The past year saw the effect of the recession in endovascular procedures trickle down to vascular closure devices (VCDs): fewer catheterizations and fewer interventions led to at least a slowing—if not a reversal—of the persistent growth seen in VCDs in the past decade. Despite the economic realities of a maturing market, diminishing growth, and increased competition, a number of new devices made their appearance. Several devices had significant changes in platform, and at least one important new technological concept was introduced. As in the previous 6 years, I will review the status of the existing technologies, introduce technologies in the works, discuss some of the practical and theoretical issues affecting vascular closure, and comment on a few of the more important articles in the medical literature. I will take the liberty of using my annual soapbox on safety, discuss VCD complications in general, and revisit the issue of retroperitoneal hemorrhage and VCDs. Finally, the classification system first introduced in this review 2 years ago has now been adopted in an increasing number of settings but is included as Table 1 for those who are unfamiliar.

**EXISTING TECHNOLOGY**

Angio-Seal (St. Jude Medical, Inc., St. Paul, MN), a “belts-and-suspenders” device because it incorporates active approximation of the arteriotomy along with a thrombosing agent in the tissue track, continues to dominate the vascular closure market. It is favored with a short learning curve, a high success rate even in the setting of full anticoagulation, and a modest (but very important) complication rate. It is handicapped by two properties inherent to the technology. First, the anchor placed inside the vessel produces a transiently visible filling defect in the arterial lumen and is occasionally obstructive, either at the puncture site or with embolization. Second, it leaves a mass of collagen inside the tissue track and a suture that extends from the arteriotomy to near the skin surface, providing both a nidus and a wick for potential infection. Repuncture should be done with caution during the first 3 months, although a small published series demonstrated no complications.1

Perclose (Abbott Vascular, Santa Clara, CA) remains popular among those who prefer the well-established surgical approach of suturing arteriotomies. It leaves less foreign body inside either the artery or tissue track, but unlike Angio-Seal, does not resorb. StarClose (Abbott Vascular) deploys a nitinol clip rather than suture, is simpler to use than Perclose, and is designed not to leave behind any intraluminal foreign body. In general classification terms, it is similar to Perclose, featuring active approximation, a permanent foreign body, and no thrombosing agent; thus, it has less of a nidus for infection but more of a predisposition to ooze after the procedure in fully anticoagulated patients. The latter may be exacerbated by the diameter of the StarClose deployment shaft. Both Perclose and StarClose lend themselves well to immediate repuncture. There is no restriction on reaccess after Perclose; the evidence base for repuncture after StarClose is modest but has worked well in our experience.

The Boomerang ClosureWire (Cardiva Medical, Mountain View, CA) has a unique niche in vascular closure. Unlike Angio-Seal, Perclose, or StarClose, it is a passive approximator, relying on a nitinol disk inside the artery, with a spring mechanism to maintain traction at the arteriotomy inside the vessel until hemostasis occurs. A theoretical drawback is the need to withdraw the relatively low-profile collapsed assembly through the freshly formed plug, requiring additional compression. Its appeal includes the lack of any foreign body left behind (reducing the risk of infection), ability to repuncture with the same considerations as if manual compression had been used, and deployment through the original procedural sheath. A new version, the Boomerang Catalyst, is designed to provide facilitated thrombosis in the tissue track by exposing two agents on the shaft of the device to stimulate coagulation, platelet adhesion, and platelet aggregation when tension is applied to the disk inside the
As with other passive approximators, the litmus test for this device will be its success and complication rate in the setting of the vigorous anticoagulation environment of interventional cases. A more extensive list of devices is included in Table 1.

NEW TECHNOLOGY
The Thresholds for Successful New VCDs
Most laboratories cannot afford the shelf space or inventory management issues raised by stocking more than two or three closure devices. A successful new device in the increasingly crowded VCD marketplace has to meet one or more of the following standards:

- A high enough success rate in both diagnostic and interventional procedures to be the primary, go-to device in the lab
- Favorable features (ease of use, short learning curve, slick deployment mechanism)
- A niche that is perceived valuable
- Perceived low risk of associated infection
- Favorable features for use in peripheral vascular disease or puncture outside the common femoral artery
- Favorable features for use in nonfemoral access
- Manufacturing costs that allow a sustainable profit

The last item, manufacturing costs, may seem tangential to the other considerations, but I suspect this has been the primary cause of some otherwise novel technologies never making it to market. The original VCD, VasoSeal (Datascope...
Corp., Montvale, NJ), consisted of a few molded plastic parts and one or two collagen plugs. More complex technologies, with finely milled pieces made of expensive metals and multiple moving parts can be prohibitively expensive to manufacture. Device failure, not just failure to achieve hemostasis but failure to function perfectly, is not acceptable to clinicians, patients, or their lawyers, thus the technical demands in this crowded intellectual property space require substantial creativity.

Return of the Unanchored Plugs

After the demise of both the Duett (Vascular Solutions, Inc., Minneapolis, MN) and VasoSeal (both available from the manufacturer but no longer actively marketed), it appeared that the potential drawbacks of passive closure were proving to be a significant factor in VCD success rates and acceptability. Although both devices had secular issues (VasoSeal had a high failure rate, particularly in fully anticoagulated patients, whereas the Duett was associated with occasional intra-arterial injection, sometimes with catastrophic results), the lack of active approximation was perceived to be a drawback for use in the interventional environment. Failure of devices in anticoagulated patients is at best messy, requiring prolonged compression with or without adjunctive use of other devices and is associated with a significant complication rate. The greater success rates of active approximators, such as Angio-Seal and Perclose, relegated the unanchored plugs to small shares in the VCD market.

Thus, it is something of a surprise that the most prominent new VCD marketed in 2007 and the next important device likely to be released are both unanchored plugs. Both devices, the Mynx (AccessClosure, Mountain View, CA) and ExoSeal (Cordis Corporation, Warren, NJ), also share several other characteristics: they utilize biopolymers that are sealing rather than thrombosing agents, both deploy through the existing vascular sheath, and both feature streamlined, short learning curve delivery mechanisms. The Mynx (polyethylene glycol) is being actively marketed, and the ExoSeal (polyglycolic acid) has finished its pivotal trial but is not yet FDA approved. Although both devices appear to have high success rates, yet to be determined are the failure rates in the real-world interventional environment and how well sealing agents stack up against thrombosing agents (ie, biopolymers vs collagen) with regard to tissue track oozing in fully anticoagulated patients.

Given the low single-digit failure rates that operators expect with closure devices in interventional cases, the challenge for these unanchored plugs will be to match that standard in the full anticoagulation/antiplatelet agent environment. If they do, these devices will benefit from their ease of use; if they do not, they will be relegat-
ed to that second tier reserved for VCDs used primarily for diagnostic catheterizations.

TECHNOLOGY IN THE WORKS

A new class of devices has entered the VCD world, best described as “closure begins with access,” or CBA. This should be distinguished from “preclosure,” typically the deployment of Perclose at the time of initial access and before upsizing the sheath from 6 F or so to very large sizes (up to 24 F in some cases). Preclosure has been around for at least a decade and has had considerable success in settings such as percutaneous stent graft placement for abdominal aortic aneurysms. Now, two true CBA devices have appeared. The FISH (Femoral Introducer Sheath and Hemostasis) device (Morris Innovative Research, Bloomington, IN) uses small intestinal submucosa wrapped around the access sheath, which is deployed as the sheath is withdrawn at the end of the case. This device is FDA approved. Considerable interest has been provoked by the initial presentation of data on the Arstasis device (Modesitt, San Carlos, CA).

This technology creates a dissection plane in the femoral artery at the time of access to create a self-sealing mechanism as the sheath is withdrawn at the end of the case. Unlike FISH, the Arstasis concept leaves no foreign body behind. A small, first-in-man pilot study presented at the TCT 2007 meeting was reasonably successful. Several important issues need to be answered before it will be possible to meaningfully comment on the long-term future of the Arstasis concept:

- The applicability of devices based on this technology to interventional cases
- The applicability to femoral arteries with atherosclerosis and particularly calcification
- The potential implications of high or low femoral access
- The ability to use these devices in patients with perivascular fibrosis, such as is seen after multiple femoral access procedures
- The nature of postprocedure healing as compared with manual compression or current VCDs

Both of these devices raise the issue of a need to evaluate the femoral artery before access so as to avoid small or diseased arteries. The need to enter a healthy segment of the common femoral artery may help speed up an
evolution of two approaches I have advocated in *Endovascular Today* in the past. First, there will be benefit from performance of better and more comprehensive evaluation of the common femoral artery for disease and level of bifurcation before access is obtained. Second, use of fluoroscopic and ultrasound techniques can ensure entry into the ideal target zone (Figure 1) in the common femoral artery rather than in one of the bifurcation vessels or above the inguinal ligament.

**VCDs FOR OTHER APPLICATIONS**

Several VCDs are being adapted for applications other than vessel closure. A logical consideration for suture technologies has been expansion to closure of patent foramen ovale (PFO). Sutura, Inc. has had a recent first-in-man series with the SuperStitch EL, a modification designed for percutaneous PFO closure. At least one PFO was sealed in 2006 with Perclose, and a spin-off from Abbott (Ovalis, Mountain View, CA) has been developing a percutaneous device for this indication. Cardica Medical (Redwood City, CA), which is developing a VCD, is also developing a PFO closure device, although the nature of their technology is not in the public domain.

**THE DARK SIDE**

All enthusiasm for VCDs needs to be tempered by the dark side of all medical devices: complications. In the VCD world, this issue is exacerbated by the continuing unresolved issue of the risk/benefit ratio of VCDs versus manual compression. Figure 2 shows the relative risk of VCDs versus manual compression in a number of metaanalyses and propensity analyses. There is tremendous noise in these data and, as discussed in several of our previous reviews in *Endovascular Today*, the results are muddled by learning curve issues, changing device platforms, changing clinical practices, and the inclusion of devices or generations of devices that have been supplanted by better technology.

**Retroperitoneal Hemorrhage Revisited**

Nevertheless, it is clear that some complications are additive to manual compression. These include infection (discussed in detail in last year’s review), vascular obstruction, retroperitoneal hemorrhage (RPH), and possibly nerve entrapment. RPH has been discussed in previous years in this article, but in lecturing on this subject, I am reminded that awareness of the potential additional risk of deploying VCDs in high sticks has not been adequately disseminated to the interventional community.

The salient factors are as follows: high sticks, those above the inferior epigastric artery’s lowest point of excursion (Figure 1), are associated with an odds ratio as high as 17:1 of RPH. The mechanism has obvious and somewhat more subtle features. The obvious is the potential for free bleeding into the retroperitoneal space once the inguinal ligament has been crossed. The less obvious is...
the mechanism of failure when a closure device is utilized. Figure 3 shows why a plug (and possibly a stitch, clip, or other element in a closure device approaching through the tissue track) would fail to land on the arterial surface: the presence of layers of tissue, notably the transversus abdominis muscle, obstructs passage down to the artery.

Although still lacking a solid evidence base, several straightforward recommendations for postprocedure management deserve to be emphasized (Table 2). Ultimately, RPH continues to challenge excellent institutions and interventionists. It is unfortunate, because it remains a cause of mortality in every hospital. In my opinion, if the routine steps in Table 2 are followed, the
rate of RPH and its consequences can be decreased substantially, although unfortunately not eliminated.

The FDA Database

Although suffering from grossly incomplete reporting, the FDA Manufacturer and User Facility Device Experience (MAUDE) database remains a treasure trove for assessing the complications associated with technology including VCDs. I reviewed the reports for 2007 available as of February 2008. It is important to point out that a minority of complications are reported, that the details of individual cases are notoriously incomplete, that the data are replete with noise, and there is some duplication. No Clinical Events Committee adjudicates these reports, and thus assignment of causality is hazardous. Further, different institutions, and for that matter, different vendors have disparate reporting standards.

“The FDA MAUDE database remains a treasure trove for assessing the complications associated with technology including VCDs.”

The five closure devices with a significant footprint in the database (Angio-Seal, Perclose, StarClose, Mynx, and Boomerang) had a total of 1,499 adverse event reports in 2007, including 22 deaths, of which several may not have been device related. Of these 22, 15 were due to bleeding, almost all retroperitoneal hemorrhage, four were due to infection, and three were complications of vascular obstruction. The devices had various propensities for mechanical failure, obstruction of the artery, need for surgical removal, infection, pseudoaneurysm formation, and most importantly, blood loss. It is important to point out that there is no MAUDE database for manual compression, and despite Figure 2, the verdict may never be in on a clear risk-benefit ratio.

The MEDICAL LITERATURE

Four articles deserve particular mention from the past year. The overall complication rate of vascular access and closure is decreasing, as shown in an analysis of more than 36,000 PCI patients from the Northern New England Cardiovascular Disease Study Group. In the interval between 2002 and 2006, the rate of major vascular complications decreased from 3.4% to 2%. The extent to which this resulted from better access techniques, better adjunctive sheath and pharmacological management, or better VCDs and better VCD deployment techniques is unknown. For a surgeon’s perspective on VCD complications, including a suggested algorithm for complication management, the latest article on this subject by Eidt and colleagues is enlightening.

A cost-minimization analysis of VCD versus manual compression by Resnic and colleagues suggests potential cost savings with VCD use, despite the cost of these devices, largely based on a lower complication rate with VCDs—a finding that will not apply universally to all hospitals, operators, or types of VCDs. Finally, a carefully conducted propensity analysis of nearly 13,000 patients undergoing diagnostic catheterization and PCI showed statistically significant lowering of complications with VCD use (Figure 2). This study is part of an overall trend suggesting improving VCD results and hopefully reflects the increasing attention being paid to vascular access and closure in general.

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