Next Frontiers in Simulation

A look at the new technology, what is on the horizon, and how medical simulation can be used as part of endovascular training.

BY DAVID L. DAWSON, MD

By now, nearly all practicing endovascular specialists have some personal experience or familiarity with the use of simulation for training or evaluation.

The endovascular device industry has played an important role in the development of a user base for virtual reality systems. The use of simulators with computer-generated graphics, haptic interfaces, and realistic clinical scenarios was given a major boost with the introduction of carotid artery stenting (CAS). Although simulation-based training was not a specific requirement from the FDA, the agency did require industry to provide education, including device-specific technical training, to new or transitioning CAS operators. At the time of (or prior to) the US product launch of their CAS systems, both Guidant (now Abbott Vascular, Santa Clara, CA) and Cordis Corporation (Warren, NJ) rolled out training programs that included simulation as a key feature. Boston Scientific Corporation (Natick, MA) provided simulation training to new users when it introduced cardiologists to its embolic protection device for saphenocoronary graft interventions. In addition, many physicians have had hands-on opportunities to use endovascular simulators at educational symposia, including VIVA, meetings of professional societies, and other continuing medical education programs.

What is next? What new capabilities have been developed? What is in the pipeline? What applications of simulation technologies can be expected to be a part of endovascular training and practice in the near future?

There are three main areas in which endovascular specialists can expect to see expansion of the use of procedure simulation. First, simulation-based training accelerates novice users' acquisition of basic procedural knowledge and skills (Figures 1-4). Simulation as a component of graduate medical education (GME), either integrated into the residency program or through experiences in regional programs, will become the norm.[1,2]

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Second, there will be new uses for simulation to provide device- and procedure-specific training to practicing physicians. Lastly, the use of simulation technologies as a component of maintenance of certification (MOC) has already been adopted, and increased use of practical testing with simulation is predicted to be a part of competency-based training curricula, physician credentialing, and certification by specialty boards.

GRADUATE MEDICAL EDUCATION

The use of simulation in GME presents practical challenges. There remains a gap between capability and the current reality. It has been established that skills training and procedure simulation benefits students and residents.[2-6] Simulation can help bridge the gap between available and needed training.[7] Even relatively brief and focused simulation experiences can improve residents' endovascular skills.[4] Programs offering endovascular simulation training can also use this experience as a tool to instruct physicians in preliminary phases of training (eg, general surgery residents),[8] which may help attract those with aptitude and interest to vascular fellowships. Virtual reality simulators can reduce costs by providing an effective substitute for the more expensive training option of the animal laboratory. Endovascular training with simulation is four to 16 times less expensive than training on animals.[9] Despite the established value of simulation, large organizations and bureaucracies generally resist change unless compelled or if there are specific perceived incentives.

(Courtesy of Medical Simulation Corporation.)

Figure 1. Endovascular simulators allow practice of specific technical steps, sequencing of steps for complex procedures, and integration of clinical and physiologic information into intraprocedural decision making. Exposure to technical complications and practice of their management is facilitated.

(Courtesy of Medical Simulation Corporation.)

Figure 2. Vascular access can be simulated by devices with computer-generated graphics (as illustrated) or with the use of skills trainers that incorporate ultrasound phantoms.

Although the advantages provided by the use of simulation-based training are recognized, there are obstacles to widespread incorporation of simulation into GME. First and foremost, there are direct costs. The capital cost to purchase an endovascular simulator is approximately $200,000, and there may be associated costs for facilities and staff. Other financial considerations include loss of potential clinical revenue due to the commitment of faculty time in nonclinical activities. It may be anticipated that simulation will become the norm in training programs when standardized curricula include the expectation for simulator experiences and when this training is sanctioned as a legitimate alternative to a portion of training that would otherwise have to be provided in clinical experience.

Specific to the future training of vascular surgeons, there is growing interest in designing curricula for vascular surgery residencies that include skills laboratories and simulation training. The Association of Program Directors in Vascular Surgery (APDVS) established a Skills Lab and Simulation Committee in 2008 to consider how to develop a modular curriculum for use by program directors. The APDVS effort, however, is very preliminary. Widespread or compulsory use of simulation-based training in vascular GME programs is still a vision—not a reality.

To date, no specialty board accepts simulated case experience as a surrogate for clinical case numbers. A consensus recommendation for neurological subspecialties' GME committee published in 2005 suggested that this would be acceptable as the technology matures.[10] Although current simulation technology was not judged to be a valid substitute for clinical experience, it was anticipated that in the future, simulation might provide up to 20% of the required training experience in procedural techniques.

Although specific requirements for simulation-based training do not exist and educational institutions are unlikely to see a substantial economic return on their investment in simulation capability, endovascular simulators are becoming relatively common in hospital and university settings. Mentice Medical (Göteburg, Sweden) and Medical Simulation Corporation (Denver, CO), two of the companies producing endovascular simulators, report there are more than 60 systems in

(Courtesy of Medical Simulation Corporation.)

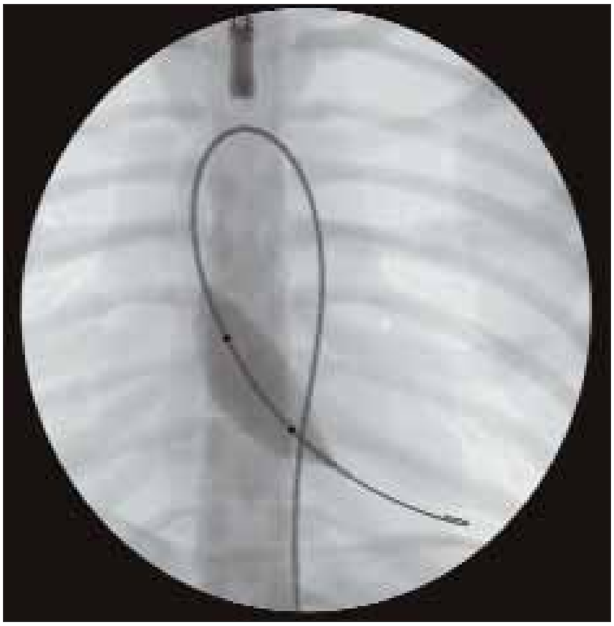

Figure 3. Simulation of interventions for structural heart disease provides examples of cases that reproduce the actions of large devices in the aorta and heart, such as this example of an image from a balloon aortic valvuloplasty.

(Courtesy of Medical Simulation Corporation.)

Figure 4. Interventions for structural heart disease can be simulated with both arterial and venous catheterizations.

noncommercial educational centers. Optimizing utilization remains problematic, however, as many of these simulators may be used infrequently.

There is no uniform approach to using simulators in GME programs. For most, teaching with simulators is a part-time activity of interested faculty. One-on-one or small-group teaching by a clinical expert is an ideal way to provide simulation training, but it is resource-intensive. It competes with other clinical or academic activities, and it is a relatively inefficient use of faculty time. In some facilities, such as in installed SimSuites (Medical Simulation Corporation), an educational specialist staffs the simulation facility, providing support for a variety of users. The salary expense associated with staffing by a clinical specialist (eg, cardiovascular technologist) is less than physician staffing. This approach is still costly, but it provides predicable access and support. Most simulation and skills training centers will have some dedicated support personnel who have responsibilities in multiple areas, not just endovascular training. One practical approach is to develop training modules that require only limited direct involvement of endovascular faculty, and then allow learners to practice cases with peer or senior resident guidance. Technical support from the staff helps learners with simulator operation.

DEVICE- AND PROCEDURE-SPECIFIC TRAINING

Device- and procedure-specific training are important issues for the medical device industry, and these applications have continued to provide much of the incentive and economic support for the development of commercially produced endovascular procedure simulators.

CAS was the first endovascular procedure to be introduced to broad clinical use with simulation-based train-

TABLE 1. 2008 COMMERCIALLY AVAILABLE VIRTUAL REALITY ENDOVASCULAR SIMULATORS

Simulator	Manufacturer	Web site
Endovascular AccuTouch Simulator	Immersion Medical, Gaithersburg, MD	http://www.immersion.com/medical
Angio Mentor	Simbionix USA Corp., Cleveland, OH	http://www.simbionix.com
SimSuite	Medical Simulation Corporation, Denver, CO	http://www.medsimulation.com
Procedicus VIST, Vascular Intervention System Training	Mentice Medical, Göteburg, Sweden	http://www.mentice.com

ing programs. With the initial US approval of CAS, the FDA required companies marketing CAS systems to provide appropriate training. The use of simulators was embraced as a means to meet this requirement. The experience with CAS training has shown that simulation is generally accepted by trainees, performance on simulators improves with training and practice, and simulation before first performing endovascular procedures can improve clinical performance.[1,11] Specific to CAS, the value of educational programs using simulators appeared to be tangible because trained but inexperienced CAS operators were able to achieve clinical results comparable to those of physicians with extensive CAS experience.[12] Even experienced interventionists can refine their technique with advanced training that employs simulation.[13]

In addition to training physicians in the technical aspects of endovascular procedures, simulators offer a way to provide meaningful training to others involved in supporting the procedures. For example, simulators may be used as part of the training program for industry product representatives, clinical support personnel, and others. The hands-on experience facilitates understanding of critical procedural steps. Increasingly, lessons learned from other industries, aviation in particular, have shown the benefit of training directed at optimizing team function, such as that of the team working together in the operating room or endovascular suite.[14] Simulation offers an effective means to accomplish team training.

There has been a continued evolution in the capabilities of commercially available endovascular procedure simulators. Part of this evolution has been to improve the fidelity of the simulation. Technical improvements that have been incorporated into current systems include more lifelike graphic representations of patient anatomy, improved haptic interfaces (more realistic catheter "feel"), and software revisions that model catheter and guidewire behavior in a manner that more realistically reflects what is encountered in patients.

Although the number and type of peripheral intervention simulations were limited in early models, manufacturers have continued to expand the array of tools (catheters and devices) that can be simulated. New case scenarios, including more options to simulate complications and variations, have been developed. Simulation capabilities for many new applications have been introduced during the past 2 years, including simulations for structural heart disease therapies, inferior vena cava filter placement and retrieval (Figure 5), and interventions for femoral artery occlusive disease.

(Courtesy of Mentice Medical.)

Figure 5. Vena cava filter deployment and recovery can be simulated with the current version of the Procedicus VIST system (Mentice Medical).

One conspicuous gap in simulation capability is the absence (to date) of aortic interventions in commercially produced simulators (Table 1). None of the companies marketing endografts for abdominal aortic aneurysms (AAAs) have incorporated virtual reality simulations in their training programs. Although the idea of using virtual reality simulation to train endovascular specialists in the endovascular AAA repair (EVAR) was addressed in the 1990s,[15] simulation technology was not commercially available when EVAR technologies were first introduced to the US market in 1999. Getting basic endovascular training was a challenge facing vascular surgeons in the late 1990s and the early part of this decade, but EVAR is now a well-established part of vascular surgery practice, and competence with EVAR is fundamental to contemporary practice. The need for EVAR simulation is primarily an issue for residents and fellows, and prototype systems do exist.[16]

Less practical experience exists with thoracic endovascular aortic aneurysm repair (TEVAR). Thoracic aortic aneurysms are less common and can be technically challenging. For these reasons, in part, one of the two companies introducing a TEVAR system to the US market this year has elected to use simulation as a component of its training program. The physician training for the use of the Thoracic Talent Stent Graft System (Medtronic Vascular, Santa Rosa, CA) will include simulation experiences (Figure 6). Three goals have been identified by the company:

- To allow users to practice and improve skill sets in a safe, realistic, and guided environment

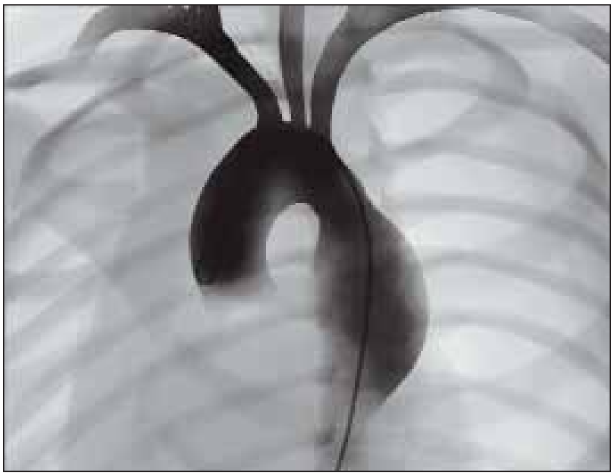
(Courtesy of Medtronic Vascular.)

Figure 6. Endovascular repair of aneurysms of the descending thoracic aorta can be simulated. Training programs for Medtronic Vascular's Thoracic Talent Graft have been developed to support the device's US release.

- To provide opportunities for operators to experience and manage several potential procedural complications (without risk to a patient)
- To support focused, interactive, educational interactions for physicians at all skill levels

Further expanding the case repertoire of an endovascular simulation will increase the market available to simulator manufacturers. It will also increase a training center's ability to maximize the utilization of its simulators. It seems reasonable to assume that simulation technology, as well as other aspects of medicine, will continue to evolve in a continuous manner. More types of simulated cases and more variations are likely to be seen in the future.

PHYSICIAN CREDENTIALING AND MAINTENANCE OF CERTIFICATION

There has been interest in the use of simulation as a means of assessing cognitive expertise and technical proficiency, including for the purposes of credentialing or certification. The American Board of Internal Medicine (ABIM) recently introduced a new option for interventional cardiology diplomats to earn credit toward completion of their Self-Evaluation of Medical Knowledge requirement for MOC.[17] This is the ABIM's initial effort to use simulation to evaluate physician competence. Interventional Cardiology Simulations is an ABIM-developed set of representative cases that were developed to duplicate what an interventional cardiologist might see in daily practice.

The ABIM uses Medical Simulation Corporation's SimSuite technology to replicate a catheterization lab suite setting, and the five case scenarios developed by ABIM include common problems faced by interventional cardiologists. Cardiologists can complete the simulated cases at one of Medical Simulation Corporation's SimSuite education centers or at one of several cardiology meetings and conferences throughout the year. ABIM-certified cardiologists enrolled in MOC can register at www.abim.org for a simulator session at one of the SimSuite centers or during the cardiology society meetings and conferences.

Recognizing the need to expand the role of simulation for the training and evaluation of surgical specialists, the American College of Surgeons (ACS), through its Division of Education, has developed an accreditation program for educational centers that employ skills training and simulation.[18]

The ACS has established two levels of standards for accreditation of training centers. Centers select the level of accreditation they seek, and the ACS applies the appropriate set of Standards and Criteria to measure the centers' level of compliance. The accreditation criteria consider the number and type of users (learners), the curricula, the level of technical support (including the types of simulators employed), and the resources dedicated to the educational institute's operations. Application for ACS accreditation is purely voluntary and is supported by the individual education institute or parent institution seeking accreditation.

A Basic Education Institute (BEI), or Level II institute, is an organization that offers education to address fundamental areas of knowledge and skills. A Level I institute, or Comprehensive Education Institute (CEI), offers a complete range of educational programs to address complex knowledge and technical skill virtual reality simulators and other technologies. Endovascular procedure training is an important programmatic component of many Level I institutes. CEIs support activities involving precepting, mentoring, faculty development, and research.

By promoting the development and accreditation of CEIs, the ACS seeks to establish a network of institutions that can advance the level of simulation-based training and validate testing methodologies. To date, more than two dozen centers have received Level 1 CEI accreditation. To achieve this status, the programs must include several different types of activities:

- Curriculum development
- Curriculum validation
- Expansion of practice
- Interdisciplinary training
- Introduction of new skills
- Long-term follow-up of the learner

- Maintenance of skills
- Training multiple specialties
- Research

In addition, CEI programs may also include collaboration with other Institutes, remediation of practice, and interdisciplinary team training.

At present, the role of simulation in credentialing and maintenance of certification is in education—not assessment. Physicians seeking credentialing or to maintain certification are required to document the adequacy of their training and their completion of continuing medical education. Training activities that include simulation can be part of this required experience. Testing physicians' knowledge or procedural competence with simulation and then making a determination of adequacy is a more complex problem. Preliminary experience shows that technical skills evaluation with simulation can discriminate between inexperienced and experienced interventionists in specific applications (eg, CAS).[19] However, additional work is needed to develop tests that are comprehensive, reproducible, and able to discriminate among operators who are competent and safe and those who are not. Formal testing modalities must be developed and robustly validated by psychometricians (specialists in testing methodology and statistical analysis)—time-consuming and expensive steps that are yet to come.

> "Using only system-generated performance metrics . . . does not take full advantage of simulation as an assessment tool."

There are different options for using simulators to test individual performance. The systems can track performance metrics, such as the fluoroscopy time, contrast use, accuracy of angioplasty balloon positioning, accuracy of catheter tracking, and many other parameters that are recorded during the simulated cases. These system-measured performance metrics have been used in many of the studies used to establish the efficacy of simulator-based endovascular training.[3-5,9,10,20,21] Using only system-generated performance metrics, however, does not take full advantage of simulation as an assessment tool.

The potential to use simulation for the critical assessment of technical proficiency may be best when an expert observer watches and grades the performance of a simulated case.[22] An expert observer can readily distinguish between errors due to lack of familiarity with the simulator interface and those due to deficiencies in cognitive or technical ability. In the conventional setting of an oral examination for specialty board examination, oral examiners evaluate knowledge and decision making with the presentation of clinical vignettes. A similar type of structured assessment by subject matter experts can be done in the setting of a simulated clinical environment, thus incorporating potential relevant context into the testing. ■

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