

'Paradigm shift' in how physicians treat peripheral artery disease

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A balloon angioplasty device that sucks up dangerous plaque debris could trigger a "paradigm shift" in how physicians treat peripheral artery disease, researchers write in the current issue of *Endovascular Today*.

"We will see a shift in how we treat lesions," write Dr. Robert Dieter of Loyola University Health System and Dr. Aravinda Nanjundappa of West Virginia University.

In two clinical trials totaling 123 patients, the device had a success rate of 97 percent to 99 percent and consistently outperformed filter devices typically used to capture debris particles, Dieter and Nanjundappa write.

The [Food and Drug Administration](#) has approved the device, Proteus®, made by Angioslide, for angioplasties that treat [peripheral artery disease](#) (PAD) in the legs. PAD is caused by clogged [arteries](#) that restrict [blood flow](#) to the legs. Symptoms include painful cramping in the hips, thighs or calves when walking, climbing stairs or exercising. Advanced PAD can cause gangrene or even lead to limb loss.

A [balloon angioplasty](#) is among the standard treatments for PAD. A physician inserts a catheter in an artery and guides it to the blockage, then opens the artery by inflating a balloon at the tip of the catheter. The physician typically deploys a stent to keep the artery open.

Inflating the balloon can knock loose particles of plaque, which travel down the leg. A large particle can block blood flow, a condition called distal embolization. In the most severe cases, distal embolizations can require leg amputation or even be fatal.

Until now, some physicians have used a filter device to prevent debris from escaping. However, the filter can damage the artery, and can be

difficult to deploy. Moreover the FDA has not approved filter devices for use in leg arteries. Using filters for PAD procedures, although routine, must be done "off label."

The new device that Dieter used opens the artery just like a standard angioplasty balloon. After the artery is opened, the physician deflates the balloon. The negative pressure sucks up the debris, which is trapped inside as the balloon retracts.

"This is a much more simple and elegant approach than filter devices," said Dieter, an interventional cardiologist and vascular specialist.

Dieter is an assistant professor in the Department of Medicine, Division of Cardiology at Loyola University Chicago Stritch School of Medicine and Director of Vascular Medicine and Peripheral Vascular Interventions at Edward Hines VA Hospital. Dieter has used the device on patients at Loyola and Hines.

His first Loyola patient was Patricia Durkin of Oak Forest, IL. Before the procedure, the top of the iliac artery that supplies blood to her left leg was 90 percent blocked. "If I walked in the mall, I had to stop every few minutes," she said. "It made my leg feel heavy. It got to the point where I didn't want to walk any distance."

The procedure restored normal blood flow. "I don't have that heavy feeling anymore," Durkin said.

Other interventional cardiologists at Loyola also plan to use the device, said Dr. John Lopez, director of Interventional Cardiology Research and professor in the Department of Medicine, Division of Cardiology.

"At Loyola, interventional cardiology is very progressive, and at the forefront of technology for the treatment of PAD," Lopez said.

Provided by Loyola University

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