

Director: Zoher Ghogawala, MD

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Zoher Ghogawala, MD
Director
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A Message from Our Director

In this issue of the WCTC newsletter, I would like to explain where we've been and where we're going.

Our History

Our first research efforts began in 2002 with the SLIP Study, an ongoing study to compare fusion vs. no fusion following spinal decompression. This initial work was made possible by generous funds from **Lucinda B. Watson**.

Soon thereafter, donations from **Lawrence and Stephanie Flinn, James and Elizabeth Li**, and from the estate of **Olive C. Watson** allowed Greenwich Hospital to take the lead in establishing the SLIP study as a national, multi-center clinical trial.

Now, five years later, the SLIP Study is nearly complete, having enrolled 92 patients. We expect to publish the results within two years, following independent data analysis by **Fred G. Barker, II, MD** from the Massachusetts General Hospital.

Last year, **David and Jean Wallace**, after discussions with Greenwich Hospital CEO **Frank Corvino**, kindly donated

\$500,000 to expand our efforts in new directions, allowing us to establish a comprehensive clinical trials program at the hospital.

Today, at the Wallace Clinical Trials Center, we are running three national trials of our own and are participating with industry (Integra LifeSciences) in a fourth. **Elynn Wasserberger** has served as our clinical coordinator since the beginning of our first study in 2002.

Our Goals

Our mission is simple: Ask the important questions relevant to a patient's quality of life after surgery, design the appropriate studies to answer these questions, and maintain excellence in executing on those studies.

The Greenwich community has responded warmly and generously to our mission. To date, we have raised one million dollars in donations and grants. Clearly, the public understands that clinical research has the potential to enhance the health and well-being of individual patients and society as a whole.

Our Vision

In his bestseller, *The World Is Flat*, Thomas Friedman describes how the information age has empowered countries around the world by "flattening" the playing field both economically and politically.

In a similar way, rapid access to medical information via the internet has empowered patients to manage their health more intelligently and proactively.

At the WCTC, we are using the internet in creative ways to further our clinical and research goals. We have created a **Spinal Experts Network**—a group of experienced spine surgeons across the country—that provides our study patients with multiple "second opinions" regarding surgery.

Let me describe how we use the **Spinal Experts Network**. For patients who are considering entering the SLIP Study, we download their pertinent spine-related history and images (anonymously, using a number rather than a name). [cont. page 3]

A Welcome to Our Summer Interns!

- **Alex Mojcher** is studying neuroscience at the University of Massachusetts. He will be a sophomore in the Fall. At the WCTC, he is focusing on creating patient education videos that describe our current clinical trials, including our patients' experiences in the trials. He will be assisting us with various other research-related activities as well. Outside of the office, he enjoys playing guitars and working with computers.

- **Kate Reid** is entering her senior year at Duke University and is a psychology major with a concentration in neuroscience. Her minor is in biology and chemistry. Kate has been busy writing an abstract regarding carotid plaque length and how this affects cerebral blood flow. She has also helped us organize and catalog our carotid research reference papers. In her spare time she enjoys tennis and philanthropy work.

- **Rachel Potter** joins us from Colgate University where she is entering her junior year. She is a psychology major with a minor in art history. She is assisting us in evaluating the cost effectiveness of surgery for cervical spondylotic myelopathy. She is also helping us to graph data on SLIP Study patients. In her free time she enjoys downhill skiing and working with children.



We are pleased to have three interns working with us this summer. **From left to right: Alex Mojcher, Kate Reid, and Rachel Potter**

Ongoing Clinical Trials at WCTC



The Wallace Clinical Trials Center is currently accruing patients for four national, multi-center clinical trials.

- **SLIP Study:** a prospective, randomized, multi-center clinical trial that tests the benefit of adding fusion to laminectomy for symptomatic spinal stenosis with grade 1 spondylolisthesis (SLIP).

- **Cognitive Outcome after Carotid Surgery Study:** a prospective, non-randomized study involving four centers comparing cognitive outcomes of traditional carotid endarterectomy and the newer, less invasive, carotid artery stenting.

- **CSM Study:** a prospective, non-randomized, multi-center trial designed to determine the optimal surgical approach (front vs. back) for patients with multi-level cervical spondylotic myelopathy (CSM).

- **DuragenPlus® Study:** Sponsored by Integra LifeSciences Corp. A multi-center, controlled, randomized trial with blinded evaluation, designed to evaluate the safety and efficacy of DuragenPlus® Adhesion Barrier Matrix, a substance that may prevent scar tissue formation around nerves after spine surgery.

Patient Enrollment:

SLIP: 92

CAROTID: 37

CSM: 12

DURAGEN: 7

Interview with SLIP Study Participant

Ms. Sandra Borowik entered the SLIP Study in 2006. Of the seven surgeons in the Spinal Experts Network who evaluated her scans, six felt that either the "fusion" or the "no fusion" strategy was acceptable. She was randomly assigned to "no fusion."

In March of 2006, then, Ms. Borowik underwent a laminectomy alone (decompression) for spinal stenosis associated with spondylolisthesis (a "slip").

Q: How did your life change as a result of the surgery?

A: Surgery gave me my life back. Before surgery, I had difficulty walking due to pain and spasms in my legs. Now, I'm grateful to be able to enjoy walks with my husband. I'm also able to enjoy spending time with my grandchild!

Q: What made you decide to go the surgical route?



A: I had tried physical therapy for three or four months. In retrospect, I think I tried it for too long—if it was going to help it should have helped sooner. I also had three epidural steroid injections. I was still in pain.

Q: Any other thoughts?

A: Yes, it's great to feel normal again! Also, I would advise other patients to take more control of their own health care. If a treatment is not working, then it's best to seek other options.

A Message from Our Director (cont.)

For each patient, we receive seven to nine opinions via the **Spinal Experts Network**. Each surgeon comments on their preferred approach (fusion vs. no fusion) and whether or not there is enough uncertainty regarding best approach that it would be appropriate to "randomize" that patient.

Patients who are randomized are randomly assigned to either the "fusion" or "no fusion" strategy via computer. In other words, the final surgical decision is not made by the patient or the

surgeon. This randomization allows for the most equitable, unbiased comparison of both strategies.

Before and at various intervals after surgery, patients complete questionnaires about their symptoms and level of functioning, allowing WCTC researchers to compare outcomes in a scientific manner.

In addition, all study patients have scans performed after surgery that are independently reviewed by Greenwich

Hospital neuroradiologists, **Richard Velaj, MD** and **Scott Sullivan, MD**.

It is our sincere hope that through our studies at the WCTC, we will learn which operations works best and under what circumstances, ultimately leading to improved outcomes for patients with spinal and other neurological disorders.

We thank so many members of our community for supporting us. We look forward to providing you with updates on our progress.

"It is our sincere hope that through our studies here at the Wallace Clinical Trials Center, we will learn which operations work best and under what circumstances."

- Zoher Ghogawala, MD
Director, WCTC

Donations may be sent to:

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Charitable Donations

Our success here at the Wallace Clinical Trials Center is made possible only through the generous donations of individuals as well as private foundations. Please consider making a **fully tax-deductible** donation to:

Wallace Clinical Trials Center Fund

-or-

Greenwich Lumbar Stenosis SLIP Study Fund

Our Staff

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Katrina S. Firlík, MD
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Nazish Omar
 Grant Writing Specialist

The WCTC would like to congratulate Nazish Omar on being hired as a Grant Writing Specialist. Ms. Omar brings a wealth of experience to our office having completed a Master's degree in Public Administration at NYU, specializing in Health and Finance Management, as well as having completed degrees at Cambridge University and the University of Karachi. She has held various positions in corporate finance and most recently served as a consultant for a university-based health management project.

