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The Next-Generation PolarCath System

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The PolarCath System (NuCryo Vascular, LLC) is a unique, time-tested biological peripheral dilatation system that combines angioplasty and precise cryotherapy (cooling) to uniformly dilate peripheral vessels and reduce vessel recoil, dissection, and restenosis for the treatment of peripheral artery disease (PAD). The PolarCath System was developed in the late 1990s by Dr. James Joye, an interventional cardiologist in Mountain View, California, in an effort to overcome the limitations of peripheral balloon angioplasty. The PolarCath System received 510(k) approval in 2002, was launched in the United States in 2003, and was acquired by Boston Scientific Corporation (BSC) in 2005. BSC successfully increased their annual revenue of the PolarCath System to greater than $40 million annually, and it quickly became their top-selling peripheral vascular product. BSC decided to discontinue manufacturing and marketing the product in 2012. In 2014, NuCryo Vascular purchased the rights to the PolarCath System to manufacture, reengineer, and relaunch it. Since that time, the PolarCath System has continued to be a proven and viable option for treating PAD.

SCIENCE

Cryoplasty combines the dilatation force of angioplasty with the simultaneous delivery of cold thermal energy to the arterial wall. Both mechanisms are achieved simultaneously by filling the angioplasty catheter with nitrous oxide instead of the usual contrast saline/solution mixture. Cryotherapy has been proven to biologically alter the behavior of arterial cellular components in a benign healing process. Several scientific studies have demonstrated that this cooling process within the vessel results in:

- weakening of the plaque, promoting uniform dilation and reducing vessel trauma;
- alteration of elastin fibers to reduce vessel wall recoil, while collagen fibers remain undisturbed and capable of maintaining architectural integrity;
- induction of smooth muscle apoptosis, which is associated with reduced neointimal formation and, subsequently, less restenosis.

SYSTEM

The next-generation PolarCath Peripheral Dilatation System (Figure 1) currently consists of a sterile disposable catheter; a sterile disposable catheter extension; a non-sterile, disposable nitrous oxide cartridge; and a non-sterile, ***reusable*** cryoplasty inflation unit.

- ***Catheter:*** Coaxial catheter shaft with two concentric, noncompliant balloon systems mounted at the distal tip of the of the shaft.
- ***Nitrous oxide cartridge:*** A cartridge filled with liquid nitrous oxide that, by way of a phase change, inflates the balloon and cools it down to -10° C. One cartridge equals one inflation.
- ***Cryo inflation unit:*** Nonsterile, reusable unit designed to regulate inflation pressure and treatment time of the PolarCath balloon. The operating pressure of the balloon is 8 atm.
- ***Connector:*** Sterile catheter shaft connecting the nonsterile inflation unit to the sterile catheter.

In contrast to the previous system, which was completely disposable, this next-generation system has introduced a reusable cryo-inflation unit (CIU2). The CIU2 is capable of completing 100 inflations and is an advance that has cut the cost per case by nearly half.

DATA

PolarCath has been studied extensively and has proven safety and efficacy.

Cryoplasty or Conventional Balloon Postdilation of Nitinol Stents for the Revascularization of Peripheral Arterial Segments (COBRA)

This 2012 trial was a prospective, multicenter, randomized controlled clinical trial of diabetic patients with complex disease that compared PolarCath to standard percutaneous transluminal angioplasty (PTA) for postdilatation of nitinol stents.[1] In this study, the primary endpoint was binary restenosis at 12 months as determined by duplex ultrasound, defined as ≥ 2.5-fold increase in peak systolic velocity ratio (PSVR) by duplex ultrasound. In lesions averaging 15 cm, many of which (50%) were chronic total occlusions, cryoplasty reduced the rate of restenosis compared to PTA by nearly 50%. These data demonstrated that cryoplasty significantly reduces binary restenosis, especially impressive in a challenging group of patients with diabetes, many of whom presented with 100% total occlusions.

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Above the Knee

The investigational device exemption (IDE) trial for the treatment of femoropopliteal arterial disease was a prospective, multicenter registry published in 2005 that evaluated the efficacy of cryoplasty.[2] There were 102 patients treated with the primary strategy of stand-alone PolarCath therapy in patients with predominantly TASC II B and C lesions, as have been tested in most contemporary stent and DCB trials. Primary patency, as adjudicated by an independent core lab, was 70.1%. In contrast to today's trials, the more stringent PSVR criteria of > 2.0 was used to determine patency. When viewed by current PSVR standards of > 2.5, these data yield a primary patency of 82%, comparable to many published DCB trials (data on file at NuCryo). Additionally, because of the lower dissection rates seen with cryoplasty, bailout stenting occurred in only 9% of patients. The IDE extended follow-up study, published in 2006, demonstrated that clinical patency (calculated by Kaplan-Meier estimate) was well maintained at 75% for over 3 years post treatment.[3]

Below the Knee

The benefits of using PolarCath below the knee (BTK) were highlighted in the BTK Chill study published in 2009.[4] The BTK Chill study was a prospective, multicenter study that examined the use of cryoplasty for BTK occlusive disease in patients with critical limb ischemia. Freedom from amputation at 365 days was 85% with an acute overall technical success rate of 97%. The technical success rate per Rutherford class 4, 5, and 6 was 95.5%, 98%, and 96.4%, respectively. The PolarCath balloon was also proven to be very safe, with clinically significant dissections of 1% in the trial.

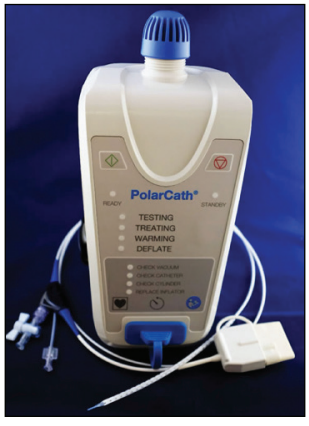
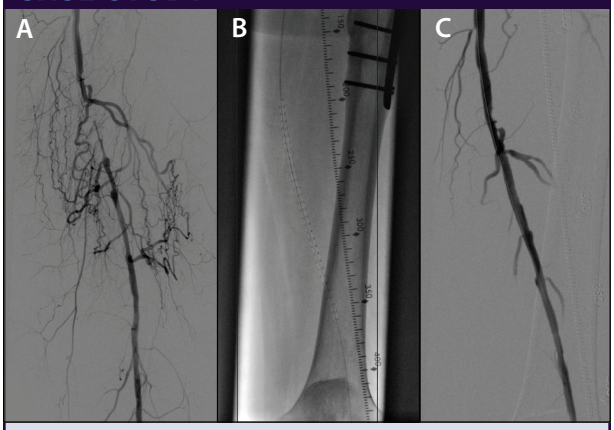


Figure 1. The PolarCath Balloon Dilatation System consists of a sterile disposable catheter; a sterile disposable catheter extension; a non-sterile, disposable nitrous oxide cartridge; and a non-sterile, reusable cryoplasty inflation unit.

REIMBURSEMENT

Cost per case is a real concern in today's practice of medicine. In my experience, cryoplasty has proven to be more economical as compared to DCB technology. Although a pass-through code was created in 2015 to help offset the costs for DCBs, cryoplasty still offered a significant savings when more than two DCBs were needed in a procedure. A single cryoplasty balloon can provide multiple inflations and treatments, unlike DCBs that only allow for a single use. As a result, the total cost associated with the use of a DCB often outweighs the savings intended with the pass-through payment. Furthermore, the Centers for Medicare & Medicaid Services ruled to eliminate that DCB pass-through code in December 2017. Effective January 1, 2018, all DCBS are reimbursed as standard PTA. PolarCath will continue to offer a significant savings over DCBs, given its lower cost point and multiuse ability during each procedure. ■

CASE STUDY



A patient returned to our institution with Rutherford class 3 life-threatening claudication after failed conservative therapy (A). Repeat angiography showed reocclusion of her right superficial femoral artery. She was treated with a 4- X 150-mm cryoplasty balloon (B) and experienced lesion reduction to < 10%, and her symptoms decreased to Rutherford class 1 (C).

1. Banerjee S, Das TS, Abu-Fadel MS, et al. Pilot trial of cryoplasty or conventional balloon post-dilation of nitinol stents for revascularization of peripheral arterial segments: the COBRA trial. J Am Coll Cardiol. 2012;60:1352–1359.
2. Laird JR, Jaff MR, Biamino G, et al. Cryoplasty for the treatment of femoropopliteal arterial disease: results of a prospective, multicenter registry. J Vasc Interv Radiol. 2005;16:1067–1073.
3. Laird JR, Biamino G, McNamara T, et al. Cryoplasty for the treatment of femoropopliteal arterial disease: extended follow-up results. J Endovasc Ther. 2006;13(Suppl 2):II52–1159.
4. Das TS, McNamara T, Gray B, et al. Primary cryoplasty therapy provides durable support for limb salvage in critical limb ischemia patients with infrapopliteal lesions: 12-month follow-up results from the BTK Chill trial. J Endovasc Ther. 2009;16(2 Suppl 2):II19–II30.

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Disclosures: None.