments for Age-Related Macular Degeneration which has likely saved the eyesight of hundreds of thousands of individuals worldwide.

The CRRF is funded through the generosity of interested individuals and tax deductible donations may be submitted to California Retina Research Foundation at 515 E. Micheltorena Street, Suite G, Santa Barbara, CA 93103.

YES, I WANT TO DONATE TO THE CALIFORNIA RETINA RESEARCH FOUNDATION (CRRF)
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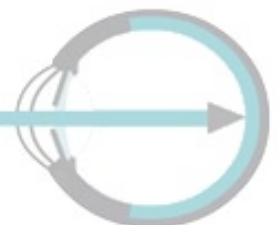
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515 East Micheltorena St. Suite G , Santa Barbara, CA 93103



EYE CARE IN ITALY



By Dr. Alessandro Castellarin



I practiced as an ophthalmologist in Italy from 1990 to 1997, working at the Department of Ophthalmology of the University of Verona and at my private practice at the same time.

The extension of universal health care coverage to the whole population is a key characteristic of the Italian Health Care System. Mandatory health insurance was established in 1943, but this system was replaced in 1978 by the institution of the National Health Service (NHS), Servizio Sanitario Nazionale. The model was similar to the British National Health Service and the universal health coverage is through the Italian State as a single payer.

In the 90's, due to the rising costs of health care, it became necessary to introduce user charges (co-payments) that led to considerable inequalities in the level of services. The co-pay for an eye exam varies between \$20-\$40 in a public hospital or accredited clinic.

Independent health units were established partially within the local authorities. The system became practically privatized, so that if individuals were willing to pay fees they would in turn receive better services. In spite of universal coverage, it appears now that citizens rely more on their own financial resources for health care, especially for pharmaceuticals, dental care, specialist consultations (including eye care), diagnostic examinations, and elective surgery.

The main reasons are

1. Long waiting lists to get non-urgent specialist and diagnostic examinations. Average waiting times vary depending upon the procedure:

Diagnostic tests (x-rays/CT, etc.): 60 days

Specialistic exams: 30-90 days

Oncologic surgery: between 30-180 days

Hip replacement: 90-450 days

Cataract surgery: 200-340 days

Non-emergent coronary angiography: 60-120 days

2. Hospitals are often over-crowded, and in the South of Italy, are often under-equipped. Patients share rooms with three to six beds, although single bedrooms are usually available with an en suite bathroom for a supplement of between €60 and €75 per day.
3. In the public hospitals, you are often required to pay an extra fee if you want to select your own doctor.

This has led to the emergence of private clinics and offices where waiting times are shorter, and most of the patients pay cash, creating a two-tiered health care system: public and private. Most of the doctors employed by the public hospitals also operate their own private practice.

The quality of eye care in Italy varies greatly depending upon the region and the hospital. In Northern Italy, the hospitals are generally more efficient and the standards are comparable to the U.S. Since the institution of the National Health System, the quality of services has declined, and there are very few resources for clinical and basic science research, which is an essential pre-requisite for the development of new drugs and innovative treatments.

There are clearly many differences between healthcare in Italy and the U.S., which is what precipitated my relocation to the States. For me, the most important factor was the opportunity to obtain outstanding clinical training. Last year I was offered a job as chairman of the Department of Ophthalmology at the main hospital of Bologna, in Italy. Despite the prestige of this position, I refused the offer for several of the reasons cited above. In addition, the Italian academic profession is subject to complex bureaucratic structures and many political strains. Last, the resources for research are very limited, and access to cutting-edge clinical trials is restricted. It is a privilege to serve our patients in California and to be part of a practice that is dedicated to funding research and finding cures to combat many blinding retinal diseases.

RECENT PUBLICATIONS BY CRC

Rabena MD, Pieramici DJ, Balles MW.

Traumatic Retinopathy

In: Albert D, Miller J, Azar D, Blodi B (ed): Albert & Jakobiec's Principles and Practice of Ophthalmology 3rd Edition. London: Saunders Publishing; 2007 Dec.

Arevalo JF, Maia M, Flynn H Jr, Saravia M, Avery RL, Wu L, Farah ME, Pieramici DJ, Berrocal MH, Sanchez JG.

Tractional Retinal Detachment following Intravitreal Bevacizumab (Avastin(R)) in patients with Severe Proliferative Diabetic Retinopathy.

Br J Ophthalmol. 2007 Oct 26; [Epub ahead of print]

Avery RL.

New treatments for age-related macular degeneration.

Lancet. 2007 Oct 27;370(9597):1479-80; author reply 1480.

Maia M, Pieramici DJ, Eong KG, Schachat AP, Rodrigues EB, Green WR.

Non-contiguous recurrence or secondary choroidal melanoma following plaque radiotherapy.

Clin Experiment Ophthalmol. 2007 Sep-Oct;35(7):657-60.

Diabetic Retinopathy Clinical Research Network, Scott IU, Edwards AR, Beck RW, Bressler NM, Chan CK, Elman MJ, Friedman SM, Greven CM, Maturi RK, Pieramici DJ, Shami M, Singerman LJ, Stockdale CR.

A phase II randomized clinical trial of intravitreal bevacizumab for diabetic macular edema.

Ophthalmology. 2007 Oct;114(10):1860-7. Epub 2007 Aug 15.

Castellarin AA, Pieramici DJ.

Open globe management.

Compr Ophthalmol Update. 2007 May-Jun;8(3):111-24. Review.

Ranked second among Medscape's top 10 downloaded ophthalmology articles of the year.

Lewis GP, Betts KE, Sethi CS, Charteris DG, Lesnik-Oberstein SY, Avery RL, Fisher SK.

Identification of ganglion cell neurites in human subretinal and epiretinal membranes.

Br J Ophthalmol. 2007 Sep;91(9):1234-8. Epub 2006 Nov 15.

Kuhn F, Pieramici DJ.

Classification of Mechanical Eye Injuries

In: F Kuhn (ed) Ocular Traumatology, New York: Springer; 2008 Ocular Traumatology

Kuhn F, Pieramici DJ.

Myths and Truths in Ocular Traumatology

In: F Kuhn (ed) Ocular Traumatology, New York: Springer; 2008 Ocular Traumatology



ANNUAL CONFERENCE PRESENTS NEW TREATMENT OPTIONS

The California Retina Research Foundation hosted their sixth annual Retinal Research Update Meeting on Saturday, October 13, welcoming 130 eye-care professionals to the Fess Parker's DoubleTree Resort in Santa Barbara.

The purpose of this meeting was to update doctors and other eye-care specialists on the latest treatments and ongoing research in the care of severe vitreoretinal diseases, with particular emphasis on age-related macular degeneration (AMD) and diabetic retinopathy.

They keynote speaker was Dr. Dan Martin, Professor of Ophthalmology and Interim Chairman at Emory University. Dr. Martin reported on the CATT (Comparison of AMD Treatments Trial) surgery.



SANTA MARIA GETS A NEW OFFICE

California Retina Consultants has recently moved to a new location in Santa Maria, located at 1510 East Main Street, suite 103. An open house for physicians and staff was held in November.

To schedule an appointment, call (805) 922-2068.

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515 E. Micheltorena St.
Suite C
Santa Barbara, CA 93103
(805) 963-1648

Santa Maria Office
1510 E. Main St.
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Santa Maria, CA 93454
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Oxnard Office
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Oxnard, CA 93030
(805) 983-8808

Bakersfield Office
5329 Office Center Ct.
Suite 120
Bakersfield, CA 93309
(661) 325-4393

Valencia Office
23861 McBean Pkwy
Suite E28
Valencia, CA 91355
(661) 253-2939

Lancaster Office
1505 West Ave J.
Suite 303
Lancaster, CA 93534
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Robert L. Avery, M.D. Ma'an A. Nasir, M.D. Dante J. Pieramici, M.D. Alessandro A. Castellarin, M.D.
Robert F. See, M.D. Stephen S. Couvillion, M.D.

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