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A top interventional cardiologist shares his insight on the future of SFA treatment and what to expect from VIVA 2005.

Superficial femoral artery (SFA) treatment is currently a topic of great debate in the endovascular community. In 5 years, which of the current treatment options will emerge as the single-best option? The best therapy for the superficial femoral artery needs to adequately address diffuse SFA disease because this is the most common disease presentation. In this time period, it will be impossible to develop a new therapy and do the necessary research. I believe that either bare metal stents or PTFE-covered stents will emerge as the single-best option for SFA disease in the next 5 years from the current treatment field of bare metal stents, PTFE-covered stents, chemically covered stents, cryoplasty, or atherectomy. After reviewing the results of surgical endarterectomy and atherectomy, it would be surprising if any atherectomy strategy will ultimately show results similar to nitinol stents in anything but focal disease. One would certainly expect that the 1-year total lesion revascularization rate (TLR) of approximately 18% to 20% that has been seen in the voluntary marketing registry for the SilverHawk underestimates the true recurrence because this study was not scientific and many of the investigators had significant financial interest in the company with its inherent bias. This, combined with the less-than-impressive improvement in ankle-brachial index from Zeller's prospective SilverHawk study and our own experience has led me to believe that this technology will ultimately go back to a niche product, which is its current role in our lab.

Similarly, our experience and the results of the CryoPlasty registry lead me to believe that it will not improve on the results of standard balloon angioplasty. The registry's duplex-defined primary endpoint for restenosis, TLR, and dissection rate were comparable to the results of the plain balloon angioplasty control arm of the IntraCoil trial.

In our 8-year experience of using well-manufactured bare nitinol stents, we have seen good clinical utility. This personal experience is supported by our prospective, multicenter study of the Smart stent, in which we found significant improvement in walking studies and Rutherford class with a 9-month duplex-defined restenosis rate of 22% in complex diffuse disease. The 1-year TLR was 17.6%, and assisted patency was greater than 97%. Similar improvement in ankle-brachial index and Rutherford class was also seen at 2 years in the SIROCCO study. I believe the concern for stent fracture will decrease as the substandard stents with poor electropolishing, such as the Memmotherm and Luminexx, are supplanted by the stents with improved polishing and more flexibility. Similarly, PTFE-covered stents, such as the recently femorally approved Viabahn, have also seen sustained clinical improvement in properly selected patient populations. I do not know if one of these platforms would be single-best based on performance. Certainly, if the clinical results are comparable, cost will be an issue for the PTFE stents.

Is it possible that none of the SFA therapies currently on the market or in clinical trials will be clearly superior, and that an as yet unavailable device or drug holds the key to this challenging anatomy? If you compare today's nitinol stent results to balloon angioplasty (as defined when utilized as the control arm) for studies such as IntraCoil, PELA, Paris, and Vienna trials, the results of nitinol stenting for disease greater than 7cm to 8 cm is clearly superior. Again, whether nitinol or PTFE will show clear superiority is still unanswered. Beyond 5 years, my best guess is that chemically covered stents, probably self-absorbing, will emerge as the single best option. Because the embryological origin of the femoral artery is distinct from the coronary artery bed, it should not be surprising that a potentially different agent or prolonged dosing regimen may be required to decrease restenosis below current levels.

What type of data would it take to show such superiority? The data necessary to show superiority will be a combination of safety and efficacy. Although one can argue that a 50% duplex-defined restenosis endpoint overestimates clinically relevant return of disease, it is reproducible and is a concrete endpoint for which to compare different technologies in like populations.

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Please tell us about the research you are currently conducting using the Viabahn stent graft in the SFA. What is the study's design, and how have the early acute results been? I am pleased to be working with a multispecialty group of nine investigators, and Co-Principal Investigator with Patrick Geharity, MD, (vascular surgery) and Mark Mewissen, MD (radiology). The purpose of the study is to compare the PTFE-covered Viabahn stent with nitinol stents. The trial is set up as a randomized comparison in patients with Fontaine class 1-4 and complex (8 cm, TASC C and D) lesions. The restenosis will be duplex defined and stent fractures will be evaluated. The investigators will study this patient population for 3 years after treatment, and we plan to enroll over 140 patients. Although sponsored by W. L. Gore & Associates, the trial will use a core lab, so the results should be sound.

You have been an outspoken critic of an article on stent fractures that appeared in *Endovascular Today*. What is your opinion on the subject of stent fractures and what, if any, future studies are required? I have been an outspoken critic because this variable is too important to the industry and to patients to be taken lightly. I found it interesting that the authors could present such detail on the fractures but could not determine important details such as the manufacturer of the stents. A peer-review journal would have been the appropriate publication vehicle for the report. I think this is especially true in light that the authors had a significant financial interest in a nonstent technology (FoxHollow).

My opinion from personal experience, and reinforced by Professor Giancarlo Biamino's data presented at TCT '04, is that complex, full-segment stent fractures are most likely related to stent design and electropolishing. These investigators and the SIROCCO investigators did not see an association between fractures in the Smart stent and restenosis. Early in our own experience, we noticed a difference between the Smart stent and the Memmotherm. The patients appeared to feel the Memmotherm, and we saw complex fractures in a couple of patients that we had not noticed with the use of the Smart stent. We then looked back over a 5-year period and found that the patients with Memmotherm stents who returned for restenosis treatment had a higher rate and complexity of fracture compared to the Smart stent. However, assisted patency and secondary patency of all these stents were high over an average of 3 years after restenosis treatment. Stent fractures should certainly be studied to allow for improved stent designs. We are currently in the process of bringing the BLASTER patients back for x-ray evaluation combined with duplex scanning to shed more light on this event.

As one of the organizers of the VIVA meeting, what can you tell us about VIVA 2005 and about how you and your colleagues anticipate it evolving in the next 5 years? VIVA is a multispecialty educational symposium designed to provide unparalleled endovascular education. During the symposium, education is first and foremost delivered with the power of interactive computer technology beyond what is utilized at any other meeting. The use of this integrated "laptop learning" technology allows for unparalleled interaction between attendees and faculty. Despite the fact that the meeting has had more than 1,100 attendees, laptop learning allows for an intimate educational setting between attendees and the world-renowned faculty. During the next 5 years, we anticipate a major expansion of the computer-based educational effort. We anticipate more customized software, potentially partnering with major software vendors; evaluating more streamlined devices; increased involvement among the various specialties evaluating and managing peripheral vascular disease; and expanding our interactions with our professional vascular societies. Our central goal is to maintain what has made VIVA the preeminent endovascular educational symposium in the US—a commitment to solid vascular and endovascular education by multispecialty leaders using the power of interactive computer-based learning.

What is unique about your method of practice and level of patient care at MidOhio Cardiology and Vascular Consultants? What makes MidOhio Cardiology and Vascular Consultants' delivery of endovascular care unique goes far beyond just the group's ability to deliver cutting-edge procedures for the delivery of endovascular care. From the beginning, we tried to foster a true multispecialty relationship in the delivery of vascular care at Riverside Methodist Hospital. By working together with our radiology and surgical colleagues, I think we have created an environment of cooperation that I do not see at most institutions. Although all groups are able to remain independent, all abdominal aortic aneurysm stent grafts and carotid stent procedures are completed with a multispecialty team to deliver the best endovascular care while, simultaneously removing the negative politics often encountered. We have developed a multispecialty endovascular section that allows for education and quality assurance to be performed in a less-threatening environment. This delivery of disease-based care instead of specialty-based care has allowed the primary care physicians to deliver a more uniform approach to the vascular patients' care and has instilled confidence that the patients will receive appropriate care, whether it is surgical or endovascular. ■