

Why Do Our Physicians Do Research?

By Joseph M. Googe Jr., M.D.

Since I started practice 20 years ago, the field has changed dramatically. We successfully treat retinal and vitreous disorders and diseases now that we couldn't treat then—there's no comparison in the scope of treatments we can now offer. SERA's physicians are proud to be part of the leading edge of these discoveries.

Private practices increasingly serve a critical role in retinal research in the U.S. In recent years the funding for research in academic settings has become more limited, and private physicians have moved to fill the gap, providing important retinal research. Expert physicians, tied into national networks



Joseph M. Googe, Jr., M.D.

of top practitioners, conduct clinical trials of newly engineered drugs and therapies from top of the line pharmaceutical and equipment companies.

Above all else, participation in cutting edge research helps SERA patients. Our deep involvement in national clinical trials allows us to offer our patients options that they might not have anywhere except some major metropolitan medical centers. Because SERA is keyed into major research initiatives, our patients don't have to travel to other centers. We bring big research to their hometowns.

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Gerwin To Join SERA Practice in Summer 2010

Dr. Brett Dennis Gerwin will begin seeing patients in the Chattanooga area SERA offices beginning in July 2010. He is looking forward to working closely with all of our referring doctors.



Brett D. Gerwin, M.D.

He joins SERA after completing an Ocular and Orbital Oncology Fellowship at the Tumori Foundation at California Pacific Medical Center in San Francisco, CA. Previously he completed a Vitreoretinal Surgery Fellowship with Retina Specialists of Alabama, LLC at UAB Medical Center in Birmingham, AL. He did his residency training in ophthalmology at the Callahan Eye Foundation Hospital in Birmingham, AL.

Dr. Gerwin earned his M.D. degree with magna cum laude honors in 2003 from the University of Alabama School of Medicine. He then completed his internship at Carraway Methodist Medical Center in Birmingham. He earned a BS in engineering from Northwestern University in Evanston, IL.

At UAB he was a course lecturer, instructor, teaching assistant, and tutor. He earned numerous awards and honors as a medical student and resident. Dr. Gerwin maintains an impressive schedule of research projects, writing, and professional presentations.

Join us in welcoming this outstanding specialist to the SERA retina and vitreous practice and also to our community of referring physicians and patients. □

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Chattanooga Area: 1-800-365-0105

Knoxville Area: 1-888-566-9738

Tri-Cities Area: 1-888-773-7287

World Wide Web Address: <http://www.tennesseeretina.com>

SERA Takes Part in National Study that Confirms New Treatment for Diabetic Macular Edema

SERA locations in Knoxville and Tri-Cities recently served as clinical sites for a landmark diabetic retinopathy treatment study whose results were just released by the National Eye Institute.

The study found that ranibizumab (Lucentis) eye injections in combination with laser treatment results in better vision than laser treatment alone for diabetes-associated swelling of the retina.

Laser treatment alone has been the standard care for the past 25 years. But the study shows that nearly 50 percent of patients who received the new treatment experienced substantial visual improvement after one year, compared to 28 percent who received the standard laser treatment.

Fifty-two clinical sites within the Diabetic Retinopathy Clinical Research Network (DRCR.net) participated in the study, supported by the National Eye Institute (NEI) and the National Institute of Diabetes and Digestive and Kidney Diseases, part of the National Institutes of Health.

The NEI study included a total of 854 eyes of 691 participants, who were on average in their early 60s, were diagnosed with type 1 or 2 diabetes and macular edema.

Diabetic retinopathy is the most common cause of vision loss in working-age Americans. This condition damages the small blood vessels in the eye's light-sensitive retinal tissue. When these damaged blood vessels begin to leak fluid near the center of the retina, known as the macula, macular edema occurs. The macula provides detailed central vision used for activities such as reading, driving, and distinguishing faces. In macular edema the retinal tissue swells, which can lead to vision loss if left untreated. □

Full study results are published in the journal *Ophthalmology* available at http://www.ophsource.org/webfiles/images/journals/ophtha/press_release.pdf

Clinical Trials Seek Volunteer Patients

SERA Clinical Trials Patients Are Special People

Our patients enjoy being in the clinical trials.

They can get the most current help and don't have to worry about the costs. Study visits, tests and study drugs are covered under the clinical trials program.

Most of the trials offer a travel allowance as well.

They want to do all they can to help find a cure for their conditions. They want to help their children, grandchildren or someone else. If they can make life better for one more individual, then it's worth it to take part in the studies, our patients tell us.

We try to help them feel as special as they are.

— Deanna Long,

Clinical Trials Coordinator, Tri-Cities SERA

To ask about requirements to take part, patients or referring physicians may call any of SERA's Clinical Trials Coordinators listed below.

Knoxville:

Tina Higdon (at Weisgarber Office)
865-588-0811 OR

Charity Morris (at Baptist Office)
865-579-3999

Chattanooga:

Paula Clark 423-756-1002

Tri-Cities:

Deanna Long 423-782-1327

Below are descriptions of clinical trials in progress (enrolling or following) at Southeastern Retina Associates' East Tennessee locations. Get more information at clinicaltrials.gov

ALIMERA SCIENCES (TRI-CITIES)
— In Progress, Enrollment Closed

This is a randomized, double-masked, sham injection controlled, parallel-group multicenter phase III, 3-year study comparing the safety and efficacy of

SERA physicians have been leading clinical trials for more than 15 years! Patient participation in trials is voluntary, and more than 800 SERA patients have taken part in the research trials.

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Physicians Do Research

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Taking part in clinical research trials also keeps SERA physicians sharp, working at the forefront of the latest developments in retinal treatments and surgical procedures. Research is part of being a complete doctor. Following the news in the medical press just isn't enough anymore. By participating in research, we have continuous communication with our colleagues around the country, providing an unmatched immediacy in obtaining and putting to use the latest methods for managing our patients' diseases.

Proximity to clinical trials gives SERA patients the opportunity to take advantage of new drugs as soon as they are available, and their participation in highly monitored studies is a service that both physician and patient can feel good about. Physicians in private practice, including those at Southeastern Retina, have been able to involve their patients in the ongoing search for improved treatments for diabetic retinopathy and age-related macular degeneration, the two most serious threats to vision from retinal damage.

Some of the largest studies with the most profound results for our patients are funded by the National Eye Institute, a part of the National Institutes of Health, which is the branch of the federal government that funds medical research.

Some of these studies are coordinated by the Diabetic Retinopathy Clinical Research Network (DRCR.net). The group facilitates clinical research of diabetic retinopathy, diabetic macular edema and associated conditions. DRCR.net was formed in September 2002 and currently includes more than 199 participat-

ing sites with more than 670 physicians in the U.S.

CATT (Comparison of Age-related Macular Degeneration Treatment Trials) is another major study sponsored by the National Eye Institute. The study compares four treatment plans for wet age-related macular degeneration (AMD), the leading cause of severe vision loss in people over 60 years old. The latest treatments include drug injections directly into the eye. Two drugs, Avastin and Lucentis, have both proven to slow vision loss and sometimes improve vision. However, the current study will determine if Avastin® is more effective, less effective, or the same as Lucentis® for treating wet AMD. These drugs are some of the marvelous discoveries of the last decade.

A promising study, AREDS II which is now underway, is looking at vitamins and other nutritional supplements to see if they can positively influence complications related to age-related macular degeneration.

It has been a great honor to have contributed to the ongoing progress in retinal research over the years, and it is inspiring to imagine the possibilities ahead. Medical care will continue to evolve. Ten or fifteen years from now we'll be doing things we can't imagine today. Just when you think things have stagnated, something else comes out that radically alters treatment. SERA physicians are committed to pursuing tomorrow's breakthroughs in retinal care for our patients.

A list of clinical trials for which SERA has open enrollment is available elsewhere in this issue of FUNDUS. Keep current on SERA research at our newly re-designed website at tennesseeretina.com □

Clinical Trials

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fluocinolone acetonide intravitreal inserts in subjects with diabetic macular edema. Sponsored by Alimera Sciences.

AREDS2 (KNOXVILLE) - In Progress, Enrollment Closed

Age-Related Eye Disease Study 2 (AREDS2) is a multi-center, randomized trial designed to assess the effects of oral supplementation of macular xanthophylls (lutein and zeaxanthin) and/or long-chain omega-3 fatty acids (docosahexaenoic acid, or DHA and eicosapentaenoic acid, or EPA) on the progression to advanced age-related macular degeneration (AMD). The study also will assess whether forms of the AREDS nutritional supplement with reduced zinc and/or no beta-carotene works as well as the origi-

nal supplement in reducing the risk of progression to advanced AMD. More info: areds1.org

CATT (KNOXVILLE) - In Progress, Enrollment Closed

CATT (Comparison of Age-related Macular Degeneration Treatment Trials) is sponsored by the National Eye Institute and compares four treatment plans for wet age-related macular degeneration (AMD). The latest treatments include drug injections directly into the eye. Avastin and Lucentis have both proven to slow vision loss and sometimes improve vision. However, the current study will determine if Avastin® is more effective, less effective, or the same as Lucentis®. Read more at <http://www.med.upenn.edu/cpob/studies/CATT.shtml> OR <http://clinicaltrials.gov/ct2/show/NCT00593450>

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**SOUTHEASTERN
RETINA
ASSOCIATES**

328-A Cummings St.
Abingdon, VA 24210
Phone (276) 623-5254

610 State Farm Rd., Suite A
Boone, NC 28607

3185 West State St., Suite 2010
Bristol, TN 37620

Jarnigan Medical Center
7268 Jarnigan Rd., Suite 300
Chattanooga, TN 37421
Phone (423) 756-1002
FAX (423) 756-1004

979 E. Third St., Suite C-235
Chattanooga, TN 37403
Phone (423) 756-1002
FAX (423) 756-1004

2253 Chambliss Ave., Suite 410
Cleveland, TN 37311

1051 Genesis Road, Suite 103
Crossville, TN 38555

1008 Professional Blvd., Suite 5
Dalton, GA 30720

Johnson City Eye Center
100 Med Tech Parkway, Suite 140
Johnson City, TN 37604
Phone (423) 434-0853
FAX (423) 434-2943

2412 N. John B. Dennis Hwy.
Kingsport, TN 37660
Phone (423) 578-4364
FAX (423) 578-4372

1124 E. Weisgarber Rd., Suite 207
Knoxville, TN 37909
Phone (865) 588-0811
FAX (865) 584-2153

2020 Kay Street
Knoxville, TN 37920
Phone (865) 579-3999
FAX (865) 579-3987

1928 Alcoa Hwy., Suite 320
Knoxville, TN 37920
Phone (865) 522-5453
FAX (865) 305-6696

939 Emerald Ave., Suite 905
Knoxville, TN 37917

140 Capital Dr.
Knoxville, TN 37922
Phone (865) 251-0727
FAX (865) 251-0996

628 Smithview Dr.
Maryville, TN 37803

1447 W. Morris Blvd., Suite C
Morristown, TN 37815

90 Vermont Ave.
Oak Ridge, TN 37830
Phone (865) 482-3127

530 W. Ridge Road
Wytheville, VA 24382

PHYSICIANS:

- John C. Hoskins, M.D.
- Randall L. Funderburk, M.D.
- Joseph M. Googe, Jr., M.D.
- James H. Miller, Jr., M.D.
- Joseph M. Gunn, M.D.
- Tod A. McMillan, M.D.
- Howard L. Cummings, M.D.
- D. Allan Couch, M.D.
- Stephen L. Perkins, M.D.
- Richard I. Breazeale, M.D.
- Nicholas G. Anderson, M.D.
- Brett D. Gerwin, M.D.

SOUTHEASTERN RETINA ASSOCIATES

Cleveland Office Has New Address

SERA's Cleveland office now has a dedicated space close to SkyRidge Medical Center. The new office is easy for new and returning patients to find. It's on the fourth floor of an office building just two doors down, or about a block, from the previous office space SERA rented at the Cleveland Eye Clinic for more than a decade.

The new office was ready for patients in early January 2010 in Suite 410, 2253 Chambliss Ave., Cleveland, TN. Dr. Randall Funderburk, senior partner in Chattanooga, will see patients in this new office. SERA's other satellite clinic locations include Crossville, TN and Dalton, GA.

Renting space at CEC had its advantages and disadvantages, said Dave Woods, a long-time Chattanooga staff member. "We shared space in a thriving practice where three other doctors see numerous patients in their general ophthalmology practice. We worked around their staff setting up SERA's equipment and records on Tuesdays. It was labor intensive for all of us." Woods is a certified surgical technologist, certified retina angiographer, and certified ophthalmic assistant.

David Freischlag, another SERA technician who assisted in planning and execution of the new office, says there are plenty of advantages for SERA patients in the new space. Flow is efficient and patients don't have to walk as far to meet with their physician and technicians. There's more seating because only SERA patients are waiting for exams, treatments, and procedures.

Sandra White, SERA office administrator, says the difference in computer operations alone is well worth the challenges of moving and renovation. "We worked directly with the builders to achieve a fully wired office environment and treatment facility. All computers and diagnostic equipment are hardwired to patient charts and test archives. Staff speed and efficiency, supported by updated technology, are much better at the new office," White says.

The office is decorated similarly to the modern suite of offices SERA calls home at Jarnigan Medical Center in Chattanooga, says White. And, she says, elevator access is convenient to the fourth floor with plenty of parking available at the site. □

Clinical Trials

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DRCR (KNOXVILLE, TRI-CITIES)
- Now Enrolling

Diabetic Retinopathy Clinical Research Network (DRCR.net) facilitates multicenter clinical research of diabetic retinopathy, diabetic macular edema and associated conditions. DRCR studies examine the use of laser treatment and injections. Several protocols are available.

The studies are funded by the National Eye Institute, a part of the federal government National Institutes of Health. More info: DRCR.net

FENRETINIDE (KNOXVILLE)
- Concluded, Enrollment Closed

The fenretinide study is a phase II, multicenter, randomized, double-masked, placebo-controlled, dose-comparison of the safety and efficacy of fenretinide in the treatment of geo-

graphic atrophy in subjects with the dry form of age-related macular degeneration (AMD). Sponsored by SIRION Therapeutics.

HORIZON 2 (KNOXVILLE)
- Will Conclude in August 2010, Enrollment Closed

Horizon 2 is an open-label, multicenter, extension study of intravitreally administered ranibizumab in subjects with macular edema secondary to RVO who have completed the 6-month treatment and 6-month observation phases (12 months total) of a Genentech sponsored study (BRAVO or CRUISE). The HORIZON 2 study will evaluate the safety and tolerability of ranibizumab.

POSURDEX (KNOXVILLE)
- In Progress, Enrollment Closed

The Posurdex study, sponsored by Allergan, Inc., will evaluate the safety and efficacy of the intravitreal dexamethasone implant in the study eye of vitrectomized subjects with diabetic macular edema. □