

# Overview of Vascular Closure Devices

The state of the art 1 year later.

BY ZOLTAN G. TURI, MD

**D**uring the past year since I had the privilege of reviewing the state of the art in vascular closure for *Endovascular Today*, the overall use of vascular closure devices has continued to grow, perhaps by as much as 20%.<sup>1</sup> To some degree this not only parallels but exceeds the steady increase in endovascular procedures world-wide. Although there has been further evidence in the literature regarding the potential benefits of these devices, future growth may be influenced by continuing uncertainty over the risk/benefit ratio and the major issue of unreimbursed cost. This observer believes that the overall safety profile of closure devices remains muddled, and that unless randomized controlled trials are introduced, this continued expansion may slow.

## IN THE PIPELINE

There are a number of devices that underwent animal and clinical testing or have received regulatory approval. These included suture based products such as the X-press (X-Site Medical, Blue Bell, PA) and staple devices such as the EVS (AngioLink, Taunton, MA). QuikSeal (Sub-Q, Inc., San Clemente, CA) has features similar to VasoSeal (Datascope, Montvale, NJ) but uses Gelfoam instead of collagen. AutoClose (Rex Medical, LP, Conshohocken, PA) has similarities to Angio-Seal (St. Jude Medical, St. Paul, MN) but uses a nitinol clip. Matrix (AccessClosure, Palo Alto, CA) is a polyethylene glycol sealant with a delivery system similar to the Duett (Vascular Solutions, Minneapolis, MN), and SuperStitch (Sutura, Fountain Valley, CA) is a system with similarities to Perclose (Abbott Vascular Devices, Redwood City, CA).

Several truly novel approaches are in the works. SoundSeal (Therus/Boston Scientific Corporation, Natick, MA) uses external application of ultrasound to the arteriotomy site to heat the vessel wall collagen and form a seal. A single series by Grube has been described (presented at TCT 2003). The device incorporates an algorithm to properly focus the ultrasound beam; it requires no invasive manipulation, and no foreign body is left behind. The key

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to its success will likely be the effectiveness of the algorithm used to target only the puncture site, and avoid neural damage, adjoining venous beds, and potential other adverse consequences of misapplication of the ultrasound energy. Epiclose (Cardiodex, Tirat-Hacarmel, Israel) is a device that uses a balloon in the tissue track to compress the arteriotomy site until hemostasis is achieved. A small study in diagnostic catheterization patients has been reported. How effective this simple concept would be in the interventional setting is unknown.

## IN OUR HANDS

Another external approach, topical application of thrombogenic agents, has continued to grow despite virtual total lack of evidence-based medicine in this area. The Syvek Patch (Marine Polymer Technologies, Danvers, MA), Closure Pad (Scion, Miami, FL), and Chito-Seal (Abbott Vascular Devices) have grown substantially in use and represent approximately 20% of the total vascular closure device market in number of patients. D-Stat (Vascular Solutions) is a thrombin pad that was introduced recently. HemaDerm (Medafor, Minneapolis, MN) and Neptune Hemostatic Pad (TZ Medical, Portland, OR) are also seeing some utilization. Although widely used for postarteriotomy closure, only some of these devices have been approved for this indication by the FDA. Their theoretical benefits, if effective, are substantial: the absence of a foreign body in the tissue track decreases the risk of infection, and the cost is substantially lower than it is for the invasive devices. Furthermore, they can more readily be applied by support staff. Theoretical disadvantages include clot retraction toward the skin surface, potentially enhancing the risk of

pseudoaneurysm, or masking retroperitoneal bleeding, a problem faced by all of the closure devices; in the absence of data these risks are purely speculative.

## EXAMINING THE LITERATURE

The literature has been only slightly more appealing to the critical reader in the past year. Possibly the most important (but unavoidably flawed) study was a meta-analysis by Koreny et al from who attempted to analyze the risk-benefit ratio across 30 randomized controlled trials.<sup>1</sup> Although their conclusion was that closure devices appeared at best “marginally effective,” they expressed concern about increased rates of hematoma formation and pseudoaneurysm. As the authors stated, and as I pointed out in *Endovascular Today* last year, the pool of available studies is methodologically weak, and it remains impossible to gauge true efficacy and safety from the existing literature. Most of the studies on which the Koreny paper is based suffered from the same weaknesses prevalent in this literature: investigators in their learning curve, mismatched anticoagulation regimens between devices and control, and failure to obtain angiograms of the access sites before device development (despite explicit requirements stated in the Instruction for Use). The latter undoubtedly resulted in devices deployed in arteries that were too small or punctures that were in the wrong location or at diseased vessel sites. This meta-analysis also included studies from a prior era of large sheaths, overanticoagulation, and devices that are now obsolete. In contrast, a number of papers in the past year have randomized patients to smaller trials where closure devices demonstrated equivalency or superiority not just in early ambulation (which we have come to take for granted), but in some measures of safety as well.

## POINTS TO CONSIDER

As pointed out last year, the primary determinant of vascular closure success is the quality of vascular access. It is my sense that somewhat more of my colleagues now use fluoroscopy for assessing puncture location, but not doing this remains a major failing on the part of most cardiologists in particular. I can only express admiration for a technique well known to interventional radiologists but foreign to all but a few cardiologists: ultrasound visualization of vessel anatomy as an adjunct to vessel puncture. It is remarkably simple, effective, cheap, and time saving, and in my opinion a method that limits access complications.

The vascular closure market currently exceeds \$400 million annually. This is driving an increasing number of medical device companies without prior exposure in closure devices into expending engineering efforts in this direction, as well as seeing new start-up ventures. Thus further innovation can continue to be expected. The continual expansion

of endovascular procedures will undoubtedly also fuel growth in this market. Despite this, there are several notes of caution, and some reasons for skepticism that I would like to share.

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The use of diagnostic angiography, both for coronary artery disease and particularly for peripheral vascular disease, is likely to decrease at some point as superb new diagnostic tools are enhanced, particularly multislice CT and MRA. Smaller diagnostic catheters make the risk/benefit ratio of closure device use, particularly the invasive devices, less appealing. The radial artery approach continues to be an important alternative and is particularly prevalent in Europe. The uncertain risk/benefit ratio of closure devices, exacerbated by the lack of good evidence-based medicine leaves practitioners to rely on their biases. These biases are fueled by the occasional major complications attributed to these devices, particularly infection, which for those who have seen it are some of the most stark in medicine. The occasional loss of limb, catastrophic bleed, and death, although rare, raise the possibility of an emperor's clothes syndrome: 5 years from now, will we wonder why we ever adopted such widespread use? I think not, but until a consortium of device manufacturers, or a major nonindustrial sponsor is willing to support a properly designed and conducted study, none of us can be sure that our clinical practice of today will look like the product of sound judgment tomorrow. In the meantime, vascular closure devices significantly enhance patient comfort and simplify postprocedure care; they avoid the risks and discomfort associated with indwelling sheaths and continue to be an appealing alternative for many physicians and patients to manual compression. ■

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1. Koreny M, Riedmuller E, Nikfardjam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. *JAMA*. 2004;291:350-357.