In the October issue of *Vascular Disease Management* we present a manuscript by Hopf-Jensen et al on micromesh carotid stent designs. The authors detail these stents’ potential to lessen the risks associated with carotid stenting by preventing tissue prolapse within stents and reducing late embolic events.

Despite profound initial enthusiasm, carotid stenting is utilized far less commonly in the United States than carotid endarterectomy in the treatment of atherosclerotic carotid disease. Carotid stenting has been the source of many intense debates. This is not the case in many other countries, where carotid stenting is the most commonly utilized treatment of atherosclerotic carotid disease. I strongly suspect that the CMS payment guidelines have resulted in the trend of lower utilization of carotid stenting in the United States. These guidelines are based on data derived from large clinical trials and the interpretation of that data.

Early carotid stenting trials SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) and ARChER (ACCULINK for Revascularization of Carotids in High-Risk patients) showed superiority of stenting over endarterectomy in certain high-risk surgical cases (for example, restenotic lesions, high lesions, hostile neck, contralateral recurrent laryngeal nerve injury). These trials generated profound enthusiasm for carotid stenting, which can be performed without surgical incision or risk of recurrent laryngeal nerve injury. Following these trials, however, there were multiple trials throughout the world comparing carotid endarterectomy to carotid artery stenting. Some of these trials were not ideally designed and some included operators with little interventional experience. Many of these trials demonstrated unacceptably high stroke rates with stenting. These trials suggested that stenting was inferior to endarterectomy as therapy of de novo carotid stenoses. Debates further intensified at cardiovascular meetings around the world.

In an effort to end the safety and efficacy debate, the large randomized, controlled, multicenter CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial) trial was designed. This trial included only accomplished interventionalists and surgeons. It was completed after many years. In this trial, unfortunately, not all cases of intervention utilized embolic protection and there was no utilization of proximal protection devices or some of...
the newer stent designs such as micromesh stents. The official interpretation of the overall data was that there was equipoise between carotid stenting and endarterectomy as a whole, with stenting resulting in slightly more strokes (often minor and self-limiting), and endarterectomy having more cases of myocardial damage (enzyme elevations). Pundits on both sides of the debate were quick to argue which of these complications were of greater importance to patients. That debate has not been settled and continues to rage at meetings throughout the world.

Subsequent to the CREST trial there have been newer devices that have been approved that may have an impact on the rate of strokes seen in CREST. Stroke is always a potential concern when comparing a relatively mature procedure such as carotid endarterectomy with a new and developing technology like carotid stenting. One class of these newer devices is proximal protection devices, which have the potential to protect against embolization throughout the entire interventional procedure. Distal protection devices were the first devices developed to lessen embolic risk with intervention. These were the only type used in the CREST trial. When using a distal protection device, the interventionalist must first cross the lesion with the device and then deploy the filter before protection can be achieved. These devices do not capture all debris, and even when captured, the pore size of the filter allows very small particulate debris to escape through the restraining membrane that must allow free blood flow. The other class of newer devices that were not utilized in CREST and have potential to improve interventional outcomes is the micromesh stents featured in the article by Hopf-Jensen et al. The authors accurately point out that only one-third of embolic events resulting in stroke with intervention are acute. As many as two-thirds of these embolic events occur late, perhaps related to plaque prolapse.

One must question whether utilization of these devices would have changed the conclusions of the CREST trial. Is it possible that these developments are not just additive but actually transformative?

Subsequent to CREST, the ACT 1 (Asymptomatic Carotid Trial 1) trial, comparing carotid endarterectomy to carotid artery stenting in asymptomatic patients, was performed to evaluate outcomes in asymptomatic patients. This trial also did not include proximal protection or micromesh stenting. The official final interpretation of this trial was one of equipoise between stenting and endarterectomy in asymptomatic de novo lesions.

Despite the fact that these 2 well designed randomized controlled trials published in major journals show equipoise between carotid stenting and endarterectomy, there have been no changes in the policies of CMS. Heated debate continues at vascular meetings. At present, CMS will only approve carotid interventions with high-grade symptomatic lesions at high surgical risk. There are far fewer limitations placed on carotid endarterectomy.

Will CMS re-evaluate its policy, or will we be asked to perform more studies? Will these studies include proximal protection and micromesh stents? Will there be newer devices that evolve during those studies that may further lessen risk and complications? These are important questions that may determine whether companies will continue to invest in new innovation related to carotid stenting.