Wallace Clinical Trials Newsletter

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In This Issue…

Controversies in Lumbar Spine Surgery

As degenerative spine disease becomes even more prevalent in our aging population, the questions raised by spine surgery become more pressing.

Which patients are appropriate candidates for surgery? Which conservative options should be tried first, and for how long? What type of spine surgery should be done? Is a decompression enough, or is a fusion required?

Patients who seek multiple opinions about their spinal condition are often surprised by the diversity of opinions they encounter.

This diversity of opinion is due, in part, to the lack of careful clinical trials in spine surgery. The bottom line is, doctors often have to rely on personal experience and opinion alone, rather than the results of good research.

The Wallace Clinical Trials Center was created with the realization that careful clinical trials will be critical to our ability to treat patients more effectively in the future.

Our first project, the SLIP Study, was designed to answer the following question: in patients with stenosis (narrowing of the spinal canal) *and* spondylolisthesis (slippage of one bone in relation to another), is decompression sufficient, or is a fusion required, in addition? Stay tuned for the answer!

Spine Surgery: Interesting Facts

• Spine surgery is performed by both neurosurgeons and orthopedic surgeons. Whereas all neurosurgeons are trained in spine surgery during residency, orthopedic surgeons who wish to perform spine surgery undergo an additional fellowship.

• In 2001, over 122,000 lumbar fusions were performed in the US for degenerative (age-related) conditions. This represents an increase of 220% compared to 1990. (Source: Deyo RA, *et al. Spine*, June 15, 2005)

• The most common operations done by neurosurgeons are (in descending order): lumbar discectomy, lumbar laminectomy, and anterior cervical discectomy and fusion (ACDF).

• Know your spine terminology, especially these three look-alikes:

spondylosis: a non-specific term referring to degenerative (age-related, arthritic) changes of the spine

spondylolisthesis: (sometimes colloquially referred to as a "slip"); a degenerative condition in which one vertebral body has slipped forward in relation to another

spondylolysis: often a congenital condition, a defect in a portion of the spine known as the pars; may lead to a "slip"

What's New at The Wallace Clinical Trials Center

We received very positive feedback regarding our inaugural newsletter in January. This quarterly newsletter is designed to keep our referring physicians, investigators, patients, and donors updated on our research efforts. Here is the latest news:

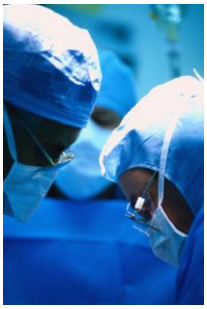
• The WCTC recently submitted applications for two grants for ongoing research in carotid disease and cervical spondylotic myelopathy.

• The WCTC welcomes our new research intern, Nazish Omar. Her background in business and economics will be invaluable to our center as we begin to explore cost analyses related to spine disease. Welcome, Nazish!

• This summer, Rachel Potter (Colgate University) and Kate Reid (Duke University) will be joining us for six-week internships. Both of these young women are majoring in psychology and have an interest in neuroscience. We look forward to working with them!

• Dr. Ghogawala's manuscript, *Clinical Eligibility for Cervical Spondylotic Myelopathy Trial* was published in the February 15th issue of *Spine*.

• Dr. Ghogawala was named as the Chair of Clinical Trials for the Executive Council of the AANS/CNS Joint Section of the Spine.



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: 84

CAROTID: 35

CSM: 9

DURAGEN: 2

Interview with SLIP Study Participant

Ms. Sandra Landi entered the SLIP Study in 2004. She was randomized to decompression and fusion and underwent surgery in June of 2004 for spinal stenosis associated with spondylolisthesis (a "slip").

Prior to surgery, Ms. Landi was developing progressive difficulty with walking due to back and leg pain. After recoving from surgery, she was able to return to walking up to three miles per day.

Q: How was your experience with the surgery?

A: Amazing. Before surgery, I was in agony for two years. After 12 weeks of recuperation, I had no pain. I had heard scary stories about spine surgery, but that was not my experience.

Q: What made you decide to participate in the study?

A: I work in the medical field and I thought the study was fascinating. Dr. Ghogawala was very straightforward with everything, which really helped.

Q: Did you have any reservations about the randomization process?

A: No, not really.

Q: Any other words of wisdom?

A: I would recommend the surgery to anybody!

Interview with NeuroClinical Research Coordinator

Ms. Ellyn Wasserberger is the NeuroClinical Research Coordinator at the Wallace Clinical Trials Center.

Q: How long have you been involved in this research?

A: I have been involved since April, 2002, when the SLIP Study was just getting started, before the first patient was enrolled.

Q: What is the most rewarding part of your work?

A: The most rewarding part for me is following the progress of the study patients. I speak to them on the phone, and have been following many of them for three or four years. I've gotten to know them. Knowing how much they have improved, and knowing that they are still feeling well so long after surgery, is nice.

Q: Do you feel that patients benefit from being a part of a study?

A: I do think that patients benefit from being in a study. We are pro-active in following up with them at designated intervals, instead of hearing from them if there is a problem. They are being monitored and called every few months in the beginning, and they get to talk about how they are feeling. They get to ask questions and voice their concerns.

Q: What motivates patients to participate in studies?

A: I think that most patients participate in our studies to help the surgeon investigators learn more about what works best for their condition. I think they seriously want to help.

"Most patients participate in our studies to help the surgeon investigators learn more about what works best for their condition. I think they seriously want to help ."

Ellyn Wasserberger

Donations may be sent to:

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Greenwich Lumbar Stenosis SLIP Study Fund

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