SFA Disease: Facing Reality

Why does this vessel continue to elude long-term success, and which technique, if any, will ultimately solve this problem?

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It's no secret to today's interventionists that we have yet to conquer our most frequent adversary, superficial femoral artery (SFA) disease. Despite having numerous devices and techniques in our arsenal, we have in large part been unable to devise a treatment that yields not only excellent, safe, and reproducible acute outcomes, but also consistently good results at long-term follow-up. Industry has worked with innovative physician-inventors and has funded teams of engineers and researchers in the hopes of finding a truly successful procedure. These efforts have provided us with an astonishing array of options, most if not all of which have been refined to the point of producing very respectable "acute" results.

However, none has established itself as considerably better than the others, or better than bypass surgery, which is the current gold standard therapy. Furthermore, none has proven to be sufficiently effective at preventing long-term restenosis. This is primarily because the SFA is a very harsh environment for any endovascular device. SFA disease is often characterized by long, diffuse, occlusions (as opposed to mild focal stenoses), with relatively low flow and high-resistance outflow, relatively small target vessels, and exposure to mechanical stress due to joint flexions. All of these factors are known to negatively impact the long-term outcome of any endovascular intervention.

ANGIOPLASTY AND STENTING

Although not perfect, and not as effective as the endovascular procedures we are currently performing in other anatomic locations (eg, renal, carotid, iliac stenting), the options we currently have for treating the SFA have improved and show increasing promise. The most reliable and commonly used endovascular treatment remains angioplasty and stenting, but the last several years have seen new options emerge, stirring what has become an intense debate on which is safest, most effective, and most practical. In fact, it could be argued that the battles being waged regarding the SFA are now among the most contentious in all of vascular care. Critics of stenting point to reports of fractures and other device failures causing unacceptable rates of restenosis; on the other hand, those who regularly employ stenting as their primary treatment option defend the procedure by citing the high technical success rate, excellent safety profile, and the low incidences of stent fractures.

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DRUG-ELUTING STENTS

Recently, hopes that a drug-eluting stent (DES) might prove a useful solution to long-term restenosis in the SFA were dashed by the SIROCCO I and II trials. Although these trials did not show long-term efficacy of DESs in the SFA, they did garner some favorable attention because of the surprisingly satisfactory performance

of the control arm, which utilized the bare nitinol Smart stents (Cordis Endovascular, a Johnson & Johnson company, Miami, FL). One reason why the SIROCCO trials failed to show superiority of DESs over bare-metal stents was that the latter performed much better than expected. The results of these and other SFA stenting trials are summarized on page 68. It is hoped that further refinement in drug dosing and elution formula will show the benefit of DESs in this vascular bed. Such attempts include the Cook (Bloomington, IN) Zilver PTX trial (US and OUS phase 1 ongoing) and the Guidant (Indianapolis, IN) STRIDE trial (US phase 1 to be launched later this year).

ALTERNATIVES TO STENTING

Plaque excision, a descendent of atherectomy, is another technique that is both under relentless attack by its critics and vehemently defended by its proponents. Initial results and anecdotal reports have been impressive, but controversy surrounds this technology. Long-term results are still forthcoming, and some have taken issue with the voluntary design of the TALON registry and the financial relationship the majority of physicians involved in the study have with FoxHollow Technologies, Inc. (Redwood City, CA), the manufacturer of the SilverHawk Plaque Excision System. In this issue of *Endovascular Today*, we present the first reporting of the TALON registry's 6-month results. On the day of this writing, FoxHollow (FOXH) is traded on the NASDAQ at $39 per share, and the market cap is at an astonishing $880 MM. This points to the large potential market size as well as the excitement surrounding this disease state.

Two other devices that have had their share of skeptics and supporters are the recently acquired CryoVascular PolarCath System (Boston Scientific Corporation, Natick, MA) and the ClirPath Excimer Laser (Spectranetics Corporation, Colorado Springs, CO). Both devices have ardent supporters who attest to their successful outcomes in treating peripheral artery disease and detractors who have cited the absence of compelling data to support their use. CryoVascular began the Big Chill Registry and Spectranetics sponsored the LACI and PELA trials, both of which showed promising but inconclusive results due to the design of the trials (nonrandomized). These studies are also summarized in the SFA study chart on page 85.

LOOKING AHEAD

The future for SFA treatments may lie in some of the studies presently taking place, which are also summarized in this issue. Two brave companies, Edwards Lifesciences (Irvine, CA) and C.R. Bard, Inc. (Murray Hill, NJ) are each conducting prospective, multicenter, randomized trials that may prove the effectiveness or futility of using their respective bare-metal stents to treat the SFA. Regardless of their success, randomized trials such as these are sorely needed to test our theories of treatment and improve our understanding of treating this vessel, and we in the medical community should applaud those efforts. NovoStent (Santa Clara, CA) has also developed a novel stent that is low profile and accurate to deploy. Most importantly, its fracture resistance is 10- to 20-fold higher than any existing nitinol stent due to the unique spiral design. Human trials are expected to be launched in Q4 2005.

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Endovascular Today is presenting the following SFA articles as individual physician's views and experiences with several of these respective technologies, as well as a few more techniques to consider. We do not claim that these articles represent the definitive word on the treatment of the SFA or the individual technologies. In fact, many interventionists who specialize in treating the SFA recognize the need to become familiar with the full array of devices until one device is clinically proven to be superior to the others. The controversies surrounding these various devices may be the result of the insufficient data to support any one technology. For the time being, I think it is fair to say that surgical bypass remains the gold standard for more advanced SFA disease (TASC type D), and angioplasty with nitinol stents is a very reasonable option for the remainder of SFA disease. Hopefully, the updated TASC document, which will be published later this year, will reflect many of the endovascular advances made in this field. We intend to continue to explore the validity of these technologies, and I recommend that you look to the August issue of *Endovascular Today*, which will provide both a critique and defense of many of these exciting yet unproven options. ■

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