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In Vitro and *In Vivo* Performance Testing of a Novel 24F Aspiration/Guide Catheter

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Abstract

This report documents the performance of a novel 24F aspiration/guide catheter (8 mm OD; 7.1 mm ID) manufactured by Retriever Medical Inc. (Las Vegas, Nevada, USA) using *in vitro* and *in vivo* modeling. Results demonstrated excellent trackability with ability to navigate tortuous anatomy and serial 90 - 180 degree turns. At a radius of curvature of 6 mm, catheter ovalization (lumen collapse) was not encountered while it was encountered in a similar 24F catheter that at baseline (when positioned straight) had an inner ID 0.2 mm smaller than the novel catheter studied in this report. The capability of the Retriever Medical,Inc 24 F catheter to navigate tortuous anatomy without associated luminal collapse makes it an ideal conduit for thrombus aspiration with and without simultaneous use of a transaxially delivered mechanical thrombectomy device.

Keywords: Catheter; Testing; Retriever; Thrombectomy

Introduction

Percutaneous endovascular thrombectomy procedures for the treatment of deep venous thrombosis (DVT), pulmonary embolism (PE) and peripheral arterial thromboembolic occlusion necessitates the availability of large bore catheters that, despite their size, can readily navigate through tortuous anatomy without risk of kinking or ovalization. Distortion of such devices' inner diameters can significantly hamper a surgeon's ability to generate the vacuum forces needed to aspirate thromboemboli. Distortion can also make delivery of coaxially placed mechanical thrombectomy devices difficult or impossible due to catheter lumen collapse. This report documents the capability of a novel catheter system to traverse tortuous anatomy both *in vitro* and *in vivo*.

Device Description

Retriever Medical (Las Vegas, Nevada, USA) thrombectomy catheters are designed for aspiration and guide purposes and are available in 24F (8 mm OD; 7.1 mm ID), 20F (6.7mm OD; 5.8 mm ID), and 16F (5.3 mm OD, 4.6 mm ID). Catheters come with both unshaped and pre-shaped tip versions making access to peripheral veins, pulmonary arteries and pulmonary artery branches possible (Figure 1). Each of these catheters will permit advancement of the Retriever Clot Hound mechanical thrombectomy device (Figure 2) through the catheter's lumen without negating the ability to contiinue to aspirate during simultaneous use of the mechanical device.

Methods

In this study, the Retriever Medical 24F aspiration/guide catheter

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(8 mm OD; 7.1 mm ID) was tested both *in vitro* and *in vivo* using mechanical radius bending and an anesthetized living animal porcine subject. Direct visualization and X-ray fluoroscopy provided visualization of catheter contour. Radius of curvature and angular measurements were made using the catheter's manufactured diameters to account for fluoroscopic magnification.

Results

Mechanical radius bending

Mechanical radius bending was used to place the 24F catheter into a radius of curvature measuring approximately 6 mm and angulation of 180 degrees. No kinking was identified. A control was performed with another manufacturer's 24F aspiration catheter with a 0.2 mm smaller ID (8 mm OD; 6.9 mm ID) which demonstrated catheter kinking and ovalization at a radius of curvature of approximately 6 mm and angulation of 180 degrees thus demonstrating the test's usefulness in detecting device distortion in a tortuous setting (Figure 3). Ovalization reduced the available ID cross sectional area such that it was 10% less than in the non-distorted Retriever catheter.

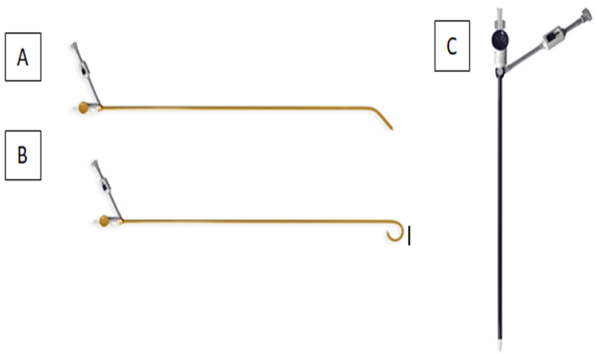

Figure 1: (A) 24F angled pulmonary artery guide/aspiration catheter for PE thrombectomy; (B) Preshaped curved 20F pulmonary artery guide/aspiration catheter for engaging and entering more distal PA branch vessels for PE thrombectomy; (C) 16F straight venous guide/aspiration catheter for DVT thrombectomy.

Figure 2: Clot Hound mechanical thrombectomy device.

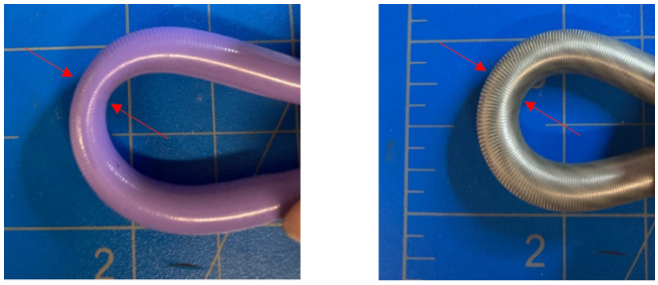

Figure 3: Left image shows currently available 24F catheter bent with radius of curvature of approximately 6 mm and 180 degrees. Red arrows point to region of catheter ovalization; Right image shows Retriever Medical's 24 F catheter with radius of curvature of approximately 6 mm and 180 degrees. The ovalization reduces the ID area to 0.48 inch^2 compared to 0.53 inch^2 in the non-ovalized Retriever catheter (10% reduction in cross sectional area).

In vivo Porcine Model:

When the 24F device was advanced over a wire from the femoral artery to the distal left pulmonary artery in a 79 kg porcine subject, no kinking was identified under fluoroscopic imaging despite navigation of vascular turns measuring <10 mm radius of curvature at 180 degrees (Figure 3). Aspiration of material from the left pulmonary artery was no different from that experienced when aspirating through a straight catheter. A Retriever Medical mechanical thrombectomy device easily advanced through the 24F catheter's lumen without noticeable resistance. The device could also be advanced through the 20F and 16F catheters without resistance. Each of the different catheter's ID dimensions permitted for simultaneous aspiration and mechanical thrombectomy (Figure. 4).

Discussion

Previous publications have documented the functionality of a variety of endovascular devices developed by the authors to aid in the performance of mechanical thrombectomy in the peripheral and pulmonary vascular environments (1-4). This manuscript describes a novel 24F guide/aspiration catheter measuring 8 mm OD and 7.1 mm ID that has no difficulty advancing through tortuous *in vitro* and *in vivo* test settings that aimed to mimic those curvatures encountered during human endovascular thrombectomy procedures. Catheter kinking was not encountered despite radius of curvature and degree of curvature <10mm at 180 degrees, respectively. These test settings were validated by showing kinking of a similar device made by another manufacturer when the catheter was subjected to near identical radius of curvature and angulation.

Conclusion

Retriever Medical's 24F large bore delivery and aspiration catheter demonstrates absence of kinking and distortion when tested in both *in vitro* and *in vivo* settings that mimic those stresses encountered during human endovascular procedures

Horowitz MB., Cardiol Cardiovasc Med 2024
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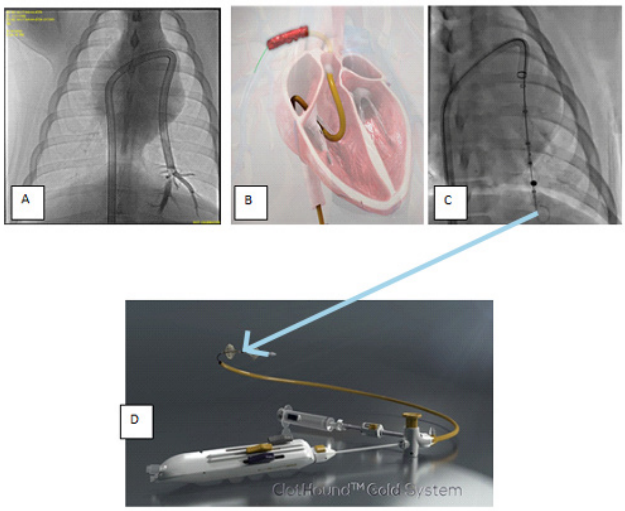

Figure 4: (A) Fluoroscopic visualization of the 24F pulmonary aspiration catheter advanced from the right femoral artery into the porcine distal left pulmonary artery. The smallest radius of curvature and largest degree measurement in this image is 5-6mm and 180 degrees, respectively. No kinking or ovalization is identified; (B) Schematic drawing showing 24F catheter positioned in right pulmonary artery proximal to the pulmonary artery embolic clot (red); (C) Fluoroscopic image. Showing Retriever Medical's mechanical thrombectomy device (arrow) advanced through the 24F catheter (arrowhead) into the distal pulmonary artery; (D) Retriever Medical's Clot Hound mechanical thrombectomy device shown in (C) advanced through the 24F aspiration/guide. catheter.

for peripheral and pulmonary thrombectomy. The ID of the 24F, 20F and 16F catheters permitted simultaneous aspiration during coaxial delivery of Retriever Medical's mechanical thrombectomy device.

Author Responsibilities:

MH: Manuscript preparation; BB: Manuscript preparation; BR: Manuscript preparation; HL: Manuscript preparation

Competing Interests

MH: Founder and Partner Retriever Medical, LLC; BB: Founder, Partner and CEO Retriever Medical, LLC; BR: Chief Science Officer Retriever Medical, LLC; HL: Vice-President Research and Development Retriever Medical, Inc.

Declarations

Ethics approval

This article does not report intervention results on human participants. Animal use was approved by the State University of New York at Buffalo, Canon Stroke and Vascular Research Center IRB # NSG07123N. Human blood was personally provided by the author (MH) and routine laboratory testing was performed. IRB approval was not required for testing of the author's (MH) blood. All data is publishable under the IRB Board guidelines and consent for use of blood test results from the author's (MH) blood has been provided by MH.

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Availability of data and materials

All data sets have been provided in the Manuscript's Results section. Any additional information regarding the tested device can be obtained through the corresponding author (MH).

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