

CASE STUDY

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Embolization of Benign Prostatic Hyperplasia

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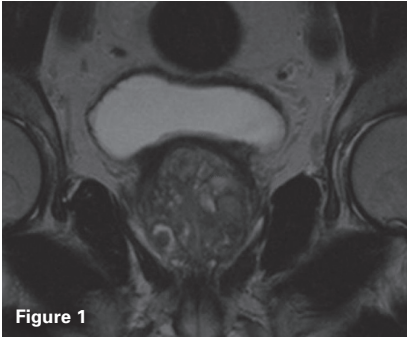


Figure 1

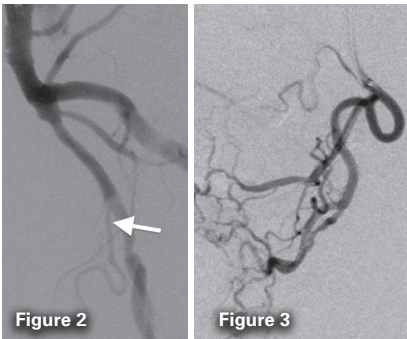


Figure 2

Figure 3

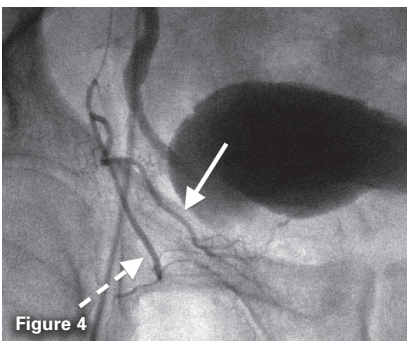


Figure 4

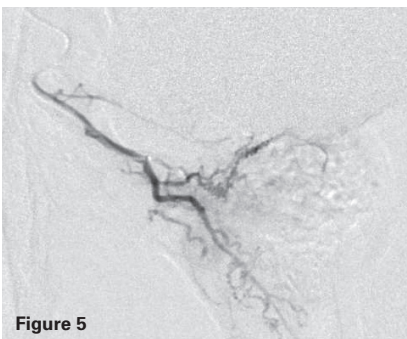


Figure 5

Benign prostatic hyperplasia (BPH) affects more than 15 million men in the United States. Patients typically present with symptoms such as frequency, nocturia, urgency, weak stream, and feeling of incomplete emptying. Although medical therapy or lifestyle modification may be suitable for most patients, those with moderate or severe symptoms will likely require surgical intervention. Currently available transurethral procedures, such as transurethral resection or photoselective vaporization, work by increasing the luminal diameter of the prostatic urethra. These come at a significant cost of complications, including incontinence, impotence, bleeding, or retrograde ejaculation. Because BPH is also hypervascular,^{1,2} particularly in the central gland, interventional radiologists have used prostatic artery embolization (PAE) to reduce the size of these hypervascular nodules and improve symptoms from BPH. Results from clinical trials³ have demonstrated a significant reduction in symptoms from BPH with a very low risk of complication. Significant technical challenges exist with PAE, including tortuous anatomy with small distal target vasculature and the need for high-quality imaging and embolic material injection.

A 62-year-old male with severe lower urinary tract symptoms from BPH was referred to the clinic for evaluation of PAE. His peak urine flow rate was severely decreased at 2 cc/sec and his prostate was enlarged to 90 cc (Figure 1). He was in good health and sexually active and wanted to avoid transurethral therapy because of the risk of sexual side effects. After discussion with the patient and consulting urologist, the patient was scheduled for the procedure.

“Embolization was performed through Direxion proximally and then advanced distally without a wire to allow for further embolization.”

A 6 F vascular sheath was placed in the right common femoral artery and a 6 F guiding catheter was placed in the left hypogastric artery. Digital subtraction angiography depicts a tortuous left prostatic artery (Figure 2), which is typical in appearance. A pre-shaped 2.4 F Direxion microcatheter was used to select the left prostatic artery and subselective angiography was performed (Figure 3). **Embolization was performed through the Direxion Microcatheter proximally and then advanced distally without a wire to allow for further embolization.**

Smaller size spherical particulate (100 micron) and gelfoam were utilized in the main trunk. On the right side, the prostatic artery originated from the obturator artery (Figure 4) and the pre-shaped tip was directed in to the prostatic artery to perform selective angiography and embolization (Figure 5). Embolization was performed to stasis and he was discharged without complications. He noted more than 50% reduction in his symptoms by 1 month and has continued to do well at his routine follow up.

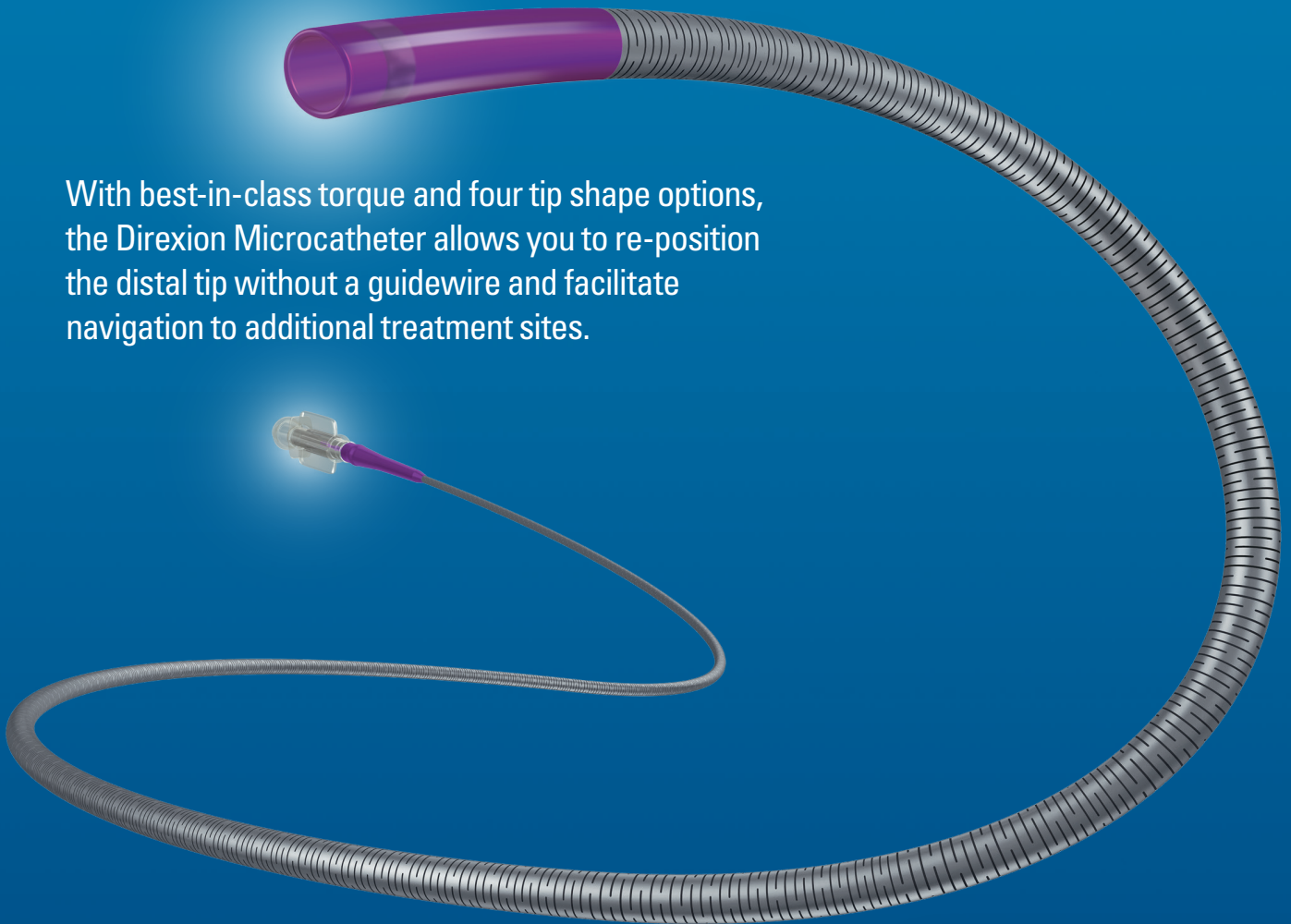
Tortuosity and size of the prostatic artery remain the greatest challenges to PAE. In this case, **Direxion allowed for reliable torqueability of the distal pre-shaped tip.** This can be used to select the prostatic artery when originating from a distal non-target vessel as on the right side in this patient. It is also useful when the operator would like to advance within the target vessel with careful rotation.

1. Deering RE, Bigler SA, Brown M, Brawer MK. Microvasculature in benign prostatic hyperplasia. *Prostate*. 1995;26:III-115.
2. Stefanou D, Batsitatu A, Kamina S, et al. Expression of vascular endothelial growth factor (VEGF) and association with microvessel density in benign prostatic hyperplasia and prostate cancer. *In Vivo*. 2004;18:155-160.
3. Schreuder SM, Scholtens AE, Reekers JA, Bipat S. The role of prostatic arterial embolization in patients with benign prostatic hyperplasia: a systematic review. *Cardiovasc Intervent Radiol*. 2014;37:1198-1219.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel. **CONTRAINDICATIONS:** None known. **WARNINGS:** • Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation.

• This Direxion Microcatheter family is not intended for use in the coronary vasculature or neurovasculature. • The Direxion HI-FLO Microcatheter is not designed for the delivery of embolic coils. • Use of excessive force to manipulate the microcatheter against resistance can cause a fracture in the nitinol shaft. Take care not to over-torque the microcatheter, and to relieve any tension before withdrawal by rotating the microcatheter in the opposite direction. **PRECAUTIONS:** • This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. • Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter. • Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal. **ADVERSE EVENTS:** The Adverse Events include, but are not limited to: • Allergic reaction • Death • Embolism • Hemorrhage/Hematoma • Infection • Pseudoaneurysm • Stroke • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel trauma (dissection, perforation, rupture) **REV AB**

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