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Cardiovascular Revascularization Medicine 11 (2010) 155–158

CARDIOVASCULAR REVASCULARIZATION MEDICINE

# Mechanism of lumen gain with a novel rotational aspiration atherectomy system for peripheral arterial disease: examination by intravascular ultrasound

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Received 2 March 2009; accepted 5 May 2009

**Abstract**

**Objective:** The purpose of this study was to evaluate the mechanism of luminal gain with a novel atheroablation system (Pathway PV) for the treatment of peripheral artery disease using intravascular ultrasound (IVUS).

**Methods:** The atherectomy system is a rotational atherectomy device, which employs expandable rotating blades with ports that allow flushing and aspiration of the plaque material or thrombus. In this first-in-man clinical study, IVUS analysis was available in 6 patients with lower limb ischemia treated with this device. The treatment results were assessed using IVUS at pre and post atherectomy. Lumen beyond burr size (LBB) was defined as lumen gain divided by the estimated burr area determined by the burr-size.

**Results:** IVUS analysis was available in six patients (superficial femoral artery $n$=3, popliteal artery $n$=2, posterior tibial artery $n$=1). Atheroablation achieved a significant increase in lumen area (LA) (preintervention 3.9±0.4, postatheroablation 8.0±1.7 mm$^2$, $P$<.05), and significant reduction in plaque area (27.5±4.0, 23.7±3.1 mm$^2$, $P$=.001), while there was no change in the vessel area (31.3±4.2, 32.1±2.8 mm$^2$, $P$=.4). LBB was 57.4±51.3%.

**Conclusion:** This novel rotational aspiration atherectomy device achieved significant luminal gain by debulking in the absence of vessel stretching. The LA was greater than burr-sized lumen expectancy at cross-sections along the treated segments, suggesting a complimentary role of aspiration in luminal gain in atherosclerotic peripheral artery lesions.



*Keywords:* Peripheral vascular intervention; Atherectomy; Rotablator; Intravascular ultrasound

## 1. Introduction

Achieving adequate results for peripheral artery disease remains a challenge for percutaneous interventions. Balloon angioplasty of femoropopliteal lesions is limited by poor long-term success rates [1–5]. Although there have been encouraging mid-term results of novel drug-eluting balloon technologies in the treatment of atherosclerotic peripheral artery disease [6], percutaneous removal of obstructive material may represent a theoretically alternative approach for improving procedural success, as well as long-term outcomes.

Pathway PV Rotational aspiration system (Pathway Medical Technologies, Redmond, WA, USA) is a novel atherectomy system, utilizing a unique combination of

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doi:10.1016/j.carrev.2009.05.001

rotablation and aspiration of the plaque. The system is designed for optimal luminal gain without causing unnecessary barotraumas or distal embolization. The purpose of this IVUS study, therefore, was to investigate the debulking mechanism of this rotational atherectomy system in peripheral artery disease interventions using intravascular ultrasound (IVUS).

## 2. Methods

### 2.1. Patient population

The data are derived from a prospective, single-arm, multicenter study to evaluate safety and efficacy for the Pathway PV atherectomy system in the peripheral vasculature as previously described [7]. In brief, patients with lower limb ischemia were enrolled at German study sites. Main inclusion criteria were a vessel diameter between 3.0 and 5.0 mm and maximal lesion length of 10 cm for femoropopliteal lesions or 3 cm for tibial lesions. From this clinical trial, the IVUS analyses at pre and post procedure were available in six patients.

### 2.2. Device description

This atherectomy system is a rotating, aspirating, expandable catheter for active removal of atherosclerotic debris and thrombus from the peripheral vasculature. The system uses a fluted, differentially cutting catheter tip to preferentially remove both hard and soft diseased tissue from peripheral arteries with minimal damage to the vessel wall. The catheter tip remains at a defined nominal diameter (2.1 mm) when spinning clockwise, but expands to a defined maximum diameter (3.0 mm) when rotating counterclockwise (Fig. 1). The integral control unit provides rotational drive to the catheter and a user interface via a top-mounted membrane switch to control device rotational speed and tip size.

Isomolar saline solution is delivered to the proximal end of the catheter using two dedicated lines. One line flushes the motor assembly to maintain an airtight seal, maximizing embolic protection; the other infuses saline to the treatment area through ports located on the distal body of the catheter to optimize the catheter's debulking and aspiration capabilities. The excised material is aspirated via ports in the fluted tip into the catheter lumen and transported to a collection bag located on the console, which includes two peristaltic pumps for aspiration (26–38 ml/min) and infusion (53–89 ml/min), a system controller, power supply, keypad interface and indicator lights for device operational status. Detailed description of this device and procedure steps are previously described [7].

### 2.3. IVUS imaging protocol

IVUS was performed at baseline (pre intervention), and at post atheroablation. All IVUS images were acquired using a commercially available ultrasound system. The imaging catheter was advanced distal to the lesion site and withdrawn with manual pullback. Images were recorded on a CD/DVD for offline quantitative analysis. All the analysis was performed at an independent core laboratory (Cardiovascular Core Analysis Laboratory, Stanford, CA, USA). Images were analyzed utilizing a commercially available planimetry system (Tape Measure, Indec Systems, Santa Clara, CA, USA).

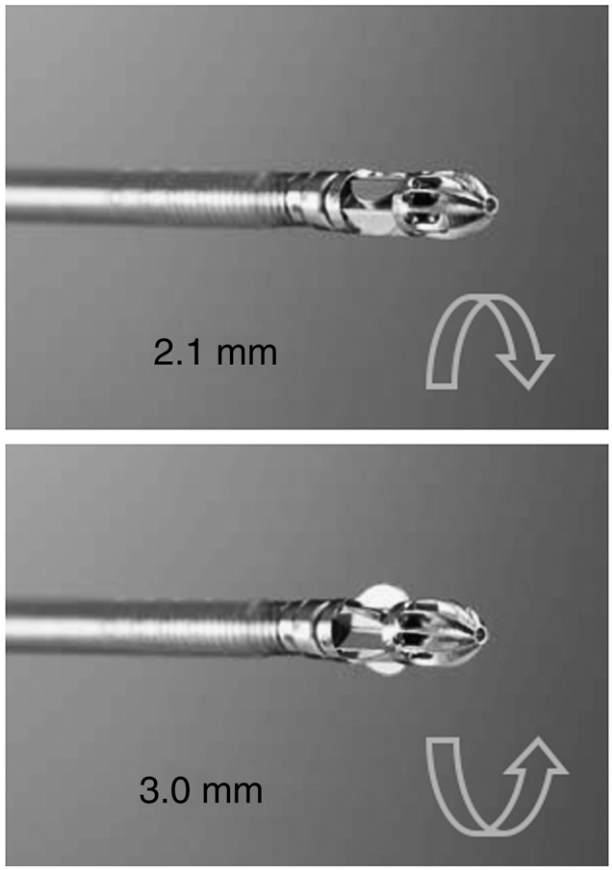


Fig. 1. This figure shows the expandable catheter tip. The burr size of the catheter is 2.1 mm when rotating clockwise (upper image). The blade comes out when the catheter undergoes counterclockwise rotation, giving the burr size diameter of 3.0 mm (lower image).

By using one or more reproducible axial landmarks (e.g., small branches, calcium deposits), identical segments on serial studies (preatherectomy, postatherectomy) were identified for a comparative analysis. Quantitative IVUS measurements consisted of: (1) lumen area (LA), (2) external elastic membrane area (EEMA), and (3) plaque plus media area (calculated as EEMA−LA). Lumen area and EEMA were manually traced. Plaque area was measured as EEM area minus LA. Two-dimensional analysis was performed at the minimal LA (MLA) at post-procedure. To further clarify the mechanism of luminal gain, an additional measurement was done in another cross-section chosen as the tightest position at least 20 mm away from the MLA site. Luminal area beyond burr size was calculated as lumen gain (post-