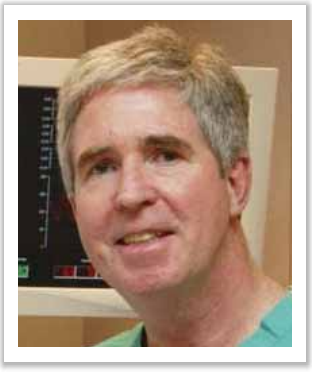
Daniel McCormick, DO

An expert in carotid artery stenting discusses the CREST trial, embolic protection device decisions, and the importance of medical simulation technology in training the next generation of physicians.

How have the CREST trial results affected your decision making in terms of how you perform or select patients for carotid artery stenting (CAS)?

CREST is the first and largest United States trial to compare protected CAS versus carotid endarterectomy (CEA) in standard-surgical-risk (symptomatic and asymptomatic) patients. It represents level 1 evidence that has shown that CEA and CAS are equivalent in their major perioperative morbidity and mortality rates, as well as in long-term stroke prevention. The study met all of its prespecified endpoints, and a significant and consistent reduction in stroke/death for CAS was noted for the last 50% of the patients enrolled in the study. The lack of change in CEA outcomes emphasizes the strong learning curve associated with CAS. This is a large triumph for a therapy that has only been practiced for 15 years compared to the 60-year-old technique of CEA.



However, the problem is that interventionists do not have access to treat the standard-surgical-risk population with CAS because there is no reimbursement. Despite the fact that the US Food and Drug Administration (FDA) has approved CAS for the treatment of moderate-risk carotid artery stenosis patients, the Centers for Medicare & Medicaid Services (CMS) will not reimburse this care, making it difficult to plan the proper treatment strategy for a group of patients who need this care but will not be reimbursed. Therefore, the CREST results have not changed my selection criteria for possible CAS patients because I can still only choose high-risk patients.

To change this, CMS will have to approve reimbursement for patients requiring carotid revascularization in order to have access to CAS. I would substantially expand my selection of those receiving CAS, keeping in mind that there are always patients who, even though they are eligible for a particular revascularization technique, will individually prove to be high risk for that technique based on age, anatomic factors, clinical factors, and symptomatic status. The patients would be the winners because they would have access to a safe, minimally invasive treatment option for carotid artery disease, expanding treatment options for preventing stroke.

Which other recent CAS trials or smaller studies are of the most interest to you?

The three that are of the most interest to me are the European CAS trials: EVA-3S, SPACE, and ICSS. These trials contradict the results of the American carotid registries and randomized trials and go against outcomes that we have seen for CAS when compared to CEA. We saw in the CREST trial that 30-day outcomes for CAS met the accepted thresholds for clinical benefit compared to medical therapy as required by the American Heart Association Consensus for CEA, which is < 6% stroke/death for symptomatic patients (CREST reported a 6% stroke/death rate for symptomatic CAS patients) and < 3% for asymptomatic patients (in the CREST trial, it was 2.5% for asymptomatic CAS patients).

These results contradict the results of the recent randomized European trials because the European trial results showed the superiority of CEA over CAS. These European trials are of the most interest to me because they show the importance and power of trial design. There needs to be consistency in high training standards, experience, and technique. The European trials demonstrated that there are many possible reasons for the differences that were observed, but poor technical aspects such as operator inexperience, the use of training proctors on enrolled cases, the use of multiple stents in single trials, and the absence of a requirement for embolic protection in all patients were strong contributing factors to the surprisingly negative CAS outcomes.

I also think the EMPIRE trial was very important because it was the first to study the application of flow reversal as a method of cerebral protection. It had the lowest major adverse cardiac event rates and the best possible patient outcomes compared to any of the previous new device registries. EMPIRE showed the potential power and impact of improvement of technology to produce better patient outcomes.

We have been stuck in this logjam of technology due to an inability of inventors and industry to invest in the improvement of carotid technology because of the lack of patient access and reimbursement. It is going to kill the field

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because we cannot advance the technology. You have to get some return on your initial research and development investment to continue to progress the technology. If patients are not eligible for a treatment and a technology, there is not going to be any investment in improvement.

What is your process for selecting optimal cerebral protection during CAS?

I use cerebral protection on all cases, otherwise the patient is referred for CEA. My process for making a decision regarding embolic filters is based on arch angulation, the angulation of internal carotid lesions, proximal tortuosity, and distal tortuosity. The more likely that the aforementioned characteristics are present in multiple combinations, the less likely I am to choose the patient at all for CAS and am more likely to favor a surgical approach.

The availability of proximal protection devices really has expanded the capacity to protect patients. When I am deciding whether to use a proximal or distal protection device, I think proximal protection fits very nicely for patients who are symptomatic (especially with recent symptoms), have unfavorable lesion characteristics such as ulceration or haziness, and have large plaque burdens. Proximal protection also has a lot of value for internal carotid arteries that may have unfavorable anatomic characteristics such as acute angulation and severe distal tortuosity, in which a distal filter would unlikely be safely delivered. Distal embolic protection devices function best in routine, noncomplex anatomy.

What do you think is the next frontier in improving CAS technology?

We should be able to reduce major CAS complication rates to a new threshold of < 1% at 30-day follow-up. Stent scaffolding properties will play a critical role in reducing late periprocedural events (> 12 h). Stent design and geometry may contribute to plaque prolapse containment and wall coverage improvement. The increased use of proximal protection may reduce the threshold of microembolic burden. Optimal operator training and expanding operator volume will have a profound impact on improving patient outcomes. Regular interaction between endovascular experts and the companies involved in carotid device development are critical and can only take place when there is further market expansion.

How are medical simulation applications progressing in terms of cardiovascular interventions?

In 2001, Dr. Michael Jaff and I developed the first carotid simulation training system for Medical Simulation Corporation (Denver, CO), which was used to train novice physicians in CAS. This technology has been used at medical meetings and subsequently as a training requirement to credential physicians to be certified to perform CAS by the FDA. The FDA included simulation as a training requirement for physicians as part of the labeling instructions for carotid devices as they were approved. It has also been applied as part of the accreditation process by the American Board of Internal Medicine for interventional cardiology recertification.

High-risk interventional procedures are an area of special capability for simulation because it allows the operator to repeat a technical procedure until he or she reaches a certain level of expertise without any procedural hazard to a patient. Another distinct advantage of simulation is that it allows the operator to experience procedural complications and develop an appropriate problem-solving approach without jeopardizing a patient's welfare.

My partner, Dr. Sheldon Goldberg, and I have been actively involved in the development of simulation in the interventional cardiovascular realm, which has proven to be effective in CAS, renal artery stenting, coronary stenting, ST-elevation myocardial infarction, coronary intervention, atrial septal defect/patent foramen ovale closure, and in testing technology and devices, such as atherectomy. Medical simulation has improved tremendously in terms of the haptics. The sense of feel to the procedure has significantly improved during the last 5 years. It is a great tool for cardiology fellows and junior attendings who are trying to access case experience without being directly responsible for patient care.

The roadblocks to medical simulation technology are basically economic. Industry is still trying to figure who is going to assume the expense for the development of the very expensive simulation modules and who will pay for the training experiences. Eligible sponsors for this type of critical training experience could include: (1) the hospitals, where the procedures are performed; (2) industry, which needs certification technology to allow their devices to be safely deployed; (3) the insurance industry, which wants their patients to get access to the best possibly trained physicians; and (4) the medical community at large, in which individual physician training is typically paid for by the physician who benefits from the training experience. But, if everyone keeps looking to the person to his or her right, that will be the major roadblock in disseminating this technology. ■

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