

A Novel Mechanical Thrombectomy Device for Retrieval of Intravascular Thrombus

Wayne L. Monsky · Stephanos Finitsis ·
Dino De Cicco · John M. Brock · John Kucharczyk ·
Richard E. Latchaw

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Abstract

Purpose Thrombotic and embolic vascular occlusion represents a leading cause of morbidity and mortality. Currently available thrombectomy devices have limitations, including difficulty removing organized thrombus and clot fragmentation with distal embolization. A novel mechanical thrombectomy device (MTD), designed to remove both hard and soft thrombus without trauma to the blood vessel, was tested in preclinical porcine models evaluating efficacy, safety, and ease of use.

Materials and Methods A total of 26 vessels in 14 pigs underwent mechanical thrombectomy with MTD. Thrombectomy was performed in nine superficial femoral arteries, eight subclavian arteries, five primary branches of the subclavian artery, lateral thoracic artery or the thyrocervical trunk, and four external carotids. Subacute organized fibrin-laden thrombus was injected into the arteries producing vascular occlusion. The MTD was then used for thrombectomy to restore patency and blood flow.

Results Intact thrombus was retrieved from 24 of 26 of the vessels with a single pass of the MTD, resulting in complete restoration of patency in 21 vessels and partial patency in 4 vessels. In 8 cases that used an early design, the embolic material fragmented during withdrawal from the access sheath. In 4 procedures that used an early design, the MTD failed to deploy fully and the embolus was not completely captured. No intraprocedural complications or vascular damage occurred.

Conclusions The present pilot studies demonstrate basic safety and efficacy of a novel MTD with design attributes suitable for retrieval of intact acute and organized chronic thrombus. The device has potential intracranial and peripheral utility.

Keywords Thrombectomy · Device · Clot · Artery

Introduction

Current thrombectomy devices and thrombolytic drugs do not reliably remove large or hard blood clots, and some drugs and devices are associated with significant adverse outcomes [1–4]. Pharmacologic thrombolysis also commonly results in longer procedure times, often with prolonged observation required in an intensive care unit with resulting increased procedure-related costs. It would therefore be advantageous to have a simple mechanical device that could safely and efficiently remove intact complex acute, subacute, and chronic thrombus from any vascular bed.

We have evaluated a novel catheter-based mechanical retriever shown in prior benchtop in vitro tests to be capable of mechanically retracting both acute soft and hard chronic, organized thrombus. The mechanical thrombectomy device (MTD) design is intended to allow easier

W. L. Monsky (✉) · J. M. Brock · R. E. Latchaw
Department of Radiology, University of California Davis
Medical Center, 4860 Y Street, Suite 3100, Sacramento,
CA 95817, USA
e-mail: wayne.monsky@ucdmc.ucdavis.edu

S. Finitsis
Department of Diagnostic and Interventional Neuroradiology,
University of Thessaloniki, Kerasoundos 14,
55131 Thessaloniki, Greece

D. De Cicco
NexGen Medical Systems Inc., 1050 West NASA Blvd. Ste.
136B, Melbourne, FL 32901, USA

J. Kucharczyk
NexGen Medical Systems Inc., 10471 Double R Blvd.,
Suite C, Reno Tahoe Tech Center, Reno, NV 89521, USA

access into anatomically difficult locations: it can be delivered through a 4F angiographic or 2.7F microcatheter for the small branches of the subclavian artery, depending on the target vessel. The MTD described here is based on materials utilized for guide wires and intracranial aneurysm coil construction is not traumatic to the vascular wall, with minimal risk of intimal dissection or endothelial injury.

Here we report the results of a series of preclinical studies conducted to evaluate the technical efficacy, device-related complications, and ease of device use of the MTD in a porcine model of embolic/thrombotic arterial occlusion.

Materials and Methods

Device Design and Description of Components

The MTD, manufactured by NexGen Medical Systems (Reno, NV), is similar in general design to a vascular guide wire and detachable coil. The device consists of a platinum

microcoil element for head and neck arteries, and a stainless steel microcoil element for peripheral blood vessels. A hollow catheter shaft is attached to the microcoil, and eyelets are set at discrete locations along the microcoil (Fig. 1). A metal core wire travels through the lumen of the catheter shaft, goes through the eyelets of the microcoils, and attaches to the distal tip of the microcoil complex (Fig. 1A–F). Pulling on the core wire forms a loop (Fig. 1D–F) of a given microcoil. Microcoil loop diameters are based on the distance between eyelets, and also on the degree of pull on the core wire, which provides design flexibility to vary the diameter of each loop formed. The actuated coils (those with loops) are used to capture, encapsulate, and retrieve a blood clot or other obstruction (Fig. 2).

When performing thrombectomy in the branches of the subclavian or external carotid arteries, the MTD had a shaft length of 175 cm with distal loops measuring 3.5 mm wide by 1.0 cm long, and proximal loops measuring 5 mm × 6 cm. For neurothrombectomy applications, evaluated in the external carotid artery, the loops also measured 3.5 mm in

Fig. 1 Device design. Components of the MTD are illustrated. **A** The device consists of a platinum or stainless steel coil element attached to a stainless steel hypotube via a polyamide transition tube (A, B). Within the tubes and coil element is a stainless steel core wire (A–F). Near the distal tip, the core wire exits the device and runs alongside the coil element, reentering the coil element at defined eyelets (C). The eyelet portion of the coil element forms discrete loops when the user retracts the proximal end of the core wire (D–F). Proximal to the eyelet section, the coil element is preshaped to form a spiraled coil shape (E)

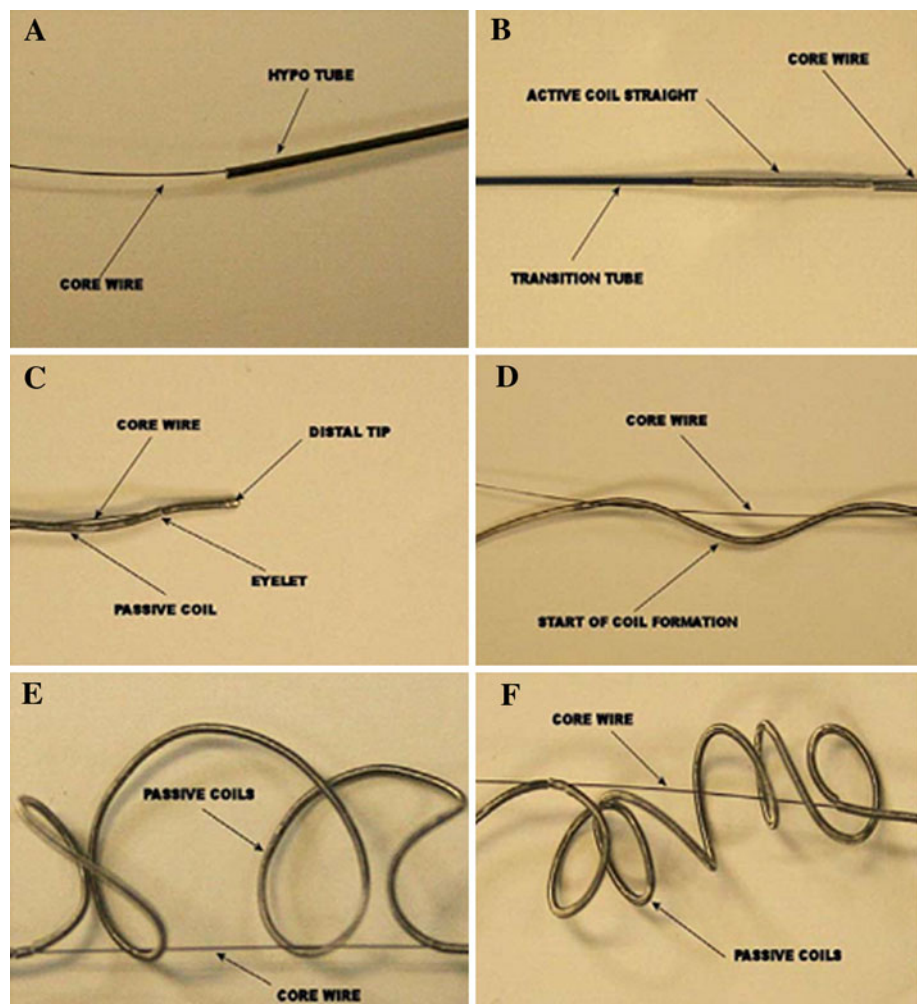
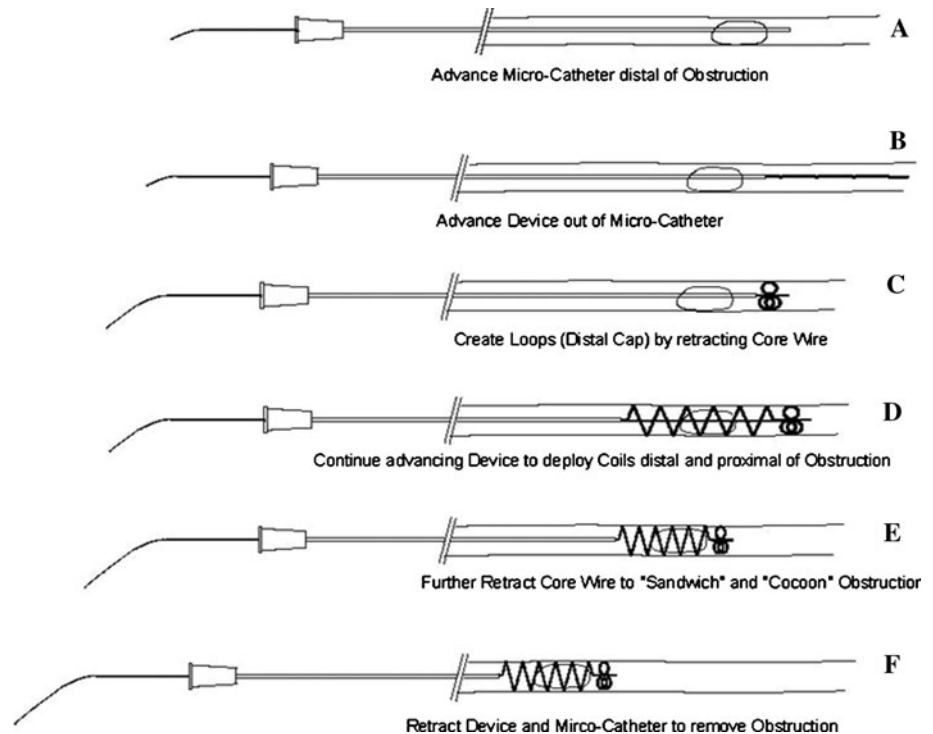


Fig. 2 Principles of operation. Device is passed distal to the thrombus coils are formed distal, within, and proximal to the thrombus. The thrombus is then cocooned within the MTD and retracted from the vessel



diameter, the outside diameter of the MTD was 0.021 in. at the eyelet locations, and the device was designed so that it could be inserted through a microcatheter with an internal lumen of 0.027 in. For thrombectomy procedures in the superficial femoral arteries, the device loops measured up to 16 mm in diameter by 10 cm in length in the unrestrained (not within the vessel) configuration. In four of nine cases, the thrombus extended from the superficial femoral artery into a smaller-diameter popliteal artery, profunda femoral artery, or muscular perforating branch. For these cases, the device had three tapering distal coils measuring 5, 4, and 3 mm in diameter. Thus, the MTD dimensions and specifications can be varied for optimal functioning in occluded vessels of differing diameter and length.

Principle of Operation

The MTD is inserted into a 4F angiographic catheter or 0.027-in. microcatheter positioned distal to the obstruction, using conventional over-the-wire coaxial angiographic technique (Fig. 2A). The device is advanced (Fig. 2B) and then actuated to form the distal loops (Fig. 2C). These loops act as a cap over the distal aspect of the thrombus. To ensure retrieval of the intact clot or other obstruction, the preshaped coils are then advanced out of the microcatheter around the midportion of the thrombus and then the proximal portion of the clot as the catheter is progressively pulled back to unsheath the device (Fig. 2D). Once placed, the core wire is further retracted to tighten the coil structure around the obstructing thrombus (Fig. 2E). The obstructing

thrombus, now fully encapsulated within the coil element, can be safely and completely removed without fragmentation (Fig. 2F).

Animal Preparation

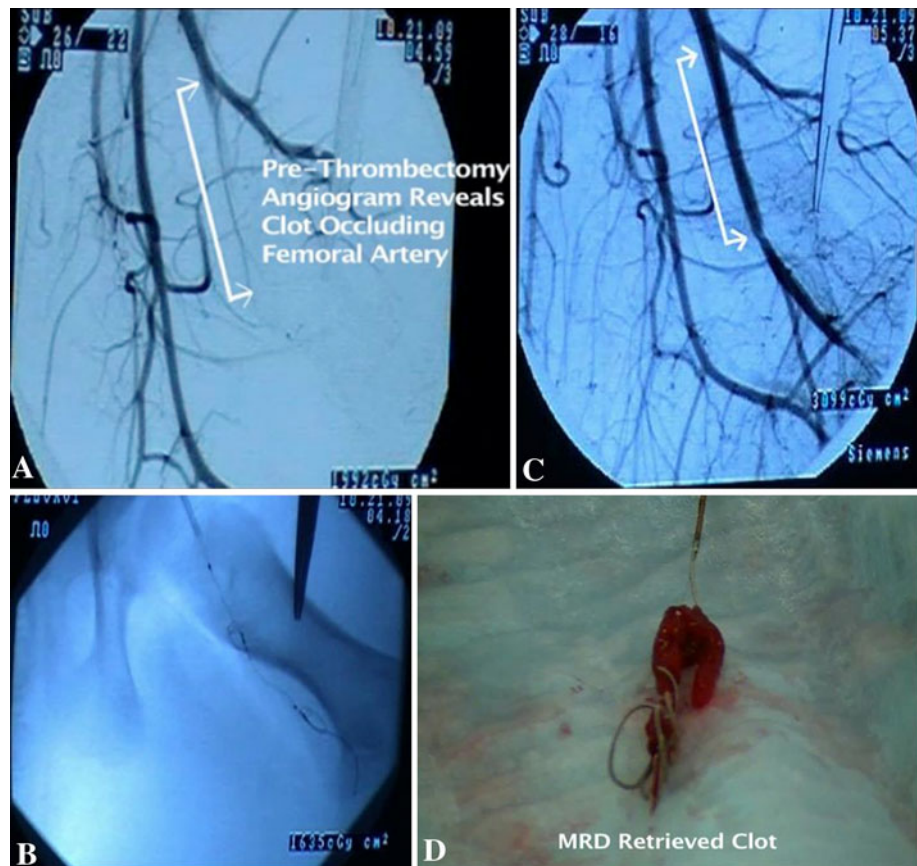
All studies involving experimental animals were performed at the University of California at Davis (UCD) in full compliance with U.S. National Institutes of Health Guidelines. UCD research ethics board approval was obtained in advance of conducting any experiments involving animals.

Four- to 6-month-old Yorkshire pigs (34–46 kg body weight) were tranquilized with a combination of ketamine hydrochloride (20 mg/kg, i.m.) and xylazine (2 mg/kg, i.m.) or with Telazol (4.5 mg/kg, i.m.) by qualified animal care technologists. After endotracheal intubation, the animal was anesthetized with 2% isoflurane gaseous inhalent. An intravenous line was placed for collection of blood samples and administration of heparin (150 U/kg body weight). Animals were transferred to the angiography suite of the surgical research facility. Continuous physiological monitoring of the animal was performed throughout the angiographic procedures.

Thrombus-Embolic Model

Thrombi were produced from fresh pig blood drawn in a previous experiment. The initial experiments were performed with whole pig blood that was allowed to stand in a glass beaker in a refrigerator for 4 days. This produced

Fig. 3 Angiography during porcine femoral thrombectomy. **A** Prethrombectomy angiography demonstrates complete femoral artery occlusion. **B** MTD being deployed at site of thrombotic occlusion. **C** Postthrombectomy angiography demonstrates complete revascularization, restoration of vascular patency, after a single application of the MTD. **D** MTD with thrombus within coil network after thrombectomy



both a white fibrin clot and a red, more gelatinous clot. We cut a portion of the white fibrin material from the total and embolized it into the vessel of interest. This material was chosen to represent a hard clot, such as might be seen in a patient with atrial fibrillation. A similar thrombus model has been described [5]. The clot size varied, depending on the vessel to be embolized. For branches of the subclavian or external carotid artery, hard fibrin-laden clots 4 mm in diameter by 6 mm in length were cut from the experimental clot. For embolization into the superficial femoral artery and its branches, the clot was approximately 8 mm in diameter and 5 to 10 cm long. The single clot was delivered intact through a 10F sheath. The clot was not mixed with contrast in order to avoid changing its consistency and thus was not radiopaque. Placement and retrieval were demonstrated by pre- and postthrombectomy angiography (Fig. 3A–C) and extracted thrombus evaluated (Fig. 3D). In all cases, the vessel was completely occluded with thrombus before thrombectomy.

Experimental Procedure

The goal of the experiments was to evaluate this thrombectomy device in a number of vascular distributions, which might be relevant to clinical practice. A total of 26

vessels in 14 pigs underwent mechanical thrombectomy by MTD. Thrombectomy was performed in nine superficial femoral arteries, eight subclavian arteries, five primary branches of the subclavian artery including the lateral thoracic artery and the thyrocervical trunk, and four external carotid arteries. Vessels measured between 3 and 9 mm in diameter.

After surgical exposure of the right common femoral artery, a 10F femoral sheath with a nonremovable hub was inserted using the Seldinger technique. Angiography was performed with a Siemens Power Mobil C-Arm. Angiography was initially performed of the artery to be studied, including the subclavian, external carotid, and superficial femoral arteries, with a 9F intra-arterial guiding catheter. Selective catheterization of these vessels or their branches was followed by injection of the thrombus to produce selective focal occlusion of the vessel, which was confirmed with subsequent angiography. A 4F angled glide catheter (Cook, Bloomington, IN) without or with a 2.7F Fastracker or Infusion microcatheter (Boston Scientific, Boston, MA) with a 0.014-in. micro-guide wire (Boston Scientific) were used to attain position distal to the thrombus under fluoroscopy with road mapping capability. After removal of the guide wire, the MTD was passed through the catheter and positioned so that the tip was

distal to the intra-arterial embolic occlusion. Angiographic visualization was used to confirm the position of the device in relation to the embolus. The distal coils of the MTD were activated to form a cap on the distal surface of the embolus, after which the catheter was pulled back so that more proximal coils of the device were exposed to surround the midportion of the embolus. After pulling the catheter proximal to the embolus, more coils were formed to abut the proximal aspect of the thrombus. The distal and proximal coils of the device were drawn together by the pull string/pull wire to enmesh the embolus securely at both its distal and proximal aspects. The embolus was then retracted toward the guide catheter and removed from the blood vessel (Fig. 2). A photograph was made of the extracted clot and device coil mesh. Angiography was repeated after a single sweep with the thrombectomy device, and restoration of flow was evaluated to determine the degree of recanalization of the previously occluded blood vessel (Fig. 3). Angiographic data were recorded on tape and archived for subsequent analysis.

In three experiments, embolized blood vessels were surgically removed after the thrombectomy procedure for histopathologic assessment of vascular wall damage.

Data Recording and Analysis

The primary endpoint of the studies was to determine the efficacy of the MTD for the removal of obstructing thrombus. This was determined by the degree of vascular recanalization immediately after a single pass of the thrombectomy device, as well as at 15 and 30 min after the procedure. An analysis of device safety was also conducted as a primary endpoint of the study. Device safety was determined through evaluation of device failure and procedural complications. Device failure was evaluated by fluoroscopy or direct inspection in relation to the following safety measures: (1) solder point breakage during removal of the thrombus, (2) unraveling or breakage of distal loops, eyelets, or proximal loops, (3) breakage of coil bond to transition tube, and (4) breakage of transition tube bond to hypo tube. Procedural complications were evaluated on the basis of the following measures: (1) vascular perforation, (2) intramural arterial dissection, (3) embolization to previously uninvolved vascular territory or territories, (4) hemorrhage in the vascular region of interest, (5) vasospasm of the treated vessel, (6) access site injury, (7) embolic fragmentation, and (8) distal migration of embolic fragment or fragments.

Secondary endpoints of the study included subjective operator evaluation of MTD performance. The following technical and procedural data were recorded for each device used in each study: (1) general ease of use by the physician, (2) adequacy of device length and number of coils, (3) ease of loading the device into the catheter, (4)

navigability to the site of embolic occlusion in a blood vessel, (5) ease with which the device tip passed to the distal side of the embolus, (6) ease of deployment of distal and proximal coils, (7) ease with which distal and proximal coils engage the embolus, (8) ease of retrieval of the embolus from the occluded blood vessel without fragmentation, and (9) visibility of the device.

Results

Device Efficacy

Results are summarized in Table 1. After single-pass thrombectomy with the MTD, retrieval of embolus from the occlusion site achieved complete angiographically determined recanalization in 21 (81%) of 26 trials. Partial (>50%) removal of the thrombus from the occluded vessel was demonstrated in another three vessels. Overall, partial or complete recanalization was observed in 24 (92%) of 26 vessels treated with a single pass of the MTD.

Device Safety: Procedural Complications

There were no major complications associated with the MTD thrombectomy procedure, including vascular perforation, intramural arterial dissection, distal embolization from an embolic fragment, hemorrhage, or access site injury. In initial studies with the MTD, the animals were not pretreated with intra-arterial papaverine. Consequently, vasospasm of the embolized blood vessel occurred in 8 (30%) of 26 vessels. This vasospasm was qualified as slight except in one case of moderate vasospasm. Manipulations were not strong or excessive during the procedure.

Studies indicate that porcine blood vessels are generally very susceptible to vasospasm, and smaller caliber vessels would be more susceptible to vasospasm even with wire manipulations. In all instances in which vasospasm was observed, the vasospasm resolved with intra-arterial papaverine, without sequelae of vascular injury suggested on subsequent angiography. In subsequent procedures in the external carotid and smaller branch vessels, the occluded vessel was pretreated with papaverine, which eliminated vasospasm.

Thromboemboli fragmented during 5 of 26 procedures that used an early version of the MTD. In one case, fragmentation seemed to have resulted from incomplete coil engagement. In 4 other cases, the embolus apparently fragmented during withdrawal from the body, when pulling the microcatheter into the guide catheter, or out of the access sheath. After the distal coils of the MTD were reinforced with slightly thicker platinum, no further cases of distal embolization were observed.

Table 1 Summary of results of preclinical studies

Outcomes measures	Incidence	Success rate (%)
<i>Device efficacy parameters (single pass with device)</i>		
Retrieval of embolus from occlusion site	24/26	92
Removal of embolus from body	18/26	69
Complete vascular recanalization	21/26	81
<i>Device utility parameters</i>		
Adequate general ease of use	26/26	100
Adequate ease of loading into standard microcatheter	26/26	100
Adequate navigability within tortuous vasculature	26/26	100
Adequate navigability to site of embolic occlusion	26/26	100
Adequate deployment of device tip to distal side of embolus	26/26	100
Adequate deployment of distal coils	25/26	96
Adequate deployment of proximal coils	25/26	96
Adequate engagement of embolus by distal coils	25/26	96
Adequate engagement of embolus by proximal coils	25/26	94
Adequate drawing together of distal and proximal coils by pull string to surround and secure embolus	23/26	88
Adequate tensile strength of device to retrieve embolus from occlusion site	26/26	100
Adequate tensile strength of device to remove embolus from body	26/26	100
Adequate enmeshing strength of distal and proximal coils to remove embolus without fragmentation	25/26	96
<i>Device safety parameters</i>		
<i>Procedural complications</i>		
Vascular perforation	0/26	100
Intramural arterial dissection	0/26	100
Distal embolization from embolic fragment	0/26	100
Hemorrhage	0/26	100
Vasospasm in embolized blood vessel	8/26	30
Access site injury	0/26	100
Embolic fragmentation	5/26	19
<i>Device failure</i>		
Unraveling of distal loops	1/26	96
Unraveling of proximal loops	1/26	96
Breakage of coil bond to transition tube	1/26	96
Breakage of transition tube bond to hypo tube	0/26	100

Histopathological analyses were performed by an independent pathologist on three excised femoral artery vessels treated with the MTD. The results were compared to contralateral femoral artery segments treated with an

inflated Fogarty balloon. No arterial wall damage or other vascular injury was seen with either device.

The consistency of the clot generated in this animal model may not exactly match that of acute and chronic human embolic/thrombotic clot. However, initial clinical trials, now underway in human patients, suggest similar or better results.

Device Failure

As shown in Table 1, unraveling of proximal or distal loops during withdrawal of the embolus was observed in only one procedure. In one test during withdrawal of an embolus, the coil bond at the transition tube broke. Otherwise, device failure was not observed during coil deployment, thrombus capture, or during withdrawal of the obstructing thrombus. The MTD tensile strength is greater or equal to 0.7 lb at the catheter-coil joint.

Device Adequacy and Ease of Use

Each step of the MTD operation was evaluated for ease of use during the procedure. Overall ease of use, ease of device loading into a standard microcatheter, and device navigability to the site of embolic occlusion was adequate in all trials. The device is designed to be easy to use, allowing rapid mechanical thrombectomy requiring approximately 4 min to load, actuate, and sweep the occluded vessel.

The porcine iliac and subclavian arteries are quite tortuous and are generally similar to human vessels with a moderate degree of tortuosity. During bench-top evaluation of the MTD, plastic tubing (SLA) models were constructed on the basis of computed tomographic angiography from patients. Acute angles encountered in peripheral and intracranial vessels were modeled. This tubing was used in initial pre-animal testing of the device in order to optimize pushability, flexibility, and trackability of the MTD.

The MTD was successfully deployed distal to the embolus in all cases. The proximal and distal coils formed in 25 (96%) of 26 vessels tested. In one vessel, the distal and proximal coils seemed to unravel such that the embolus could not be removed. Adequate drawing together of distal and proximal coils by the pull string to surround the entire embolus occurred in 23 (88%) of 26 vessels tested. In three tests, the embolus was not completely secured by the coils after the pull string was drawn. However, it was withdrawn from the vessel resulting in restored patency. Adequate tensile strength of the MTD to retrieve an embolus from the occluded vessel was found in all cases. Adequate enmeshing strength of distal and proximal coils to remove an embolus without fragmentation was demonstrated in 25 cases (94%). In one trial, embolus fragmentation was

apparently caused by incomplete coil engagement, during removal from the guide catheter and sheath.

Discussion

Vascular recanalization should be rapid, safe, and efficacious. Current strategies often use thrombolysis initially with subsequent use of MTDs if thrombolysis is inadequate to recanalize the vessel [6, 7]. Thrombolysis can be a lengthy and costly procedure with inherent risk. Thrombectomy devices have been developed in an attempt to prolong the therapeutic time window for stroke and to treat patients with contra-indications to thrombolysis [6]. A MTD that is easy to use and consistently opens vessels could become the first line of treatment [2]. In the current preclinical study, no thrombolytic agent was used.

A number of devices exist for peripheral mechanical thrombectomy, and fewer devices exist for extra- or intracranial thrombectomy in the setting of stroke [7–16]. For each of the devices, there are reported technical success and complication rates [2, 3, 7, 12, 13]. The MTD is designed to negotiate tortuous vessels and fully enmesh and remove hard organized fibrin-laden thrombus as well as soft acute thrombus with minimal distal embolization and without vascular injury.

The results of this study show high rates of complete recanalization after single-pass thrombectomy with the MTD, which compare favorably to those reported for other MTDs used in the setting of stroke. Rha and Saver conducted a meta-analysis of the stroke literature and reported vascular recanalization rates of 83.6% with mechanical devices [17]. In the Multi-MERCI trial, the recanalization rate with the new L5 system was 57.3% [18]. The first Penumbra stroke trial reported 100% recanalization with Thrombolysis in Myocardial Infarction (TIMI) II, incomplete or partial recanalization of the primary occlusion with distal flow, of 48%, and TIMI III, complete recanalization of the primary occlusion with distal flow, in 52%, of the vessels [19]. An 81.6% recanalization rate (54.4% TIMI II and 27.2% TIMI III) is reported in the subsequent Penumbra Pivotal Stroke study [14]. In our pilot study, successful removal of intravascular embolic/thrombotic obstruction, including soft and hard thrombus, was demonstrated in a number of arteries, including the external carotid artery, the subclavian and its primary branches, and the superficial femoral artery. Thus, efficacy was evaluated in arteries relevant to both stroke and peripheral thromboembolic ischemic disease. The rate of 81% TIMI III recanalization with a single pass and no use of a thrombolytic agent compares favorably with the best reports in the literature to date.

The present data suggest that the MTD may have several practical and conceptual advantages over current

commercially available mechanical retrieval systems. One clear advantage of the proposed device is its small size and navigability, which enable retrieval of obstructions from small and tortuous vessels. The ability to navigate small and tortuous vessels is clinically relevant because it is known that many ischemic strokes are a result of the occlusion of intracranial arteries, such as the middle cerebral artery or its branches, or the basilar artery or its branches [4, 8]. In peripheral arterial thromboembolic disease, removal of thrombus from the small caliber popliteal and or tibial branches is essential and often entails navigation of tortuous vessels such as the iliac arteries when contralateral access is used.

It has been reported that current peripheral arterial thrombectomy devices have a 2–18% rate of distal embolization [2, 12]. In vitro flow studies have been used to compare distal embolization rates of a number of commonly used rheolytic and MTDs [13]. Initial clinical trials evaluating the Trellis device (Bacchus Vascular, Santa Clara, CA) suggested an 11% incidence of distal embolization [16]. The design of the MTD described here may explain the absence of distal embolization during clot removal. The MTD is essentially a series of coils that are placed around the thrombus to cocoon it and then pulled tightly with a pull wire. The coil envelope keeps the thrombus from fragmenting during withdrawal [9]. This may provide a distinct advantage over other MTDs.

Angiographic visualization during the present thrombectomy studies indicated that there was no distal macroembolization, although in 4 of 26 cases there was shearing and fragmentation of thrombus from the device when removing the clot burden from the valved 10F vascular sheath. Clot could be purged from the sheath after use of the MTD, if removed over a wire. No distal embolization at the site of clot retrieval is observed angiographically. The clot burden removed from these vessels is thought to greatly exceed that removed during stroke thrombectomy. Strategies for more complete clot removal from the MTD sheath include a valveless vascular sheath and a flared, cinchable sheath for clot capture, both of which are currently being developed and optimized. Studies of the MTD using a pulsatile flow model, similar to that described by Müller-Hülsbeck et al. [13], have demonstrated that no clinically significant fragmentation of emboli are generated during MTD removal of blood clots. Device failure with MTD procedures was rarely encountered and most commonly resulted from unraveling of the coil complex and inadequate first-pass retrieval of the intact thrombus. All operators' subjective measures of ease of use and most measures of adequacy were favorable.

The occurrence of hemolysis, with resultant adenosine release and possible bradycardia, has been reported in 6–14% cases when rheolytic thrombectomy devices are

used [12]. Ultrasound-assisted thrombolytic approaches also have associated hemolysis, although at a lower level than with the AngioJet device [15]. By comparison, hemolysis is unlikely with the MTD because no maceration of blood constituents occurs during thrombectomy.

Traumatic adverse events, including hemorrhage in 6–10% cases, dissection in 6–8% cases, and vessel perforation in 4% cases, have been reported for a number of current MTDs [12]. In contrast, no vascular injury was demonstrated angiographically or by histopathologic evaluation after use of the MTD in the present study. This is likely because the MTD uses soft and nontraumatic coils to mechanically retract blood clots. The MTD coils have an adjustable stiffness that provides reliable dynamic compliance matching the viscoelastic properties of the obstructing thrombus being retrieved, thereby facilitating control of gripping forces on the obstruction while reducing circumferential contact of the device with the blood vessel endoluminal surfaces.

A final notable attribute of the MTD is that the thrombectomy procedure time is approximately 2 to 6 min, without extensive preparation time as with other thrombectomy devices. Furthermore, because a thrombolytic agent is not required, there is no lost time, as when a “lyse and wait” or other thrombolytic infusion strategies are used. All operators’ subjective measures of ease of use and most measures of adequacy were favorable with the MTD.

In conclusion, the MTD is intended to remove both soft acute blood clot and hard, organized embolic/thrombotic obstructions. These initial porcine studies demonstrate that the MTD is safe, effective, and easy to use. The design of the MTD allows it to be easily modified and optimized for mechanical thrombectomy procedures in any vascular territory. The preliminary animal- study data reported here also indicate that this device may be useful in several clinical settings, including acute stroke, dialysis graft/fistula salvage, deep venous thrombosis, peripheral thrombotic/embolic arterial occlusion, pulmonary embolism thrombectomy, and coronary artery thrombotic/embolic occlusion. Clinical trials with the MTD thrombectomy device are now underway.

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