



SFA Stenting Update: The VALIANT Trial

Interventions of the superficial femoral artery continue to present difficulty, but the results of the VALIANT trial will evaluate whether this new technology is up to the challenge.

BY GARY M. ANSEL, MD, AND KRISHNA ROCHA-SINGH, MD

The superficial femoral artery (SFA) is one of the most controversial areas of revascularization. It is also one of the most exciting because we have the potential to take what is essentially a poor surgical procedure—a femoral-popliteal bypass (poor because of the morbidity and risk that may be involved)—and change it to an outpatient therapy that is very easy, especially if we can incorporate dependable vascular closure devices.

CHALLENGES OF THE SFA

The SFA is probably the last bastion in trying to achieve favorable endovascular results. It has a very unfavorable anatomy, and the inflow and runoff pose a constant challenge. We have to worry not only about the vessel located in the thigh, but also what is above, in the iliac and aorta, as well as below in the runoff trifurcation vessels. There are two vascular bifurcations, one at the profunda level and one at the tibial vessels. There are also articulation points because of the joints at the hip and the knee. The adductor canal gives unique vessel forces, which include flexion, compression, torsion, and elongation. Commonly, diffuse disease is present, similar to what can be found in the coronary vessels. Intravascular ultrasound in coronary vessels that have focal stenosis can commonly demonstrate more disease than is appreciated using angiography. There is no vascular bed that has the vessel length of the SFA. It also has a high incidence of total occlusion disease, and the lesion morphologies are often very complex. There is also an unusually high prevalence of calcification.

HISTORIC RESULTS

The angioplasty results in the SFA have historically been poor. Compared to the aortoiliac region, acute success has been reported in the range of 72% to 95% in the SFA versus approximately 95% to 97% in the aortoiliac region. The 1-

to 3-year patency rates at follow-up are in the 50% to 60% range. In the recently completed Peripheral Excimer Laser Angioplasty (PELA) trial, the average lesion length was almost 20 cm in each group, randomized to approximately 100 patients in the laser group and 90 in the balloon angioplasty group. The primary patency was <50%, as determined by ultrasound with no reintervention. Statistically, there is really no difference in balloon versus laser groups. Looking at the 12-month duplex ultrasound, the number of patients that have <50% stenosis is under 50% of the laser patients and 58% in the balloon-treated group.

Not surprisingly, we simply are not seeing adequate results with balloon angioplasty alone, because in coronary intervention, when the length of a lesion exceeds 15 mm to 20 mm, the restenosis rates become exceedingly high. Radiation certainly has shown success in the coronary literature, just as it does in some of the other areas. For exam-

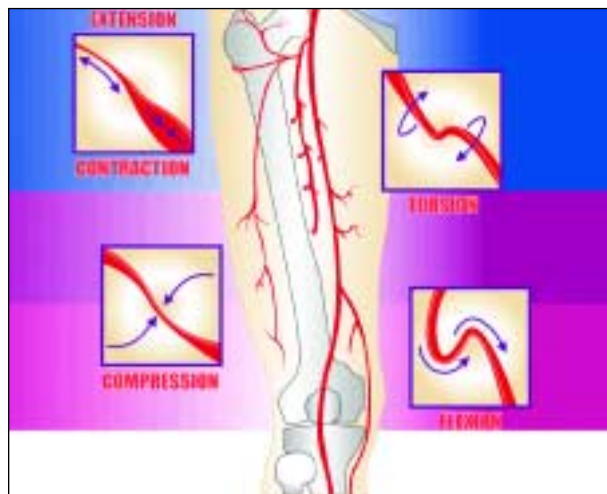


Figure 1. The SFA is subjected to unique mechanical forces not found in almost all other arterial beds.



Figure 2. The aSpire stent (Vascular Architects, San Jose, CA).

ple, there is a high degree of success in decreasing keloids after surgery. The Peripheral Artery Radiation Investigational Study (PARIS) trial compared radiation and balloon angioplasty in de novo SFA disease. The average age and incidence of diabetes were not significantly different in the two groups. The patients studied had an average pretreatment ankle/brachial index (ABI) of 0.72. Patients were claudicants, not limb-salvage candidates. When 203 patients were randomized, 105 underwent brachiotherapy versus 98 who received placebo. However, one of the shortcomings of the trial was that repeat angiography was only completed in small numbers of the patients. This makes drawing any conclusions difficult.

The treated lesion lengths were fairly short (about 5 cm to 6 cm); reference diameters, as one would expect, were approximately 5 mm. There was no statistical difference in segmental restenosis. However, this was a poor trial with questionable results because of the lack of true follow-up. In fact, this is the first radiation trial that has not shown benefit.

If we look at the prospective Wallstent (Boston Scientific Corporation, Natick, MA) and Palmaz stent (Cordis Corporation, a Johnson & Johnson company) trials during the time period from about 1989-1997, we see dismal results: patients = 585, limbs = 600, with most of these patients being claudicants. Certainly, you can achieve a high degree of technical success putting Wallstents in the SFA. Complication rates appear to be approximately 7%, mostly from bleeding. Patency rates at 1 year were approximately 67%, decreasing at 3 years to approximately 58%. However, some trials have shown even lower patency rates. Conversely, other than compression that was seen on intervascular ultrasound, the failure of Palmaz stents may not be the result of the stent metal itself being inherently bad, leading to intimal hyperplasia.

One of the major shortcomings of these early trials is that they focused on warfarin therapy, not antiplatelet therapy. The results of these trials that utilized Wallstents and Palmaz stents may be improved with more optimal study design.

IS NITINOL THE BEST STENT MATERIAL?

Nitinol stents give us unique properties, such as dynamic interference, providing much more elasticity to the alloy.

The stent designs are better with minimal foreshortening. This metal is thermally reactive; when the stents warm to body temperature they become much firmer, which facilitates deployment.

There are unique mechanical forces in the SFA that are not present in almost any other arterial bed. Any stents used in this area must have the ability to oppose these forces. There is extension and contraction as the leg is bent; this occurrence was not fully appreciated early on. Torsion as the vessel turns during the flexion and contraction was also not appreciated (Figure 1). Compression also occurs, especially as the vessel traverses through the adductor canal.

INTRACOIL

There is only one FDA-approved nitinol stent—the Intracoil (ev3, Plymouth, MN). The Intracoil stent trial was primarily a focal lesion study. More than 60% of the vessels treated had only focal disease. This may have been because it was a randomized trial between stenting and angioplasty, and the investigators may have felt uncomfortable performing angioplasty in longer lesions. There was an insignificant trend toward slightly longer lesions in the stent group with also more occlusions. Popliteal disease was fairly similar between the two groups. Acute angiographic success was measured and was found to be similar (85% to 82%). The results of this trial showed no statistical difference in 9-month restenosis as determined by angiography, although there was a trend toward higher restenosis in the stent group. More importantly, however, is that at 9 months, TLR was <83% in both groups. In peripheral trials, there may be a clinical disconnect between what we call restenosis on an angiogram (50%) and what is clinically important restenosis. Very few of the patients in the Intracoil trial were symptomatic, even though almost 40% of them have been categorized as restenotic by angiography. The stented group had a statistically significant improvement compared to the balloon group in ABI improvement at 9 months, even if on angiography there seemed to be a higher restenosis rate. This disconnect needs to be addressed so that we can figure out how to run future trials better.

Comparing the complication rates between the two groups revealed interesting findings. The combined com-

plication rate of MACE plus abrupt closure, renal failure, major bleeding, and amputation, was statistically lower when a primary stent strategy was used. This finding may have played a large role in this stent gaining approval, since the FDA panel voted not to approve this stent. The panel's recommendation was a boon to most of us because we clearly needed a device to safely treat dissection. The study also found that even for this focal stenosis population, more than 7% crossed over to stent for bailout.

THE VALIANT TRIAL

The VALIANT Trial is an evaluation of the aSpire stent (Figure 2). This stent is a helical PTFE design that will potentially allow collaterals to stay patent the noncovered areas. The helical structure was designed to allow for control of some of the unique forces of the SFA. It was originally introduced as an 8-F device, which is now being shortened to a 7-F device to facilitate delivery. It is flexible and conformable. There appears to be side-branch protection and, hopefully, preservation of laminar flow. Because this stent is so flexible and allows for four-dimensional change in bending of the artery and all the different forces (extension, shortening, and so forth), we should be able to preserve laminar flow and not change the flow characteristics of the vessel bed. There is a high degree of radial strength without total lumen coverage, which may be very important in preserving collateral vessel flow if restenosis occurs.

When the guidewire is inside the vessel, the 7-F device comes inside with the stent actually wrapped around the delivery device. The operator can control the release, which theoretically allows for very precise positioning. The stent can be unwound and, before the ends are released, it can be rewrapped and have its location moved. There is very controlled expansion, slowly unwrapping the stent into the vascular bend allows one to assess the position prior to releasing this stent from the delivery device.

The VALIANT trial is an investigator IDE, multicenter, nonrandomized, prospective, observational trial. The primary endpoint is 9-month duplex, Doppler-defined restenosis, assessed by a core lab. VALIANT will assess the incidence of stent fracture and migration, as well as restenosis. So far, 77 patients have been enrolled, with a target enrollment of 110 patients. To date, the majority of the patients are male, with a mean age of 70 years (range, 45 to 89). A large number of patients are tobacco users, and there is a high incidence of diabetes. Some previous trials involving the SFA did not include diabetics because this population has demonstrated high restenosis rates, but this trial is now taking on this tough patient population. Most of the lesions are *de novo* with a smaller number of restenotic lesions. In-stent restenosis has been excluded.

Whereas most of the other SFA trials have looked at TASC A and B or more focal disease, VALIANT focused more on the TASC C, more diffuse, short-segment total occlusions. This study design will offer an idea as to whether this stent strategy works in clinically common lesions. The current trial enrollment has the majority of these lesions in the SFA, with only 4% of these in the popliteal artery. The mean lesion length is currently 10 cm; investigators try to stent past the lesion so that we do not leave an edge dissection. Thus, the average stented length is going to be a bit longer than the lesion length, approximately 12.5 cm. The number of tibial runoff vessels is pretty evenly divided between one-, two-, and three-vessel runoff.

This trial is going to potentially give us significant information about the real world results of SFA stenting with this type of stent in patients with multiple types of runoff. This will hopefully provide insight into the factors that affect restenosis as well. Currently, the preprocedure ABI is at a mean of 0.6. This stent seems to allow for excellent acute clinical results with an average poststent ABI in the normal range of 0.9 at discharge.

CONCLUSION

SFA stenting is in need of more scientific investigation. The poor designs of the early trials must be overcome. Nitinol stenting appears to offer a new unique form of therapy for this vascular bed that has many unique external forces. There are few prospective trials investigating the tubular nitinol stents, but early data indicate a need to assess the long-term outcome of fractures that have become evident. The VALIANT study that is currently ongoing may offer important information regarding the treatment of the SFA. This unique, covered, spiral nitinol stent design may appear to address the unique forces present in the SFA. The VALIANT trial will not only evaluate Doppler-defined restenosis, it will also investigate the incidence and significance of stent fracture using uniform criteria and methodologies. This type of evaluation should be much more accurate than angiography alone. Hopefully, the results of the VALIANT trial will provide important insights into the future of drug-eluting stent trials in the SFA by trying to define which populations will benefit from drug elution in the near future. ■

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