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TECHNICAL NOTE

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SUMMARY: A prototype endovascular electromechanical clot-extraction device was fabricated using a combination of shape memory polymer and shape memory nickel-titanium alloy (nitinol). Five embolic vascular occlusions were created in 4 rabbits by injecting thermally coagulated blood through a 4F catheter in the common carotid artery. Angiography immediately after clot injection showed complete or partial occlusion of the common carotid artery. Posttreatment angiography showed complete (2/5), partial (2/5), or no (1/5) restoration of blood flow.

Most strokes are caused by cerebral thromboembolic arterial occlusion and are conventionally treated with intravenous thrombolytic drugs. Drawbacks associated with this treatment, including the narrow (3-hour) therapeutic window and strict exclusion criteria imposed to mitigate the risk of hemorrhage, have prompted the development of alternative nonpharmacologic therapies. We report on the use of an electromechanical embolectomy device in a rabbit acute arterial occlusion model.

Description of Technique

Device Use and Fabrication

The prototype device consists of an electromechanical microactuator mounted on the distal tip of either a Prowler-14 microcatheter (1.9F distal shaft, Cordis, Miami Lakes, Fla) or a custom-made 1.5F stainless steel 55-cm-long hypotube with a 20-cm-long distal flexible coil section (Heraeus Vadnais, St Paul, Minn). A device is shown in Fig 1. The microactuator comprises a shape memory polymer (SMP) shell over a shape memory nickel-titanium alloy (nitinol) wire backbone with attached copper leads to deliver a current. The microactuator maintains a straight rod shape until the applied current, provided by a DC power supply, induces electroresistive (joule) heating of the nitinol wire, causing the microactuator to transform into a corkscrew shape capable of retrieving a blood clot. At body temperature, the overlying SMP is in a glassy (high-elastic modulus) state and maintains the nitinol corkscrew in a straight form for endovascular delivery. Once the microactuator is positioned beyond the clot, joule heating is initiated. As the surrounding SMP is heated by conduction to its characteristic glass-transition temperature ($T_g \approx 80^\circ\text{C}$), it transitions to its low-modulus rubbery state, allowing the nitinol to resume its corkscrew shape. When the current is turned off, the nitinol and the SMP cool and the elastic modulus of the SMP approaches its original

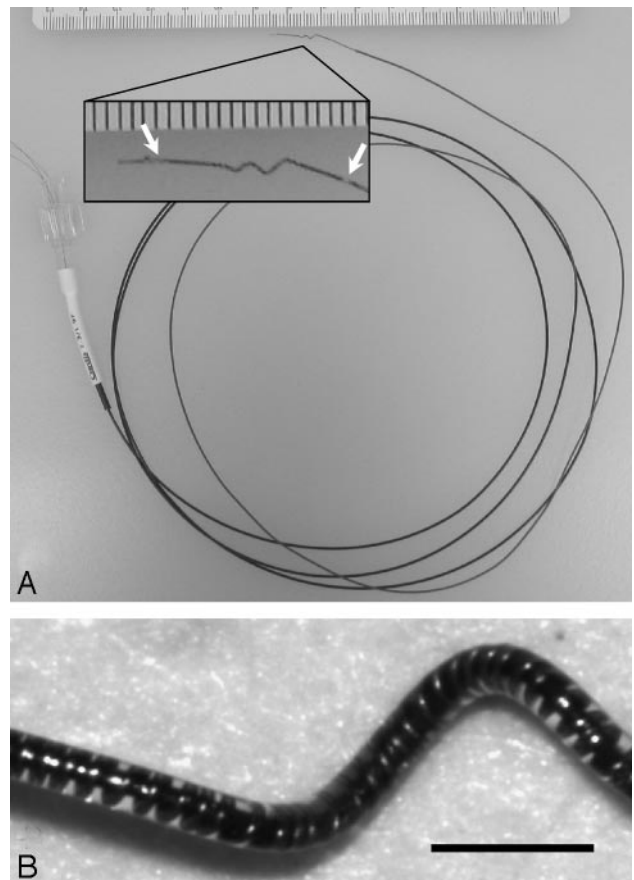


Fig 1. Electromechanical embolectomy device in its corkscrew form.

A, The SMP-nitinol corkscrew microactuator is mounted at the distal end of a microcatheter. The copper leads (and nitinol wire) extend from the proximal end of the microcatheter for connection to the power supply. A close-up of the microactuator showing the radiopaque gold markers (arrows) is seen in the inset. Scale divisions are in millimeters.

B, Microscope image of the microactuator showing the copper-wound nitinol wire encapsulated by the SMP. The diameter of the microactuator is 0.3 mm (0.012 inches). Scale bar = 1 mm.

glassy value, providing enhanced stiffness to the nitinol corkscrew and resistance to deformation (ie, stretching) during blood clot extraction.

Superelastic nitinol wire (SE508 wire, Nitinol Devices & Components, Fremont, Calif) with a diameter of 97 μm was wrapped around an aluminum mandrel and heated in a furnace at 500°C for 10 minutes to program the corkscrew shape. The nitinol reverts to the pro-

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Summary of mechanical embolectomy results

Rabbit	Occlusion Site	Angiographic Deficit	No. of Extraction Attempts	Clot Retrieved from Sheath?	Angiographic Findings Posttreatment
1	RCCA	Filling defect	1	Yes	Complete restoration
2	RCCA	Complete occlusion	3	Yes	Complete restoration
3	RCCA	Complete occlusion	3	Yes	Partial restoration
	LCCA	Complete occlusion	5	No	Complete occlusion
4	RCCA	Complete occlusion	5	Yes	Partial restoration

Note:—RCCA indicates right common carotid artery; LCCA, left common carotid artery

grammed corkscrew shape at temperatures at or above its austenite finish temperature ($A_f = 5\text{--}18^\circ\text{C}$). To route current flow through the nitinol corkscrew for joule heating, 2 polyimide-insulated 40–American wire gauge copper wire leads approximately 100 cm long were connected to the nitinol wire at each end of the corkscrew by using gold crimp tubes, which also served as radiopaque markers. The diameter of the copper wire including insulation was $95\text{ }\mu\text{m}$. The copper wire lead attached at the distal end of the nitinol corkscrew was wound back around the length of the corkscrew (Fig 1), permitting both copper wire leads to emerge from the same (proximal) end of the corkscrew.

A thermosetting urethane SMP formulation developed in-house¹ was used to encase the copper-wound nitinol. A Teflon (Dupont, Wilmington, Del) tube (inner diameter = $305\text{ }\mu\text{m}$) was placed over the straightened copper-wound nitinol corkscrew, and the SMP resin was injected into the tube. The cast SMP resin was then thermally cured, and the Teflon tube was removed. This step revealed a straight SMP rod encapsulating the copper-wound nitinol wire.

Intervention

The animal experiments were conducted at the University of California-Davis Medical Center (Sacramento, Calif) in accordance with the

National Institutes of Health Public Health Service Policy on Humane Care and Use of Laboratory Animals and approved by the Institutional Animal Care and Use Committees of the University of California-Davis and Lawrence Livermore National Laboratory. Five occlusions were treated in 4 anesthetized New Zealand white rabbits (weight, 3–4 kg). A 4F sheath was placed in the right or left femoral artery, and a 4F catheter was directed into the common carotid artery (CCA; lumen diameter, 1.5–2.0 mm) under fluoroscopic and road-map guidance by using iohexol contrast media (Omnipaque 300, GE Healthcare, Princeton, NJ); baseline angiography was performed. Blood collected from a marginal ear vein was thermally coagulated, and a clot $0.2\text{--}0.3\text{ cm}^3$ was injected through the catheter into the CCA. Angiography was performed to evaluate the resulting vascular occlusion, and additional clot was injected if necessary. Under fluoroscopic guidance, the clot extraction device was delivered through the catheter in its straight form, positioned into the external carotid artery (ECA) distal to the occlusion, and actuated to assume its corkscrew form by applying a DC current of 0.6–0.8 A for 3–5 seconds until actuation was complete (the copper-wound nitinol was visible by fluoroscopy). The device and catheter were then withdrawn simultaneously. The sheath was inspected, and any lodged clot was collected. Angiography was performed after each extraction attempt.

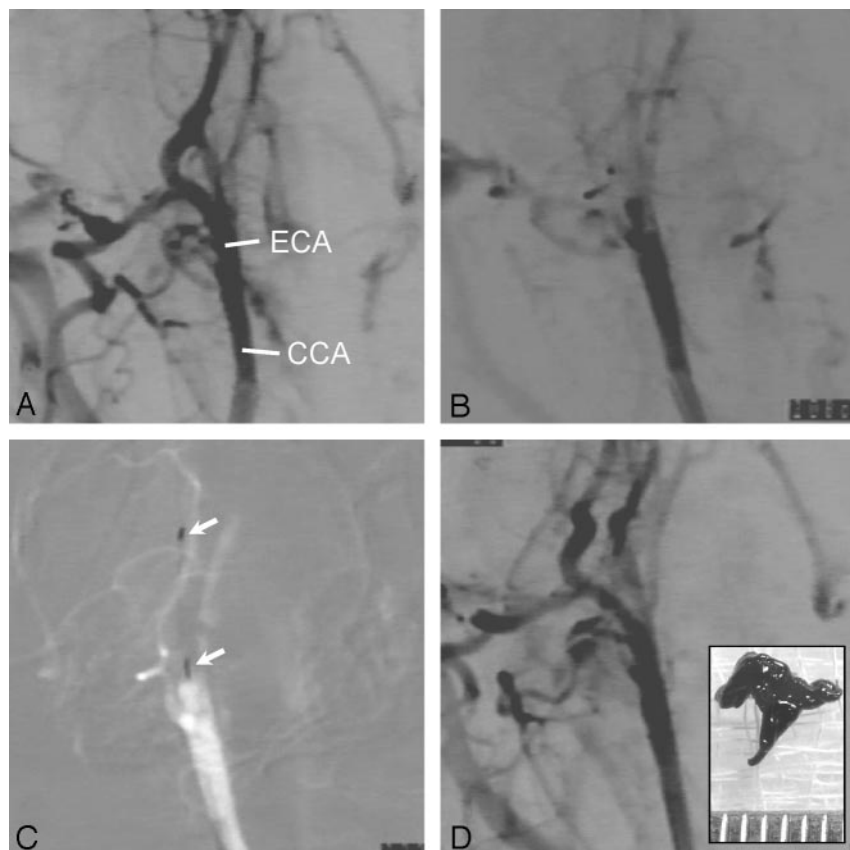


Fig 2. Angiographic images of the 2nd rabbit.

A, Baseline angiogram of the right CCA and branch vessels acquired before clot injection.

B, Angiogram showing occlusion of the CCA.

C, Fluoroscopic image showing placement of the device into the ECA distal to the occlusion (radiopaque markers indicated by arrows). The copper-wound nitinol was visible on the fluoroscopy monitors but not on the video tape recording used to capture the image.

D, Posttreatment angiogram showing complete restoration of blood flow. A photograph of the retrieved clot is shown in the inset (scale divisions in millimeters).

The results are summarized in the Table. Angiographic images of the 2nd rabbit are shown in Fig 2.

Discussion

Nonpharmacologic vascular reperfusion methods have exhibited the potential to broaden the eligibility of patients with stroke by extending the therapeutic time window and reducing the contraindications related to the risk of hemorrhage.² In particular, the US Food and Drug Administration recently approved the use of the Merci Retrieval System (Concentric Medical, Mountain View, Calif), a springlike endovascular thrombectomy device, to retrieve the clot up to 8 hours after the onset of stroke.^{3,4} In the clinical study evaluating the safety and efficacy of the Merci system, up to 6 extraction attempts were made before the effort was considered a failure, with 3 attempts made on average.⁴ Similarly, in this study, multiple attempts were usually required. This may at least in part be due to the fact that fragmentation of the injected clot occurred because of the small lumen of the 4F catheter, confirmed on benchtop injection of clot through the catheter.

Several potential performance-enhancing modifications to the current device have been identified, including a flexible distal tip, a tighter corkscrew, and a means of securing the clot (eg, aspiration into the guide catheter) for withdrawal from the body. Flow arrest, as in the Merci system,^{2,3} could facilitate clot extraction and reduce the risk of distal embolization. The actuation temperature (ie, the T_g of the SMP) would be minimized but maintained sufficiently above body temperature to prevent spontaneous actuation in the body and to reduce the risk of thermal injury to the vessel during device actuation. The T_g of the SMP can be tailored from approximately 34–

86°C by adjusting the chemical composition.¹ Because the glass transition is gradual, actuation can be achieved at temperatures $\sim 10^\circ\text{C}$ below the nominal T_g . Previous studies of energy-dissipating interventional therapeutic devices that generate temperatures and total energy dissipated on the same order of magnitude as the SMP-nitinol device have resulted in no thermal damage.⁵ Future studies may include histologic examination of tissue harvested at the site of actuation at various posttreatment time points to assess the extent of thermal injury, if any. In addition, further studies are necessary in larger animals to allow the use of larger catheters, injection of intact clot, and evaluation of the device in vessels similar in size to the human internal carotid artery.

This preliminary study suggests that an SMP-nitinol device may have application in the treatment of acute stroke or other thromboembolic disease.

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