A Review of Endovascular Options for Critical Limb Ischemia

The advantages and disadvantages of the latest advances in percutaneous intervention.

BY TAKAO OHKI, MD, PHD

Bypass surgery is the "gold standard" for the treatment of critical limb ischemia (CLI). However, due to recent advances in endovascular technologies, catheter-based intervention has become a viable option, and percutaneous treatment is becoming more widely used.

The advantages of using percutaneous interventional procedures over bypass surgery to treat CLI include:

- Avoiding complications of general anesthesia
- Avoiding making an incision in an ischemic leg and avoiding healing complications
- Less systemic stress
- Early recovery and ambulation
- Procedure may be repeated more readily than surgery

However, one needs to keep in mind that these advantages will only make sense if the interventional procedure does not preclude future surgical intervention options because no intervention lasts forever, and there is always a possibility that the patient may require a surgical treatment in the future. For example, placement of a stent in the common femoral artery or converting an otherwise above-the-knee femoropopliteal bypass into a below-the-knee bypass should be avoided.

The purpose of this article is to provide a brief overview of the percutaneous ther-

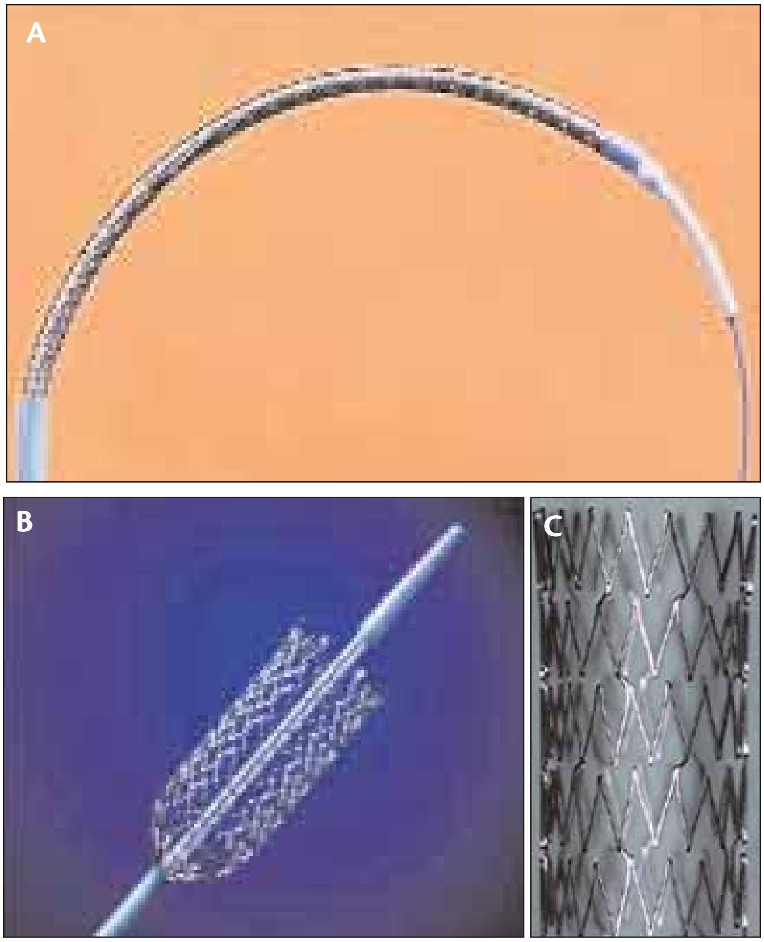

Figure 1. Nickel-titanium alloy (nitinol) stents are characterized by high flexibility, low profile, absence of deformation due to external compression, absence of foreshortening, precise placement, and the ability to treat long lesions. The S.M.A.R.T. stent (Cordis Corporation, a Johnson & Johnson company, Miami, FL) (A, B) and the Protégé EverFlex stent (ev3, Inc., Minneapolis, MN) (C).

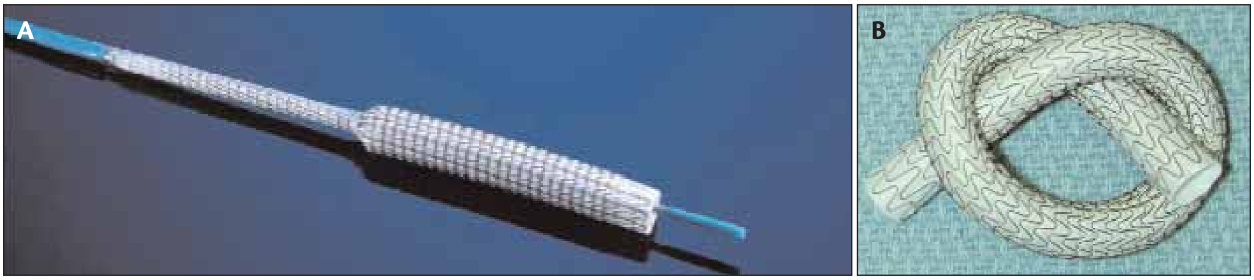

Figure 2. The Viabahn covered stent (Gore & Associates, Flagstaff, AZ).

apies available today, as well as highlight some advantages and limitations of each alternative.

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

Percutaneous transluminal angioplasty (PTA) is defined as the localized stretching of a vessel wall with a pressurized balloon to break apart plaque and restore blood flow. This stretching is accomplished with the aid of new low-profile, small-diameter balloons of varying lengths (up to 12 cm). Although PTA technique may vary according to lesion length and operator preference, Faglia et al[1] describe excellent results (83.6% technical success and 87% 1-year patency) with long inflation times (up to 3 minutes) at low pressures. Our experience also showed 90% clinical success and limb salvage rates using a subintimal approach for treating chronic total occlusions (CTOs)[2].

The advantages of PTA relative to other endovascular procedures include:

- Reasonable technical and clinical success rates (some >90%)
- Low major complication rate (<10%)
- Absence of foreign body
- PTA may be repeated as necessary while preserving future surgical options
- Unlikely to sacrifice collateral branches

The main disadvantages of PTA relative to other endovascular procedures include:

- The need for frequent patient follow-up/surveillance
- Technical success and patency have been found to vary by lesion location and morphology (eg, often better results in TASC A and much worse in TASC C or TASC D lesions)
- Frequent occurrence of dissection that may require stenting

The need for close patient follow-up, particularly in the first year, cannot be emphasized enough because nearly all studies examining the efficacy of PTA point to failures occurring within the first 6 months after treatment.

STENTING

Stenting is defined as the placement of a metallic tube in a damaged artery to support and maintain the lumen. Stents may be bare metallic (Figure 1), PTFE covered (Figure 2) or more recently, coated with drug-eluting polymers or made of bioabsorbable materials (Figure 3). Although peripheral stenting is often considered a primary therapy for focal iliac and diffuse SFA lesions, it is becoming increasingly common as a “bail-out” for infrapopliteal PTA interventions. Stenting has been shown to be highly effective, with technical success rates of 95% and 3-year primary patency rates of up to 88%.[3] Although there are a number of nitinol stents on the market, they are not created equally. Some stents fracture more than others, and one needs

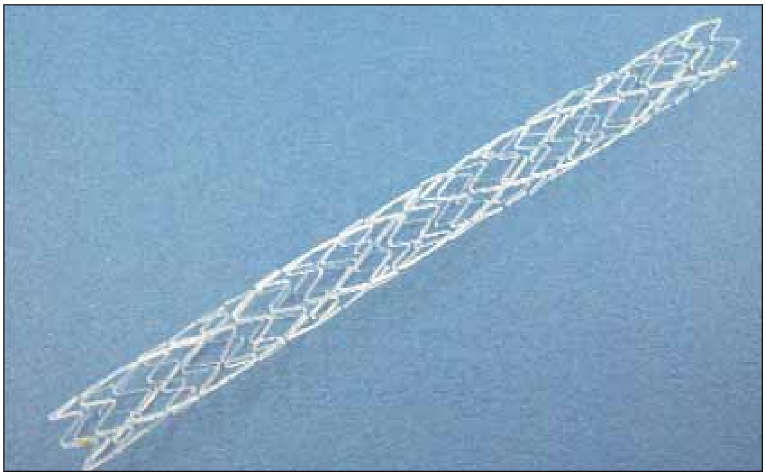

Figure 3. The Igaki-Tamai bioabsorbable stent (Igaki Medical Planning Co., Kyoto, Japan). This zigzag helical coil stent is made of poly-L-lactic acid. Two radiopaque markers denote the ends of the stent. The stent is manufactured in diameters up to 5 mm and lengths up to 78 mm.

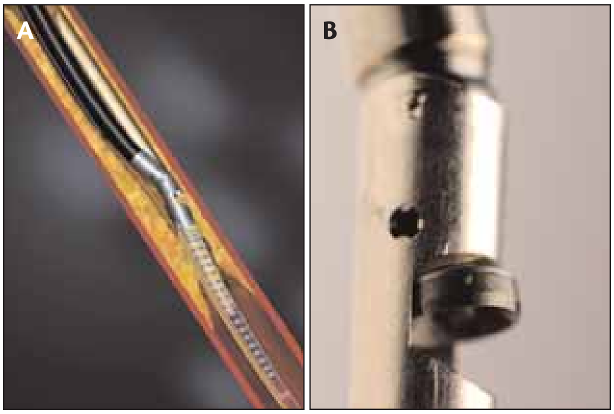

Figure 4. The SilverHawk atherectomy catheter (FoxHollow Technologies, Redwood City, CA). Excised plaque is placed in the nose cone; note the absence of a balloon for cutter apposition (A). A carbide cutter spins at 8,000 rpm (B).

to be familiar with the strengths and weaknesses of various stents.

The main advantages of stenting relative to other endovascular procedures include:

- Improved midterm patency (compared with PTA in particular)
- Predictable angiographic results
- Near absence of acute and subacute occlusions
- It is an area of rapidly evolving technology with the emergence of new long, fracture-resistant designs and the promise of new approaches such as drug-eluting and bioabsorbable peripheral stents

The main disadvantages of stenting relative to other endovascular procedures include:

- Stent fracture, while infrequent, may contribute to restenosis/thrombosis in some cases
- When restenosis occurs, the new lesion involves the entire length of the stent and is often longer than the original lesion
- More likely to sacrifice collateral vessels than PTA alone
- Increased cost
- There are limited data on efficacy of tibial stenting

Figure 5. Laser atherectomy illustration (Spectranetics Corporation, Colorado Springs, CO). The cold-tip laser utilizes pulsed energy and is characterized by markedly reduced thermal effects.

Also, similar to PTA, stenting requires frequent clinical and angiographic surveillance during the first postprocedural year.

DIRECTIONAL ATHERECTOMY

A directional atherectomy device consists of a disposable monorail catheter connected to a battery-powered control unit that drives a carbide cutting blade (Figure 4). This cutting blade "shaves" stenotic tissue as it is passed over the target lesion. Excised material is stored in the device's distal nosecone.

Directional atherectomy is best suited for the "debulking" of noncalcified lesions in the SFA, common femoral artery, popliteal, and infrapopliteal arteries and in most cases is a stand-alone therapy. While additional studies are being conducted, initial efficacy data for directional atherectomy look to be promising, with 1-year patency rates as high as 80%.[4] The recently developed atherectomy device is not only user-friendly but also more effective compared to the original directional coronary atherectomy devices.

The main advantages of directional atherectomy relative to other endovascular procedures include:

- Lower incidence of dissection and the need for stenting compared to PTA
- Absence of a foreign body
- Easy to repeat if restenosis is detected prior to complete occlusion
- Suggested reduction in vessel barotrauma that may reduce vessel response to injury

The main disadvantages of directional atherectomy relative to other endovascular procedures include:

- Directional atherectomy tools and techniques require a learning curve
- Higher profile (7-F for SFA device)
- Increased risk of distal embolization
- Lack of long-term clinical data
- Cost (up to $3,000 per device), although this may be less expensive than using two stents and several balloons

Also, like other endovascular procedures, directional atherectomy requires frequent clinical and angiographic surveillance.

Figure 6. The Peripheral Cutting Balloon device (Boston Scientific Corporation, Natick, MA).

LASER ATHERECTOMY

A laser atherectomy device consists of a series of optical fibers arranged around a central guidewire lumen (Figure 5). The device's catheter tip makes direct contact with diseased tissue and pulsed excimer laser light penetrates approximately 50 µm into the tissue, vaporizing obstructive material. Laser atherectomy is most commonly used as an adjunctive therapy to PTA for in-stent restenosis and to cross long CTOs.

Similar to its directional cousin, laser atherectomy may be an effective therapy option, with reported 85% procedural success and 90% 6-month limb-salvage rates.[5] Longer-term patency data, however, do not appear to be as promising, with 12-month reported patency rates of only 49%.[6]

The main advantage of laser atherectomy relative to other endovascular procedures is its efficacy with complex, diffuse lesions and, in particular, CTOs that cannot be crossed with traditional guidewires. Also, like the atherectomy device, it can accomplish revascularization without leaving a foreign body behind. Collateral vessels are rarely sacrificed.

The main disadvantages of laser atherectomy relative to other endovascular procedures include:

- Clinical results have not demonstrated to be higher than stand-alone PTA
- Laser atherectomy requires a capital equipment purchase and a certain learning curve
- Potential lumen is limited to the diameter of available catheters
- It may not be a true "stand-alone" therapy, and many cases require adjunctive use of PTA balloons or stents

CUTTING BALLOON

A cutting balloon is a specialized angioplasty device that contains a series of cutting blades (or athertomes), placed longitudinally along the surface of a standard angioplasty balloon (Figure 6). When inflated, these cutting blades score the lesion with incisions to facilitate dilation of the vessel.

Cutting balloons are not widely considered a primary therapy for *de novo* lesions because the longest balloon is only 2 cm in length. It is best suited for lesions such as bypass graft anastomoses, bifurcation stenoses, and no-stent–zone lesions in which stenting works poorly. Its ability to dilate the lesion at a much lower pressure (typically 3-5 atm) is also considered to be an advantage. The occurrence of dissection appears to be lower than that seen after PTA.

As with standard PTA, cutting balloons report excellent technical success rates (95%),[7] but this advantage is offset by a relatively restricted range of balloon diameters and lengths that limit the therapy's potential applications. In addition, the long-term efficacy of cutting balloons has not proven to be superior to standard balloon angioplasty.

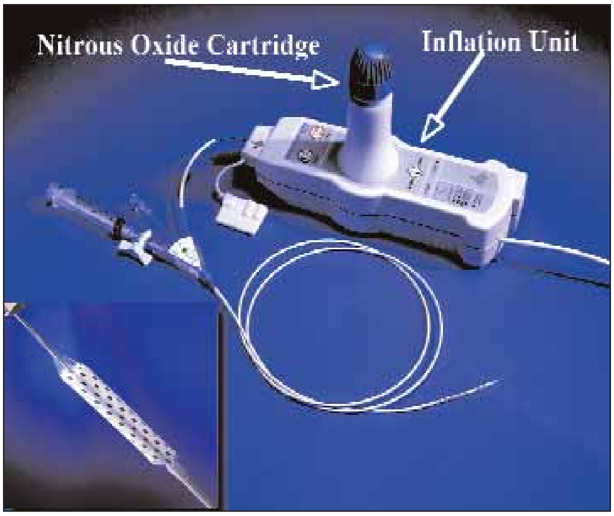

Figure 7. The PolarCath device (Boston Scientific Corporation). Cryoplasty uses nitrous oxide to inflate the angioplasty balloon to -10ºC with pressure of 8 atm for 20 seconds. The balloon with radiopaque markers (inset).

CRYOPLASTY

Cryoplasty is a specialized angioplasty balloon system that consists of a disposable catheter, a reusable power module, a reusable inflation unit, and a disposable nitrous oxide cartridge (Figure 7). When activated, liquid nitrous oxide fills the angioplasty balloon and exposes approximately 500 µm of diseased vessel wall to -10°C of cold therapy intended to induce cell apoptosis and slow restenosis response. In addition, it is believed to reduce the rate of flow-limiting dissections. Although cryoplasty may be applied to a variety of situations, it is commonly used to treat suboptimal PTA or in-stent restenosis.

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Because cryoplasty is a relatively new therapy, efficacy data are scarce, and 9-month reintervention rates have been reported as high as 15% in patients with lesions <10 cm.[8]

However, cryoplasty promises to reduce neotintimal hyperplastic response and is suggested to be less traumatic to the vessel than standard angioplasty. The main drawbacks to the therapy include:

- It has not been demonstrated to be safer or more effective than other forms of PTA
- -10°C only induces apoptosis in approximately 50% of contacted cells; this may not be enough to significantly reduce restenosis
- Additional system set up time and cost of the device (multiple catheters, cartridges, etc)
- Inability to dilate hard lesions due to the limited inflation pressure (8 atm)
- Higher crossing profile

CONCLUSION

Each percutaneous therapeutic option for treating CTOs has potential advantages and disadvantages, which must be taken into consideration and evaluated with each patient's specific needs. Ideally, an interventionist treating lower-extremity occlusive disease should be familiar with most if not all of these available technologies and also have access to them. ■

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