

Clinical Trial: Physician-Modified Endovascular Grafts Show Dramatically Improved Outcomes for AAA's



Benjamin Starnes, MD

Physician-Modified Endovascular Graft (PMEG) outcomes are dramatically improving results for patients with inoperable Abdominal Aortic Aneurysms (AAAs). Now in its third year, an important clinical trial studying PMEG implementation headed by PI, **Dr. Benjamin Starnes**, UW Professor and Chief of Vascular Surgery, Department of Surgery, is changing the way many inoperable AAAs may be treated in the future. AAAs have long been one of the most challenging and dangerous of conditions for vascular surgeons to treat. Open aneurysm repair was the main intervention for AAA's from the 1950's until endovascular aneurysm repair (EVAR) became practical in the 1990s. While not a suitable solution for every patient, EVAR holds many improvements over the traditional open method which requires large incisions and the need for the aorta to be clamped off during the repair (which can cause a host of complications). EVAR is less invasive, meaning less time in the hospital and less overall recovery time.

EVAR uses stent grafts to repair the AAA. Stent grafts are marvels of science: fabric-and-metal tubes crimped tightly enough to be threaded through an artery, then expanded and wedged in place to re-establish optimal blood flow. These stents, however, are not optimal for an aneurysm that is not in the "usual place" but is perhaps near the superior mesenteric or renal arteries. These grafts need customization to correct the aneurysm. Modifying stent grafts to handle these abnormally presenting AAAs has been possible for several years, but until recently only the stent manufacturer could provide such modifications and the process could take up to three months. For patients unable to undergo open surgery, the lag time until a customized stent graft could be manufactured often meant a poor outcome for the patient.

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Dr. Starnes faced this issue with many of his own patients and was determined to find other options. Dr. Starnes, who came to the Department of Surgery in 2007 from the US Army, is known for his technical skill, his enthusiasm and ingenuity. And, he doesn't take "no" for an answer. He concluded that by using leading-edge software which reconstructs a patient's anatomy in vivid 3D from CT and MRI scans, he could preoperatively modify the stent graft implant with fenestrations (i.e., windows), to permit continued blood flow from the aorta into the adjoining superior mesenteric and renal arteries. He could also fit those arteries with stents and join them to the main graft for greater anchorage.

Using this new technique, Dr. Starnes performed the procedure dozens of times when patients had no other options, and the vast majority of the patients had remarkably successful outcomes. However, it was determined by the Centers for Medicare & Medicaid Services (CMS) that this was an "off-label" use of a device and needed approval of the Food and Drug Administration (FDA) to be used/modified in such a procedure. CMS declined to reimburse either the hospital or professional services for this procedure until approval could be issued from the FDA.

Noridian (the Medicare third-party carrier for UW), suggested that Dr. Starnes submit an investigational device exemption request to the FDA. An objective, external review of all cases done to date was conducted by a third party. They pronounced the results of the cases done to that point, "phenomenal" and the application to the FDA was prepared.

Dr. Starnes, with the expert help from research nurse, **Ms. Billi Tatum** (pictured right), submitted a proposal that described the protocol, rationale and outcomes evidence. In January 2011, the University won unconditional approval from the FDA to conduct a 150 patient trial of PMEGs for juxtarenal aortic aneurysms. At this point, UW Medicine is the only US provider permitted by the FDA and CMS to offer this uniquely promising procedure. The study is now approximately 25% complete. It is following the patient cohort at regular intervals for five years after completion of the procedure. Results thus far



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Department of Surgery Grant Activity Report

In the fourth quarter of 2012 our department's researchers received 10 awards totaling \$1.8 million, three of which were new and competing renewals:

Principal Investigator	Title	Sponsor
Nicole Gibran, MD	Northwest Regional Burn Model System Center	US Department of Education
Nicole Gibran, MD	A prospective, open, non-controlled clinical investigation to evaluate the adequacy of a new donor site dressing in surgical burn patients	Molnlycke Health Care AB
Nam Tran, MD	A Prospective, Single-blind, Randomized, Phase III Study to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols as an Adjunct to Hemostasis during Peripheral Vascular Surgery	Grifols, Inc

In the first quarter of 2013, there were an impressive 19 new and competing renewal applications from our department. We will continue to provide the department's grant awards in future newsletter publications.

Congratulations to these investigators for their continued efforts and successes in an ever more difficult funding environment.

Other News in the Department of Surgery...

- **Monica Morrison, PA-C**, Transplant Physician Assistant was recently nominated for the Maria Hall Award for excellence in patient and family centered care. This award recognizes staff and volunteers who put patient and family centered care values into action.
- Hear the word "**Harborview**" and what do you think? The trauma center for the area's most critical cases. You're right. It's that - but it's so much more. Read the [Bellevue Reporter article](#) on **Harborview Medical Center**.

2013 Schilling Lecture — *Continued from page 3*



Thomas Varghese, MD, MS, "*Strong for Surgery: Changing Clinical Practice.*" Dr. Varghese is an Associate Professor in the Division of Cardiothoracic Surgery and Director of Thoracic Surgery at Harborview Medical Center. He is the Medical Director of the Strong for Surgery program, a novel, patient-centered approach in Washington State focused on improving outcomes by engaging patients in the pre-surgical clinic to modify surgical risk factors. Dr. Varghese presented details of the program as well as future directions.

The Helen and John Schilling Endowed Lectureship was established by the late Helen Schilling to bring distinguished scholars to the Department of Surgery at the University of Washington, and to enhance the Department's commitment to the highest standards of patient care, teaching, research and scholarship. It was Mrs. Schilling's wish that the lectureship be in honor of her husband, John.

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and prepared to do that. We get excellent clinical exposure and technical training at UW, and I rely on that training every day; it has served me well. If any of you have questions about general surgery community practice or if you'd like to spend some time with me in my practice, I encourage you to contact me. My email address is heatherkalani@gmail.com.

I hope everyone enjoys the end of the academic year, and I hope our paths cross in the future!"

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are proving that the modifications to the device are very effective. The study results will be submitted for product approval to the FDA and the governing agencies of other countries.

Dr. Starnes has recruited Dr. Matthew Sweet (Assistant Professor in the Division of Vascular Surgery) into the research study and others of his team are learning to do modifications to the stents as well. Dr. Starnes is thus far thrilled with the outcomes and with his team. He states that the team makes all the difference; without his co-investigators and the expert assistance of his Research Nurse Coordinator, Ms. Billi Tatum, along with the administrative support of the Department of Surgery, this life-saving device and technique might never have won approval.