So you think you're an interventional cardiologist? Let the simulators decide

New York, NY – It's not often new trainees have the chance to kill off a few patients before getting their skills down pat, but with the advent of virtual-reality simulators (VRSs)—some of which have the look and feel of real human patients in honest-to-goodness cath labs—interventional cardiology is primed for revolution. Carotid stenting has granted VRSs their first legitimate foothold within the field of endovascular therapy; a handful of simulator companies are also producing systems for basic interventional cardiology training, with the aim of adding other cutting-edge applications, such as PFO closures and valve-replacement procedures, in the near future.

It's probably the most exciting and the most dangerous thing that's happened in medicine in about 100 years.

But as the demand for simulator training grows, some of the foremost experts in the field are sounding alarms over just how simulators are being used, pointing out that some have the ability to teach bad habits as well as good. And just as it is important for physicians to be able to discriminate between good and bad simulators, so is it now possible for simulators themselves to distinguish between good medical devices/techniques and bad ones, not to mention singling out the truly skilled operators from the bunglers and boasters.

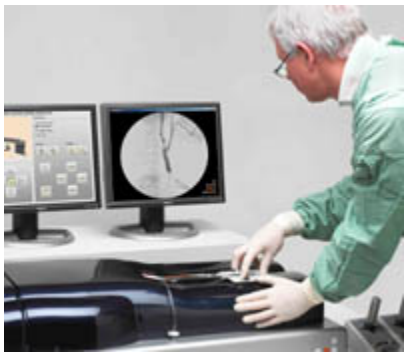
Dr Anthony Gallagher

Some physicians who have traveled to endovascular simulator training centers or have gleaming new simulation centers at their own hospitals say the technology is a funky, futuristic addition that will complement but not replace existing training programs. Others, however, say VRSs will fundamentally transform not only medical training but almost every other facet of endovascular and cardiovascular medicine as it is now practiced and policed.

"This thing is changing medicine. It's probably the most exciting and the most dangerous thing that's

happened in medicine in about 100 years," **Dr Anthony Gallagher** (Emory University, Atlanta, GA) told **heart*wire***.

Simulator companies vie for market



Procedicus VIST (Source: Mentice)

Widely hailed as one of the fathers of medical simulation is a slim, sallow brunet named "Harvey," first unveiled in 1968 at the **American Heart Association** meeting and still used at hospitals around the globe, realistically simulating a range of cardiovascular conditions through aberrant pulse, blood pressure, or heart sounds. In the past 10 years almost all medical disciplines have seen explosive growth in the design and use of increasingly sophisticated medical simulators for a wide range of applications, including endoscopic, biopsy, vascular access, needlestick, laparoscopic, and emergency-room procedures, among others. The US military has used medical simulation for team trauma training, while the University of Miami offers an antiterrorism simulated training program for emergency-response personnel. In 2003, the National University of Singapore developed a simulation program around electronic stethoscopes capable of recording, storing, and playing back soundtracks recorded from real patients to train medical students to recognize SARS symptoms during the SARS outbreak in Asia.

Most simulators, regardless of their application, entail some sort of workstation coupled with a specific software simulation package or combination of packages, which performs all the necessary calculations to create real-time virtual views (in endovascular procedures, typically cineangiograms and possibly a hemodynamic monitor), while communicating with the external devices used for the procedure. A separate monitor, in some systems, provides instructions, options, and additional information. Specific training programs or procedures can be selected at the outset, while different devices can be "chosen" during the procedure (from a drop-down menu in some systems or through the introduction of real tools in the more sophisticated systems). Inside the mannequin or box that serves as the "patient," the instruments being manipulated by the operator have a haptic interface that conveys a sense of touch to the operator, whose actions are instantly translated to the workstation, which then reflects the operator's movements on the monitor in real time.

Vascular Simulation Platform (Source: Xitact)

Endovascular and cardiovascular simulators are one of the latest additions to the field and are fast becoming the most sophisticated devices in the medical simulator world. There are at least six simulator companies producing VRSs for endovascular and cardiovascular training (**CATHI**, **Immersion**, **Medical Simulation**, **Mentice**, **Simbionix**, and **Xitact**). Carotid-artery-stenting (CAS) device manufacturers have, in the past year, partnered with specific simulator companies as part of their training programs. As a result, physicians learning to use the Guidant CAS system will train on a Mentice simulator, while training programs for the Cordis system

use both Mentice and Simbionix simulators. Boston Scientific's carotid stent and FilterWire EZ™ embolic-protection system are approved for CAS in Europe, not in the US, but the company has used Medical Simulation's SimSuite for training physicians to use the FilterWire EX™ embolic-protection system for saphenous vein graft (SVG) disease.

Virtual-reality simulators: A backhanded blessing from the FDA

VRS-based training programs for interventional cardiologists, interventional radiologists, surgeons and other specialists hoping to hone their endovascular skills were recently given the FDA's backhanded blessing as part of the agency's approval of new CAS systems.

Dr Gary Ansel (Source: OhioHealth)

In a novel twist, VRSs themselves do not fall under the purview of FDA approval; after all, they are not themselves devices that will ever be used on humans. Instead, VRS training for CAS has become a de facto requirement after the FDA accepted the CAS training programs proposed by both Guidant and Cordis/Johnson & Johnson—both of which included simulator training—as a requirement for device approval. Guidant's Acculink carotid artery stent and protection device was approved on August 30, 2004. Earlier in the year, Cordis's PRECISE nitinol stent and AngioGuard XP embolic protection guidewire squeaked through an FDA advisory panel review, which recommended that the CAS system be approvable with conditions. And while the Cordis devices have not received the FDA's final seal of approval, the FDA has granted the company permission to begin its comprehensive physician-training program, known as **Carotid Artery Stenting Education System** (CASES).

Both of the formal training programs devised by the companies make exceptions for operators who have already performed CAS procedures—primarily within the pivotal clinical trials—and are familiar with the devices used. For physicians who want to learn CAS from scratch, however, the training programs agreed on with the FDA include four to six hours of simulator-based training, along with the standard didactic component—case review, proctoring, etc. A separate part of the CASES study involves objective validation of the simulator component.

"The CASES trial is the FDA's way of testing simulator training," **Dr Gary Ansel** (Riverside Methodist Hospital, Columbus, OH) explained. "The FDA is not in the business of mandating simulator training, but they're happy with what the companies have proposed."

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Several of the physicians interviewed by **heart*wire*** had tried a range of simulators and declared them to be "a lot of fun" or said that trainees "enjoyed them."

Dr Christopher Cates

But one of the dangers, says **Dr Christopher Cates** (Emory Heart Center, Atlanta, GA), lies in thinking of these systems as video games for grown-ups, particularly since no regulatory body has as yet established a yardstick by which simulators must be measured.

> **Just like your golf swing—if you learn your golf swing wrong, it's very hard to break bad habits.**

"All simulators are not the same, and just spending a little time playing on a simulator doesn't really teach skill," Cates says. "In many ways, the dangerous part is that if you don't measure skill and have no appropriate measurement of the appropriate technique, you can teach bad habits. Just like your golf swing—if you learn your golf swing wrong, it's very hard to break bad habits."

In the case of carotid stenting, he points out, if training programs depend on simulators that do not have the sophistication to stop bad habits from forming, "that's going to translate into bad outcomes. Performing this procedure with untrained hands will kill this procedure."

Dr David Dawson (Source: UC Davis)

Dr David Dawson (UC Davis, CA) has a unique history with VRSs, having spent 10 years in the US Air Force, of which three and a half were spent at the NASA-Johnson Space Center. Not only was he involved in developing medical-procedures training programs for astronauts, which used rudimentary simulation devices, he also spent hours in aviation simulators for jets, military aircraft, and the space shuttle.

Simulation in medicine, he says, as in aviation, "is a good way not only to train for the procedures but to get a team to work together."

Dawson dismisses concerns that substandard simulators will be used for training complicated procedures like CAS. "Individual practitioners don't want to have bad outcomes, and a company making a particular stent isn't going to want bad outcomes. If the federal government said we'll pay for any procedure that you want to do regardless of outcomes, maybe that would happen and maybe that would promote bad care, but they haven't said that, and nobody wants to do a bad job."

There's simulators, and then there's simulators

Endovascular AccuTouch (Reproduced by permission. © 2005 Immersion Corp. All rights reserved.)

Cates and Gallagher have been involved in endovascular simulator design and testing since their inception, with Gallagher making the leap to vascular applications after working with and testing some of the first surgical simulators. They stop short of specifying which simulator or simulators they would advocate over others, pleading academic objectivity and insisting they have no ties to specific manufacturers. What physicians should be aware of, however, are the specific components that distinguish the games from the real goods.

"The question to ask is this," says Cates. "Is this simulator a full-physics simulator? That means, can I take a person's specific digital information, a CT or an MRI of a real patient, load that information into the simulator, and then practice the case, with the patient's exact anatomy, before I do the real thing? A full-physics simulator can do that."

Cates is also a firm advocate of metrics-based training, whereby performance by users is compared with measurable standards. He points out that recently published competence documents for carotid stenting—most notably the joint **Society for Cardiovascular Angiography and Interventions**, **Society for Vascular Medicine and Biology**, and **Society for Vascular Surgery** guidelines—employ the phrase "metric-based simulator training to proficiency."[1]

Simulators that do not incorporate validated metrics capable of assessing the movements of the wires and catheters inside the patient "are nonsense," Gallagher adds.

Dr Wolfram Voelker

Others point out that different simulators have carved out a niche for themselves in particular areas. **Dr Wolfram Voelker** (Medizinische Klinik, Wuerzburg, Germany), who was involved in the early development of the CATHI simulator—but has no financial ties to the company—points out that some simulators, like the Mentice and Medical Simulation products, have tried to simulate procedures from beginning to end, whereas the CATHI has focused on replicating the most complex parts of the intervention. "In my opinion, this is a good idea, because the introduction of the guiding catheter at the present time cannot be performed in a realistic way," Voelker says. "So if you do a procedure for the first time, and you see that this is not a very realistic step, you will become a little bit reluctant to use this technique as a whole."

The Medical Simulation SimSuite has taken the approach of replicating the entire catheterization suite, with a lifelike mannequin, the full range of screens and apparatus found in a cath lab, and even a virtual on-screen "doctor" who provides the virtual patient's history and "prebrief." SimSuite even has a 40-foot bus that serves as a virtual cath lab on wheels that has been used for a variety of training applications, including Boston Scientific's embolic-protection device.

SimSuite (Source: Medical Simulation)

Some physicians, like Dawson, point out that the SimSuite is well suited to team training and it has also captured a lot of the patient physiology and adjunctive pharmacology components of the procedures that can be practiced on it.

"I think that each of the companies has made certain compromises or assumptions as they've gone forward, and I think some of them have changed them as they've looked at what's going to be a marketable product," Dawson explains.

In the ideal world, says Cates, "two or three of the existing simulators would be melded together." But, for the time, being, Cates stands by his insistence that it is how the simulator responds to wire and catheter skills that is important: the rest is smoke and mirrors.

"There are a lot of things out there where you walk in, and it looks like the real thing, and you're wowed. It's eye candy. But in fact when you go and try to push in the catheter, it's a predefined path and it only goes in one area, and the system either lets you do something or doesn't let you do something, then someone in charge pushes a button and a dissection pops up, even if you didn't do anything to cause a dissection!" By contrast, he explains, in a full-physics simulation, a trainee can make mistakes, can go in the wrong vessel, and the simulator responds accordingly.

"I liken it to having something that looks like a Ferrari on the outside and you open up the engine and it looks like a little itty-bitty Volkswagen engine," Cates says. "Whereas the best simulator out there looks like a Volkswagen on the outside, but you open it up and it's a Ferrari on the inside."

Different aims, different simulators

Other physicians who spoke to **heart*wire*** were careful to say that all of the simulators have their pros and cons, something particularly beneficial to simulation centers that have more than one type of simulator on-site.

"At least three different professions are doing these types of procedures," Ansel reminds **heart*wire***. "You have surgeons who have very little catheter training, so they need a lot more of the really repetitive metrics of feeling the wire, watching the catheter turn, that kind of thing. The radiologists don't have nearly the experience with taking care of patients who have medical complications, hypertension, bradycardia, etc, so they need a simulator that has that. Then a cardiologist needs a little bit of everything. The fact that we [at Riverside Methodist Hospital] have different simulators that have different strengths and weaknesses has actually worked out for us."

Everyone and his brother is going to want to learn to do it.

"It's too soon to compare one simulator with another," Dawson says. "There are no accepted standards. And for something like carotid interventions, there is still a certain amount of disagreement on what the accreditation should be for individual practitioners. So cardiology groups, neuroradiology groups, interventional radiology professional societies, and surgery professional societies have all taken a slightly different approach, generally protecting their own interests but also trying to look out for the patients."

Indeed, the evolution of different simulators, with different strengths and weaknesses, speaks to the wide range of physicians who are hoping to perform carotid stenting.

"I call it the perfect storm," Cates says. "Here you have a procedure that currently is done by less than 100 people, who previously had no reimbursement, but who learned the technique during the pivotal clinical trials of the carotid-stenting devices. Now it's a procedure that's proven to be at least as effective as surgery and probably better in high-risk patients, it's a procedure that the patient wants, and it's the highest-volume vascular procedure in the US. In fact, you get paid more for carotid stenting than for carotid surgery. So in an environment where doctors are getting less and less reimbursement per unit, and we've cured restenosis with drug-eluting stents, you have a perfect scenario in which a new technology is now available, and everyone and his brother is going to want to learn to do it."

Dr Neil Strickman (Source: Texas Heart Institute)

Part of the grumbled controversy over simulators is who should be using them, particularly for carotid stent training. Most people agree that they are an ideal means for physicians with interventional skills to make the jump to carotid stent procedures. Others are like **Dr Neil Strickman** (Texas Heart Institute, Houston), who says the interventional cardiologists are less excited about the simulators than the surgeons, whom he calls the "late bloomers."

"The people who will get the most benefit out of these are the surgeons who in general are a little older and have missed out on interventional methods and endovascular techniques in their training," Strickman says.

Others emphasize that regardless of what types of specialists turn to simulators to train for specialized interventional procedures, the simulators will be used *only* as part of a comprehensive training program.

"I see a future for these simulators only in conjunction with the whole armamentarium of training tools," Voelker insists.

Dr Deepak Bhatt (Cleveland Clinic, OH) agrees. "These have to be used as part of a comprehensive educational package. I don't think people can say, oh, I've done this on a simulator 10 times; I'm good to go."

Dr Deepak Bhatt
(Source: Cleveland Clinic)

Bhatt believes carotid stent training on a simulator is a great starting point for specialists with at least some training in endovascular or interventional skills: interventional cardiologists, interventional radiologists, and vascular surgeons trained in endovascular techniques. "I'm not sure that someone who doesn't have any endovascular skills should be doing this at all. If it's a vascular surgeon with endovascular skills, that's one thing. But, for example, I don't think I could go ahead and learn to do brain surgery on one of these simulators, having never really done anything other than just scrubbed up for some cases at med school. I don't think that's in the patients' best interests in terms of safety, but I don't think there are too many people out there who are thinking they can use the simulators like that, at least I hope not."

Many of the physicians interviewed by **heart*wire*** also emphasized that simulators were still works in progress. "The simulators right now are still not that good," **Dr Christopher White** (Ochsner Clinic, New Orleans, LA), told **heart*wire***. "The people who have invested in the simulators are raving about them, and I think they're fine, but they have a long way to go. The software is nicely written, but the tactile sensation, at least in my hands, is a long way from what it really feels like, although still better than nothing at this point. I would say that in two or three years, when the tactile sensation gets to be very much closer to reality—which simply requires software changes—then I'll be a big fan of simulator training programs."

Carotid stenting and beyond . . .

Beyond carotid stenting, experts say endovascular and cardiovascular simulators will play an increasingly important role in the training of new interventional cardiologists, even for more basic interventional procedures.

"Right now, how do we train physicians? We show them one, and then they do it," Ansel says. "Without a doubt, I foresee the day that a medical student or resident or fellow will never touch a patient until he or she can pass a certain level of expertise on a simulator, just like you don't fly a commercial airline until you can pass the flight simulator."

In fact, the **American Board of Internal Medicine** (ABIM) has already given a grant to certain simulator companies to bring that sort of testing to the board exams.

> **You can have some book smarts and be all thumbs and still pass the interventional cardiology boards.**

"The reality of it is, in the current board exams for an interventional cardiologist you don't ever pick up a catheter. You can have some book smarts and be all thumbs and still pass the interventional cardiology boards!" Ansel says. "It may be something that, down the road, if you're contemplating surgery or interventional cardiology, you can actually go through the simulator training to see whether you're trainable. Orwellian theory would have it that Big Brother would watch over you and help decide which field you should go into, but the fact is, if you don't have the innate skills to do something, why waste all that time going through training only to find out, gosh, I can't do this?"

Ansel continues, "I don't think we'd ever raise the bar so high that we'd exclude people with average skills. I think we'd be hoping to exclude or train people who have below-average skills and either bring them up to an acceptable level or ask them, is this going to be your ball of wax?"

Dr Spencer King (Source: Piedmont Hospital, Atlanta, GA)

Dr Spencer King (Piedmont Hospital, Atlanta, GA) is chairing the interventional test committee of the ABIM's pilot project. So far, the study has tested more than 100 physicians, ranging from new students to expert interventional cardiologists, on six simulator cases designed by a panel of interventional cardiologists. The aim of the study is to determine how well the simulator-based testing can discriminate between the physicians, based on their level of prior training.

"Based on what we find, the ABIM will make decisions on where to go with this," King says. "To allay the fears of candidates, let me say that this is not going to show up as part of their test next year; it's still a work in progress, but it's pretty exciting."

Endless potential for simulators

CATHI-system (Source: CATHI)

Future applications for simulators, however, go far beyond the training of new physicians or the retraining of doctors wanting to specialize in carotid stenting. Loaded with the right software, simulators could be tweaked to enable physicians to train on cutting-edge interventional procedures like valve replacement and repair or to use new devices for applications like bifurcation lesions, ASD closures, and chronic total occlusions.

"New equipment comes along and industry needs ways of having people train on it," King explains. "Right now, when I observe people around the world using the rotablator, I see people doing it a hundred different ways that were not the ways that were originally planned." Teaching correct methodology using a simulator would go a long way toward reducing interoperator variability, he says.

Ansel points out that simulators may also play a key role for physicians working in low-volume centers. "In California, for example, the average cardiologist does fewer interventional procedures than the guidelines recommend, and a lot of smaller hospitals want to be able to do a few AMI procedures with no on-site surgical backup. That's the perfect case scenario in which, on a periodic basis, physicians can head to a simulation center and buff up their skills."

Voekler believes one of the most important roles for simulators will be to acquaint physicians with rare complications. "All interventionalists will be confronted with certain complications only a very few times in their life. But when these complications occur, they have to be prepared, instructed, and have the ability to react, and you can do this only if you've experienced it before. It's totally the same situation as the pilots, who need to go in a flight simulator twice per year to practice on the sorts of worst-case scenarios that they rarely confront."

Already, many simulator developers are refining their products to hone an application that Cates calls "mission rehearsal": the ability to take case information from a real patient, then load it into a full-physics simulator so

that a physician or medical team can practice on a virtual case that is identical to the pending real procedure.

Right now, says Cates, this might take 24 hours for someone with a PhD in computer programming, but the process is growing more and more streamlined by the day.

"We're hoping that the cath labs of the future will have simulators attached to the cath lab system where you could do a digital angiogram, download it, then practice the case on the simulator so that you can go in, pick your equipment, and encounter any problems by doing the case *before* you even do the case. And this is not *Star Wars*, this *is* going to happen. We can already measure every movement within the vascular system with the current simulation technology."

Equally futuristic are the implications for device design. Currently, new stents, catheters, protection devices, etc, are designed and tested in animals or cadavers before being permitted for investigational use in humans. In the future, however, device manufacturers may be able to test virtual devices in virtual patients, just by programming specific device information into simulated procedures.

"If you have a $10 000 percutaneous valve system that you're developing, you certainly want to make sure it's right for that particular patient before you try to put it in. This technology will probably evolve alongside [the simulators], so that this will be the way that new products are rolled out," Cates predicts.

Walking the walk

Certainly, the seemingly space-age uses for medical simulation leave most cardiologists googly-eyed and rubbing their hands in anticipation. Other potential uses for simulation technology, however, are distinctly less alluring. For one, with metrics-based full-physics simulators, medical-licensing organizations, hospitals, and even payers will have at their disposal a means of testing physicians already working in interventional disciplines.

"In the past, catheter and wire skills could not be objectively assessed," says Gallagher. "Now, for the first time, we can do that, and that's why I'm saying it's dangerous. It's dangerous from the physician's perspective, because now we can assess their performance."

It's also scary to a lot of people who talk a good game when they speak from the podium but may not want the light shined into certain areas where they may not be as adept with their hands as they are with their tongue.

"For the first time, we can actually measure someone's performance in a procedure that involves catheters and wires moving at some distance from a working hand, inside a patient," Cates says. "That is a phenomenal advance in medicine, but it's also scary to a lot of people who talk a good game when they speak from the podium but may not want the light shined into certain areas where they may not be as adept with their hands as they are with their tongue."

"It's definitely feasible," says Dawson, "but it's a little more contentious, because people don't want to be tested, and I think you'll see resistance."

And, Dawson warns, there are a few steps that would have to occur first. For one, the validity of the simulator as a testing device needs to be confirmed: "In other words, it's still a simulator—does someone passing that test mean that they're good at the procedure, or are they just good at using the simulator? Or, perhaps they are good at the procedure but bad at the simulator, which is what people would be most worried about."

A bumpy landing?

ANGIOmentor (Source: Simbionix)

That question is at the root of the **Simulator Training Randomized versus Invasive Vascular Experience** (STRIVE) trial, looking at physicians with interventional skills learning carotid angioplasty. The trial will compare outcomes following physicians' first carotid stenting cases after training on a simulator with outcomes from the original carotid stenting cases that made up the **SAPPHIRE** trial. Interoperative performance between the two groups can be compared blindly by comparing angiograms from both groups during the procedure. STRIVE, along with CASES, will "change medicine," Gallagher predicts.

Preliminary results from STRIVE were presented at the recent **Medicine Meets Virtual Reality** meeting in January 2005, and while Cates and Gallagher were unwilling to disclose details—enrollment has not yet been completed in the
trial—Cates says the numbers already indicate simulator training to be superior to standard metric training. An earlier trial comparing standard training with simulator-based training for laparoscopic surgery (the **VR-to-OR** trial) showed simulators to significantly improve on specific target criteria during the procedure.

Other centers around the world are also examining ways to assess simulator training. In a poster session at the 2005 **American College of Cardiology** meeting, Voelker presented results of a small, 12-person study showing that simulator-based training, as assessed using a pulsatile flow model containing different target lesions, was superior to a nonsimulated computer-based training program.

While results from STRIVE, CASES, and other trials will likely have an early impact on new trainees, the implications for physicians who have already been working for years in the field are not difficult to imagine. New York State, for example, already makes public mortality rates and volume statistics for physicians performing PCI. What if physicians performing endovascular and interventional procedures were required to disclose their simulator scores to potential patients?

"That would be a controversial process, wouldn't it?" Cates says, acknowledging that "there is a real move toward measuring quality and paper performance."

But, he adds, it is possible to look at this from the opposite vantage point as well. "If somebody is really skilled, we should be rewarding that high level of expertise, and that doesn't mean that we would penalize less than the highest level. Not every patient needs that high level. What we're saying is that not everybody needs to be the top of the top, but there should be a minimum performance criterion that is set that is the proficiency benchmark."

How and where that proficiency benchmark is set, and whom it will apply to, will be hashed out by professional societies over the months and years to come. Fasten your seat belts: there's bound to be some turbulence along the way.

Ansel has had past advisory relationships with Symbionics and Medical Simulation; King has served as a consultant to both Medical Simulation and Immersion.

Source

1. Rosenfield KM; SCAI/SVMB/SVS Writing Committee. Clinical competence statement on carotid stenting: training and credentialing for carotid stenting multispeciality. J Vasc Surg 2005; 41:160-8.

Related links

- Simultaneous bilateral carotid angioplasty and stenting feasible and safe
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