Transcatheter aortic valve replacement (TAVR) has become the standard of care for patients with aortic stenosis who are at prohibitive surgical risk.1,2 In the early TAVR experience, devices were typically delivered retrograde across the aortic annulus via femoral or subclavian cutdown. Completely percutaneous transfemoral (TF) access and antegrade transapical (TA) access were later introduced as viable methods of device delivery. Given the high-risk characteristics of most patients undergoing TAVR, procedural complications are common and frequently associated with the access site. Furthermore, major access site complications have been associated with increased mortality.1,3

Many of the characteristics that define this population as being at high surgical risk are also associated with procedural risks related to the access site, including iliofemoral vascular disease (TF access), left ventricular (LV) dysfunction, and obstructive airway disease (TA access). Although increasing operator experience and continued technical improvements to devices may have led to a reduction in TAVR complications,4 there is a real need for approaches that further limit the morbidity and mortality associated with the access site.

Dedicated closure devices for both TF and TA access have been developed with a view toward greater procedural ease, improving hemostasis at the access site, and reducing major complications. An increasing number of novel devices are under development and will be reviewed in this article. Although the less frequently used transaortic and subclavian access routes provide viable access options when TF access is not feasible, closure devices dedicated to these access routes are not yet available and therefore will not be discussed in this article.

**TF ACCESS FOR TAVR**

After the early TAVR experience using surgical cutdown, fully percutaneous TF access has become the dominant method of device delivery. Despite the routine use of femoral closure devices, meticulous patient selection and preprocedural planning still underpin the avoidance of major femoral complications, including major bleeding and vascular injury. Furthermore, the use of closure devices should in no way distract operators from the critical importance of meticulous technique when performing the arteriotomy, with particular attention to avoiding the femoral bifurcation and branches, heavily calcified or diseased segments of vessel, and an unnecessarily high arteriotomy.

All of these considerations depend heavily on careful planning using CT angiography. Ultrasound-guided femoral puncture is increasingly employed, although no published data are available regarding its use specifically in the setting of TAVR. In the setting of femoral access for coronary and peripheral angiography or intervention for stable disease, the use of ultrasound guidance has been shown to reduce complications and improve the rate of first-pass cannulation of the common femoral artery in patients with a high bifurcation.5 Direct angiographic guidance for puncture of the side intended for large sheath passage is also common, utilizing a diagnos-
tic catheter passed into the common iliac artery from the contralateral side. Following access, prompt recognition and management of complications are also key to reducing their impact.

Most fully percutaneous TF TAVR utilizes suture-mediated closure devices that were not specifically designed for the very large arteriotomy that results from the 18- to 24-F (external diameter) sheaths that are required for the current commercially available transcatheter valves. Both the Perclose ProGlide (Abbott Vascular) and the Prostar XL (Abbott Vascular) devices can provide effective hemostasis after TF TAVR, however, not without the potential for complications. At least two, and sometimes three, ProGlide devices are required, and suture capture may not be possible in very calcified vessels. Precise deployment of the Prostar device can be difficult in obese patients, those with scar tissue related to previous procedures, and those with heavily calcified femoral vessels. Although seldom used in the current TAVR era, Prostar can be considered as a second-line device to facilitate closure in the case of ProGlide failure, before opting for a surgical cutdown to ensure hemostasis.

Important novel techniques have also been developed to improve the safety and efficacy of closure with suture-based devices and warrant mention. The best described of these techniques is the crossover balloon occlusion technique, which utilizes a contralateral 0.018-inch wire passed over the aortoiliac bifurcation to allow occlusion of the external iliac artery proximal to the large sheath arteriotomy with an 8- to 10-mm angioplasty balloon (Figure 1). Not only does this technique allow for sheath removal and suture tying under reduced local arterial pressure, it can also facilitate prompt balloon tamponade in the case of major bleeding, prompt balloon angioplasty of an important residual stenosis or dissection, and guarantee wire position in the distal true lumen in the case of such complications. The crossover technique has been shown to be safe and feasible in TF TAVR closure, with very low rates of access site complications.

Temporary distal aortic balloon occlusion has also been described with similar effect.

NOVEL TF CLOSURE DEVICES
Despite meticulous patient selection and operative planning, access site complications remain a leading cause of adverse events after TAVR. As such, significant interest has developed in the area of dedicated closure devices for TF TAVR. The mechanisms of these devices can be broadly defined as suture-mediated and patch/plug technologies. Several devices of both mechanisms are in advanced stages of development for use in closure of large vessels, although they are not in wide clinical use as of yet.

The VasoStitch helical suturing system (CardioLogical Solutions) delivers a coil inside the artery, which is then withdrawn. As the coil is withdrawn, a running, helical
suture is pulled through the length of the arteriotomy, closing the access site.

The Spirx mattress suture device (Spirx Closure, LLC) houses a nitinol needle that takes a curved shape on entering the artery. The curved needle is then able to draw a Prolene suture back through the arterial wall before pulling the suture ends out to the skin distal to the arteriotomy.

The Frontier closure device (Vivasure Medical Ltd.) is a bioresorbable patch that is positioned on the inner surface of the arteriotomy utilizing an over-the-wire delivery device through the procedural sheath. Both the ProMed (Promed, Inc.) and InSeal (InSeal Medical Ltd.) devices utilize bioresorbable membranes that seal the inner surface of the arteriotomy before resorbing, leaving an underlying nitinol frame in the vessel. Whether these patch grafts might confer any benefit over suture-mediated devices remains unclear (Figure 2).

TA ACCESS FOR TAVR

TA access to the aortic annulus is frequently considered for patients in whom a TF approach is limited by severe iliofemoral disease, precluding safe sheath advancement. Several potential benefits of TA access exist, including greater ease in valve crossing, more coaxial valve positioning, and potentially a more controlled deployment given the short distance from the operator to the annulus and more effective translation of device manipulations. Furthermore, removing the need for balloon valvuloplasty prior to valve deployment may reduce the incidence of cardioembolic cerebrovascular complications. Notwithstanding these purported benefits of TA access, it typically remains a second-line option, particularly given the reducing size of TF sheaths and their wider utility in patients with vascular disease.

Although bleeding may be more of a problem with TF TAVR, access site complications, including bleeding, are a significant component of the adverse events observed after TA TAVR and may be associated with a worse prognosis. Given the use of TA access as a predominantly second-line access option in patients with significant vascular disease, TA patients are likely to have several comorbidities and risk factors for complications in general.

In addition to the intercostal incision and direct LV puncture required for TA access to the aortic annulus, traditional surgical techniques for closure using pledgeted sutures may result in significant postoperative pain related to rib or soft tissue spreading. Injury to the ventricular apex may have a negative impact on overall LV function, and hemostasis can be problematic. Although rare, bleeding directly related to apical injury can be catastrophic and a very difficult problem to manage. As such, the role of novel TA closure devices in improving patient comfort and recovery is of great importance. TA access to the mitral valve is also of interest given the growing clinical experience with mitral valve-in-valve transcatheter valve procedures, as well as the potential for future technologies directed at percutaneous mitral valve therapies from the LV apex.

NOVEL TA CLOSURE DEVICES

Similar to TF devices, specific TA closure devices employ various methods to achieve effective closure and are in varying states of development. The Apica ASC (access, stabilization, and closure) device (Apica Cardiovascular Ltd.) has been shown to be a safe and feasible method of apical closure after TAVR. The titanium Apica introducer is advanced into the myocardium in a corkscrew-like action. After valve deployment, a reaccessible apical closure cap is deployed through the existing introducer sheath. The conical shape of the coil is designed to impart radial compression at the access site, and in one small case series, successful apical closure was achieved in all patients, with no access-related bleeding.
In contrast to plug-mediated closure, the CardioClose (Entourage Medical Technology) and HeartStitch TA (HeartStitch) are suture-mediated devices. These apical suture deployment devices deploy “preclosure” sutures around the access site, through which an access sheath is inserted before suture locking and sheath withdrawal.

The Permaseal device (Micro Interventional Devices, Inc.) uses neither sutures nor plug technology, rather utilizing a web of self-sealing biopolymer anchors at the apex. The percutaneous delivery device is delivered to the epicardial side of the access site over a wire where, on deployment, it passes small anchors circumferentially around the access site, which are cross-linked by a web of elastic polymer on the epicardial side. A TAVR delivery sheath is then passed over the same guidewire and directly through this polymer web, which self-seals on removal of the delivery sheath due to its inherent elasticity (Figure 3).

Although most TA closure devices require surgical access to the apex, the Cardiapex device (Cardiapex Ltd.) uses a trochar, percutaneous delivery sheath, and apical closure plug to achieve fully percutaneous apical access and closure. This device is currently being tested in a prospective, multicenter European study.

**FUTURE DIRECTIONS**

Although TA access for TAVR is less common than TF access, increasing application of TAVR in patients with iliofemoral disease and the future possibilities of transcatheter mitral valve therapies open the way for further development in the area of TA access and closure devices. CT imaging can be used to plan TA access and is likely to evolve further in its application to guiding access for either aortic or mitral procedures. Laser-guided puncture may also further improve the accuracy of apical puncture and achievement of coaxial alignment between the...
sheath and valve of interest. Biodesorbable technologies have long been applied to femoral closure devices and could be the subject of future research given the possibility of reuse of the apex for multiple valvular procedures.

CONCLUSION

The clinical application of TAVR in the treatment of aortic stenosis continues to rapidly expand. Although the safety profile of transcatheter valves is improving, access site complications remain an important source of morbidity and mortality. Several novel femoral and apical closure devices are in various stages of development and may further reduce bleeding and other access-related complications, although this remains to be shown clinically. Careful patient selection, procedural planning using CT imaging, and meticulous closure using the current commercially available closure devices or surgical techniques remain the mainstay of safe and effective access site closure.

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