

Produced under an educational grant from Boston Scientific Corporation

Boston Scientific Takes an Integrated Approach to Treating Carotid Artery Disease

The device leader employs a program consisting of training, clinical science, and technology.

BY ROCCO G. CIOCCA, MD

Carotid artery stenting (CAS) is becoming an increasingly viable option for treating carotid artery disease (CAD). Responsible treatment of this disease requires an integrated approach to training, clinical studies, and new technology development. Boston Scientific Corporation (Natick, MA) is embracing the future of CAD treatment through its Carotid Solutions Program, which addresses all three of these important components.

Currently, only a handful of highly trained physicians are qualified to perform CAS. To meet the growing demand for this procedure, Boston Scientific has developed a CAS training program that utilizes the most advanced techniques and technologies, including hands-on simulation training, to provide physicians and sup-

port staff with a complete fund of knowledge about CAS.

BOSTON SCIENTIFIC'S APPROACH TO CAS TRAINING

Boston Scientific's CAS training program is a multifaceted mix of online and simulation training, didactic sessions, and one-on-one training—all with metrics to measure skill development through performance assessment. The Boston Scientific program is a resource for a broad audience of medical professionals, including interventionists, nurses, and technicians. This comprehensive training approach helps the interventional staff work more effectively as a team.

Boston Scientific's program is different from many

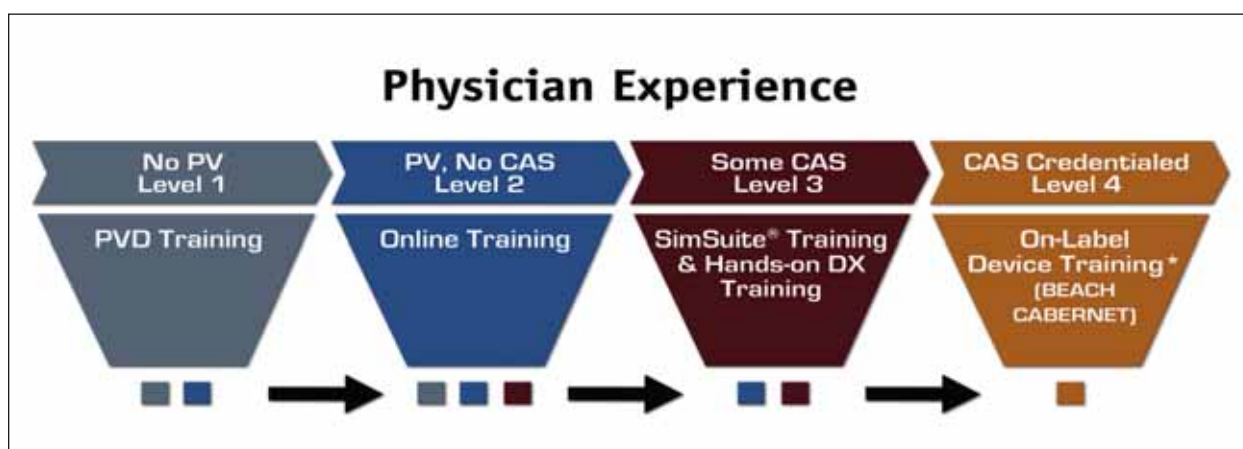


Figure 1. The Boston Scientific CAS training program has four levels of training tailored to meet the educational needs of healthcare professionals with varying degrees of experience.

other CAS training programs in that it is procedural, not device-specific, in nature. Another aspect that sets this program apart from others is its emphasis on accreditation. It is one of the few CAS training programs that is CME-accredited. One of the primary goals for Boston Scientific's CAS training pathway is to support hospital credentialing requirements, which are determined at the local level, by providing a comprehensive program that focuses on cognitive, technical, and clinical aspects of the procedure. To increase the likelihood that the program was aligned with cognitive requirements set by hospital credentialing boards, Boston Scientific sought input from multiple specialties and medical societies to understand the strengths and weaknesses of the CAS credentialing requirements for each specialty.

PROGRAM OVERVIEW

The Boston Scientific CAS training program provides four levels of training tailored to meet the educational needs of healthcare professionals with varying degrees of experience (Figure 1). The programs in the first three levels are not device-specific and are intended to facilitate the CAS credentialing process. The training in the fourth level is device-specific training designed for CAS-credentialed physicians and will be implemented upon FDA approval of Boston Scientific carotid stent platforms.

The first-level training offers education and hands-on skills in catheter-based procedures. This hospital-based training is designed for licensed physicians who have no previous peripheral endovascular (PVD) training and are looking to gain the experience needed for credentials to perform these procedures.

The second level of the program is the Online Carotid Education & Stenting Course, which provides the latest information on the management and treatment of CAD, including imaging and diagnostic skills, patient selection, complications, and more (Figure 2). The course includes animated sequences, a simu-

lated CAS procedure, and creative learning self-assessments throughout each of its seven modules (Table 1). The course was primarily designed for interventionists who are credentialed to perform PVD procedures but who have yet to gain cerebral angiography or CAS experience. It is also relevant for support staff and referring physicians. For support staff, the course enhances knowledge of CAS, the carotid anatomy, and the tools used to treat carotid disease, thus shortening procedure time. For referring physicians, it can provide information that will make referrals more appropriate and testing more efficient.

Because CAS is a procedure performed by multiple specialties, each bringing a specific skill set and cognitive features into play, the Online Carotid Education & Stenting Course was developed by a team that included an interventional cardiologist, a neurosurgeon, an interventional radiologist, and a vascular surgeon. The course was designed so that every physician, regardless of experience or specialty, could approach CAS with a similar set of skills, cognitive abilities, and understanding of procedural issues upon completion.

Physicians receive 3.5 CME credits for completing the entire course, which takes approximately 4.5 hours, or 0.5 credits for completing each of the seven modules. Although not yet accredited for support staff, nurses and

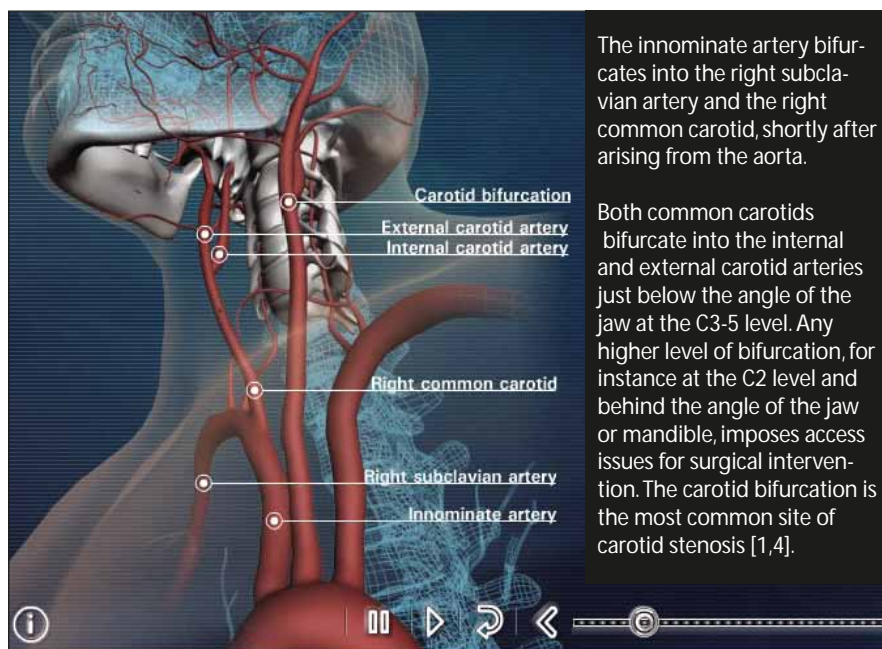


Figure 2. A snapshot of the Carotid Artery Disease and Stroke module of the Online Carotid Education and Stenting Course.

TABLE 1. ONLINE CAROTID EDUCATION & STENTING COURSE

- Introduction to Carotid Artery Disease and Stroke
- Diagnosis of Carotid Artery Disease
- Treatment of Carotid Artery Disease
- Patient Selection
- Carotid Stenting Procedure
- Carotid Stenting Simulator
- Carotid Angiography Case Review

technicians will receive the same number of CE units for completion of the program. Modules can be completed in any order and in more than one sitting. There is no cost to medical professionals to complete the program, which is supported through an unrestricted educational grant from Boston Scientific. The program can be accessed at www.carotid.com, the company's Carotid Solutions Program Web site.

The third level of training includes simulation and hands-on training. Medical simulation provides an opportunity that has not really existed before in new-device training—the opportunity to master the use of a new device as it is introduced into the marketplace. Credentialed SimSuite (Medical Simulation Corporation, Denver, CO) CAS Procedural Training offers an integrated curriculum of didactic education, live-case observation, and simulation training. Medical simulation bridges the gap from textbook learning to performing real-life procedures in the catheterization laboratory. The primary benefit of this technology is that it is risk-free because, during a simulated event, practitioners not only gain experience and confidence in a realistic, safe environment, but they also have the opportunity to encounter more variables and complications, such as stroke, than they would with actual clinical cases.

The SimSuite Carotid Education Course is a 2-day, CME-accredited program focused on CAD and stenting that is designed for interventionists credentialed to perform PVD procedures and who have some cerebral angiography experience but have minimal or no CAS experience. The SimSuite Carotid Education Course pro-

vides a state-of-the-art simulated catheterization laboratory environment that includes a preprocedure room, where patient selection, diagnostics, and preparation are performed; a procedure room that features an interactive patient simulator; and a postprocedure room in which patient issues and outcomes are reviewed. To maximize clinical interaction with instructors, the SimSuite Course is designed for small groups of physicians. Prerequisites for this step of the training include completion of the Online Carotid Education & Stenting Course or an equivalent online carotid training program; proof of hospital credentialing as a licensed peripheral vascular interventionist; previous cerebral angiography experience or attendance of a didactic seminar or course; and a clear path to credentialing for CAS within their institution.

Next, physicians receive 1 to 2 days of hospital-based, hands-on training in diagnostic imaging techniques and interpretation. This training may help them become credentialed to perform CAS within their own facility. It also provides an opportunity for significant clinical interaction with an experienced interventionist and can be used as a refresher course for physicians who want to reinforce their carotid knowledge.

Credentialed interventionists who have the potential to act as trainers and proctors for CAS training programs may participate in the fourth level of training—Boston Scientific On-Label Device Training. This hospital- and Web-based training includes in-service programs, online modules, and optional simulation-based training. Upon FDA approval, modules specific to the products used in two clinical trials, BEACH and CABERNET, will be available for new-device training.

CAROTID SOLUTIONS PROGRAM

An additional key component is Boston Scientific's rigorous clinical program highlighted most recently by the Company's BEACH trial results. Announced by Co-Principal Investigator, Christopher White, MD, the trial demonstrated positive results for CAS as a viable treatment option for carotid endarterectomy. Look for highlights in the May 2005 issue of *Endovascular Today*. Finally, Boston Scientific rounds out its integrated approach to treating CAD with a broad endovascular and surgical technology pipeline. For more information, go to www.carotid.com. ■

Rocco G. Ciocca, MD, is the Associate Medical Director, Cardiovascular Clinical Sciences, Boston Scientific Corporation, Natick, Massachusetts.