Clinical Overview of the Jetstream Atherectomy System

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ABSTRACT: There has been significant interest in percutaneous atherectomy as a technique for treating peripheral arterial disease (PAD). Relatively recently, the Jetstream Atherectomy System was approved for use in the United States. This device is unique as it incorporates an aspiration component. This manuscript includes a description of the device, its method of use, and a summary of the available clinical data regarding its use in the lower extremities.

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While bypass surgery may still be considered the standard for peripheral revascularization, the requirement for anesthesia, the relatively high incidence of morbidity, and the significant time required for postoperative recovery remain a concern. Consequently, there has been growing interest in new technologies for the percutaneous revascularization of peripheral arterial disease (PAD) in patients with chronic limb ischemia and symptoms refractory to conservative medical treatment.

In order to improve on the short- and long-term results of standard balloon angioplasty (PTA), several forms of atherectomy have been recently applied to peripheral revascularization. Our group was privileged to perform a first-in-man feasibility study in 2004 using a prototype Pathway Medical Technologies aspiration and atherectomy device for the treatment of femoral-popliteal and infrapopliteal disease. Since that time the device has gone through several iterations, dramatic refinement, and extensive clinical evaluation culminating in widespread commercial availability. A description of the device and brief summary of its clinical utility follow.

DEVICE DESCRIPTION

The Jetstream system (Bayer HealthCare) consists of two main components: (1) a nonsterile console which contains an electric motor and two peristaltic pumps (for saline infusion and blood/saline aspiration) which is mounted on an IV pole and (2) a control “pod” which is used by the operator for device activation (Figure 1). The console is attached to a standard electric power source and is reusable. The control pod is a sterile single-use component.

The current Jetstream expandable cutter (XC) catheters achieve graded atherectomy using two sets of rotating stainless steel blades. One set of blades sits within a fenestrated metal housing at the tip of the catheter. This set will affect cutting in a diameter of just over 3 mm when rotated clockwise. The second set of five blades are hinged and mounted just proximal to the distal housing. These blades will affect cutting in a diameter of 3 mm when rotated counterclockwise (Figure 2). Both sets are powered by an electric motor that spins them at 60 krpm to 70 krpm.

The Jetstream single-cutter (SC) catheters designed for subpopliteal use. The SC devices are available in 1.6 mm and 1.85 mm sizes for use in vessels with a reference diameter of 2.0 mm to 3.0 mm. The working shaft is also longer allowing the catheter to reach infrapopliteal disease. Both the XC and SC devices use the principal of differential cutting in which fibrous and calcified tissue/plaque is preferentially cut in favor of more compliant normal tissue.

All Jetstream devices must be used through a 7 Fr diameter sheath and are designed for use with 0.014” diameter, 300-cm-long guidewires. The Jetwire is a proprietary wire available through Bayer HealthCare. It should be noted that hydrophilic-coated wires are not recommended. During device activa-
tion, saline is infused through the dis-
tal tip of the catheter and aspirated at
a similar rate in order to help prevent
dissection and potentially retrieve
small embolic material into a collec-
tion bag. Saline infusion and aspira-
tion rates depend on both the cath-
eter size and the blades down or up
condition. Variables that increase these
rates are catheter size and the blade
down condition. The large catheter has
a maximum infusion rate of 43 mm/
min and aspiration rate of 51 mm/min
with the blades down. Although there
is no formal data, many operators add
vasodilators and heparin to the in-
fusion. In our lab we add 2,000 units
of heparin, 5 mg of verapamil, and 1
mg of nitroglycerin to each liter of
normal saline infusion.

Instructions for use state that the
Jetstream G3 or Navitus device is in-
tended for use in atherectomy of the
peripheral vasculature and to break
apart and remove thrombus from up-
per and lower extremity peripheral
arteries ≥3 mm in diameter. It is not
intended for coronary, carotid, iliac, or
renal vasculature. Use of this device in
the subintimal (or potentially subinti-
mal) space should be avoided in order
to reduce the chance of perforation.

When advancing the device a “peck-
ing” motion is recommended where-
by the tip of the catheter is repeatedly
advanced into the lesion with gentle
pressure and then withdrawn. This al-
 lows for the infusion to infiltrate the
lesion area and also prevents excessive
aspiration/suction with tissue collapse
around the catheter. This can result in
intimal dissection and device stalling.
When removing the device a reverse
function is used on the control pod
that causes aspiration alone without
any blade action.

CLINICAL DATA

In a seminal study designed to sup-
port regulatory approval, Zeller et al
reported on a series of 210 lesions
treated in 172 patients between 2006
and 2007 with the earlier pre-G2 iter-
at ion of the device. The patients were
relatively complex with a high preva-
ience of diabetes (47%), hyperten-
sion (93.6%), renal disease (15.75%),
prior lower extremity revasculariza-
tion (51.2%) and documented coro-
nary disease (16.9%). Maximum lesion
lengths were ≤10 cm and ≤3 cm for
femoral/popliteal and infrapopliteal
lesions respectively. Fifty-one percent
of lesions were moderately to heav-
ily calcified and 31% of lesions were
total occlusions. While thrombotic le-
sions were included, in-stent resteno-
sis lesions were excluded. The lesion
crossing and debulking success rate
was 99% with a mean device activa-
tion time of 3.5 minutes. Only 7% of
lesions were stented. Minor embolic
events were noted in 10% of cases
and 4 perforations (2%) occurred. At
6 months major adverse events had
occurred in 19% of patients. Most of
CONCLUSION

Although published data are limited, the Jetstream atherectomy device appears to be safe and has a high rate of acute success providing acceptable mid- and long-term arterial patency rates. The use of embolization protection may be beneficial when using this device.

Editor’s Note: Disclosure: The author has completed and returned the IC-MJE Form for Disclosure of Potential Conflicts of Interest. The author reports...
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