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Fast Facts

- A blockage of a blood vessel is the most common cause of more than 750,000 new or recurrent strokes in the U.S. each year
- 50% of strokes are from carotid stenosis, a treatable disease
- 80% of all strokes are preventable
- Twice as many women die from stroke than from breast cancer every year

Sources:
www.strokeassociation.org
www.ninds.nih.gov/stroke

Wallace Clinical Trials Center: An Introduction

The Wallace Clinical Trials Center is pleased to issue its inaugural newsletter. This quarterly newsletter is designed to keep our referring physicians, investigators, patients, and donors informed of the progress being made in our research efforts here at the WCTC. In our first issue, we spotlight our carotid study.

In October of this year, Dr. Ghogawala presented

our work on cognitive outcomes after carotid endarterectomy at the International Symposium for Flow Management in Cerebrovascular Surgery. The manuscript entitled *Cognitive Outcomes after Carotid Revascularization: the Role of Cerebral Emboli and Hypoperfusion* is being prepared for publication.

Other News

- Dr. Ghogawala was named to the Executive Council for the AANS/CNS Joint Section of the Spine as Chair of Clinical Trials.
- Dr. Ghogawala's manuscript, entitled *Clinical Eligibility for Cervical Spondylotic Myelopathy Trial*, will be published in the February, 2007 issue of **Spine**.

Carotid Disease: The Basics

Stroke is the third leading cause of death in the US, and the number one cause of disability. It has been estimated that eighty percent of strokes are preventable. The best way to prevent stroke is by leading a healthy lifestyle and managing the four primary risk factors—smoking, hypertension, high cholesterol, and diabetes. However, when imaging reveals a significant buildup of plaque in the carotid arteries (narrowing the vessel by sixty percent or more), these measures are not sufficient.

The surgery traditionally performed, carotid endarterectomy (CEA), involves opening the artery to remove the plaque. More recently, a minimally invasive alternative, carotid stenting, has been introduced. Despite the initial enthusiasm for stenting, adoption of the

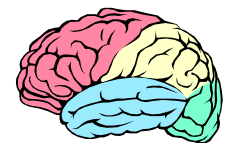
technique has been tempered by mixed results. In fact, a study published in the *New England Journal of Medicine* in October of 2006, comparing carotid endarterectomy to carotid stenting, was stopped prematurely because the rates of death and stroke were significantly higher in patients who had undergone stenting.

What is becoming increasingly clear in the debate between carotid endarterectomy and stenting is that stroke and death are not the only important variables to be studied. Cognitive outcomes—in the form of attention, language, and memory skills—may potentially differ between these two alternatives, and can affect quality of life.

With both endarterectomy and stenting, there is the potential to either

compromise or improve thinking and memory. Ischemia sustained during either procedure, via embolic events or temporary cessation of blood flow, can compromise cognition whereas enhanced blood flow following the procedure can actually improve cognition in certain patients.

In assessing which option is best for different patients, cognitive outcomes cannot be ignored. The work being done at The Wallace Clinical Trials Center is a step in that direction.



Research Update

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

SLIP Study The SLIP study is an ongoing prospective, randomized multi-center clinical trial that tests the benefit of adding fusion to laminectomy for symptomatic lumbar spinal stenosis with Grade I spondyloisthesis (SLIP). A total of 29 non-randomized and 50 randomized patients aged 50-80 have been accrued with a total study goal of 64 randomized patients by the end of 2007.

Cognitive Outcome after Carotid Surgery Study This is an ongoing prospective, non-randomized study involving four centers comparing cognitive outcomes of traditional carotid endarterectomy and the newer, less invasive, carotid artery stenting. There are currently 30 patients accrued with a total study goal of 100-150 patients.

CSM Study The CSM study is a prospective, non-randomized multi-center trial designed to determine the optimal surgical approach (front versus back) for patients with multi-level cervical

spondylotic myelopathy (CSM). Patients between the ages of 40 -85 years are accepted. Currently, there are 5 patients enrolled with a total study goal of 100-200.

DuragenPlus® Study A study sponsored by Integra LifeSciences Corp. This is a multi-center, controlled randomized trial with blinded evaluation, aimed at evaluating the safety and efficacy of DuragenPlus® Adhesion Barrier Matrix, designed to prevent scarring around nerves after spine surgery. The study goal is 500 patients over the course of one year.



MRA Image of Carotid Stenosis

Clinical Trials At A Glance

Year	SLIP		Carotid	CSM	Duragen Plus®
	Rand	Non-rand			
2002	2	4			
2003	9	9			
2004	16	2			
2005	12	10	13		
2006	11	4	17	5	
Patient Total	50	29	30	5	1
Study Goal	64	----	100-150	100-200	500

Goals for 2007

- Obtain external funding from the **Robert Wood Johnson Foundation** and the **National Institutes of Health** in order to conduct more clinical trials for neurosurgical diseases.
- Continue patient enrollment in all four ongoing clinical trials.

Conversation with Mr. Allan Mascaro

Mr. Mascaro, a retired plumbing and heating contractor, first consulted with Greenwich Neurosurgery in June of 2005 for his carotid disease. At that time, his right carotid artery was blocked by approximately 90%. Luckily, he never had any symptoms of a stroke, so his diagnosis was of asymptomatic carotid stenosis.

Based on previous clinical trials showing the benefits of surgery for blockages of 60% or more, a carotid endarterectomy was recommended. Mr. Mascaro underwent surgery that same month and agreed to take part in the Cognitive Outcome after Carotid Surgery Study.

Q: How was your experience with the surgery?

A: Enjoyable, really. It was a very positive experience. Everyone showed so much concern.

Q: What made you decide to be a part of the carotid research project?

A: Why not! I felt it would be best to find out exactly what the new blood flow was doing to my brain.

Q: How has your experience been with the research project?

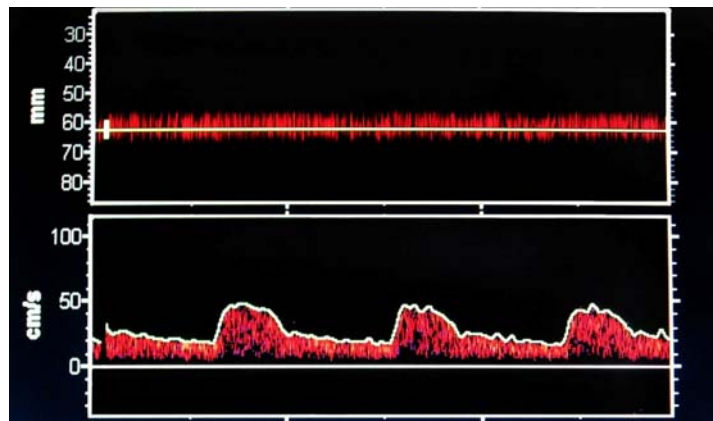
A: Fantastic, overall. Going into New York for the MRA scan was a bit of a hassle, but I understood the importance of it, so I didn't mind. Lauren (carotid project coordinator) has been great.

Q: How have you felt since surgery?

A: I haven't noticed any differences in my thinking, but I've felt so much peppier since I had it done!

Mr. Mascaro's follow-up studies have showed no evidence of any recurrent stenosis and an increase in his total cerebral blood flow. He will continue to be followed and will also continue to take a daily aspirin. He has maintained a very active lifestyle in his retirement, including part-time work at Home Depot.

We are indebted to patients like Mr. Mascaro, who allow us to answer the important questions that will help us manage future patients with carotid disease.



Transcranial Doppler (TCD) Imaging of Carotid Artery Flow During Surgery

Donations may be sent to:

c/o Marita O'Hare
Director of Development
Greenwich Hospital
89 Lake Avenue
Greenwich, CT 06830

Phone
(203) 863-3861

Charitable Donations

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

Wallace Clinical Trials Center Fund
-Or-
Greenwich Lumbar Stenosis SLIP Study Fund

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