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_Circulation_ published online Feb 20, 2006;
DOI: 10.1161/CIRCULATIONAHA.105.586727

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Real-Time Magnetic Resonance Imaging–Guided Endovascular Recanalization of Chronic Total Arterial Occlusion in a Swine Model

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Background—Endovascular recanalization (guidewire traversal) of peripheral artery chronic total occlusion (CTO) can be challenging. X-ray angiography resolves CTO poorly. Virtually “blind” device advancement during x-ray–guided interventions can lead to procedure failure, perforation, and hemorrhage. Alternatively, MRI may delineate the artery within the occluded segment to enhance procedural safety and success. We hypothesized that real-time MRI (rtMRI)–guided CTO recanalization can be accomplished in an animal model.

Methods and Results—Carotid artery CTO was created by balloon injury in 19 lipid-overfed swine. After 6 to 8 weeks, 2 underwent direct necropsy analysis for histology, 3 underwent primary x-ray–guided CTO recanalization attempts, and the remaining 14 underwent rtMRI-guided recanalization attempts in a 1.5-T interventional MRI system. Real-time MRI intervention used custom CTO catheters and guidewires that incorporated MRI receiver antennae to enhance device visibility. The mean length of the occluded segments was 13.3±1.6 cm. The rtMRI-guided CTO recanalization was successful in 11 of 14 swine and in only 1 of 3 swine with the use of x-ray alone. After unsuccessful rtMRI (n=3), x-ray–guided attempts were also unsuccessful.

Conclusions—Recanalization of long CTO is entirely feasible with the use of rtMRI guidance. Low-profile clinical-grade devices will be required to translate this experience to humans. (Circulation. 2006;113:1101-1107.)

Key Words: angioplasty ■ catheterization ■ magnetic resonance imaging ■ occlusion ■ peripheral vascular disease

Chronic total occlusion (CTO) of peripheral arteries can cause disabling intermittent claudication or critical limb ischemia. Surgical revascularization offers symptom relief and limb salvage in eligible patients; however, perioperative morbidity, lengthy hospital stay, and slow functional recovery limit wider application.1,2 Endovascular techniques are appealing because they offer prompt return of function and require neither general anesthesia nor extended hospital stay. However, endovascular recanalization of long, tortuous, occluded peripheral arteries remains challenging and risky, and therefore surgical or conservative management is typically recommended.1

X-ray fluoroscopic angiography with radiocontrast identifies the occluded inflow artery and possibly collateral-dependent outflow beyond the occlusion but cannot discriminate CTO arterial wall and lumen. In these cases, the entire occluded arterial segment remains invisible to the operator. Virtually “blind” device manipulation risks procedural failure and arterial perforation. Furthermore, ionizing radiation and nephrotoxic contrast exposure may become excessive during lengthy CTO recanalization procedures.

MRI can image the entire peripheral artery occlusion, including arterial wall, lumen content, and adjacent structures, without ionizing radiation or iodinated radiocontrast. Advances in rapid imaging, combined with development of catheter devices visible under MRI, have made real-time MRI (rtMRI)–guided therapeutic interventions feasible.3–19 We hypothesize that rtMRI can guide catheter navigation within an occluded artery and that combined CTO recanalization and percutaneous transluminal angioplasty can be conducted en-
artery length and stained with hematoxylin and eosin and Masson’s

tapered, custom tungsten-braided catheters (Minnesota MedTec).

performed at 2 weeks to confirm CTO. If the LCA remained patent

to 6 times. Contrast-enhanced MR angiography (CEMRA) was

artery (LCA), inflated to nominal pressure, and rapidly withdrawn up

high-cholesterol diet for 1 week before CTO model creation and

Distal 1-cm microcoils were mounted on 6F

Custom MRI Active CTO Support Catheter

Methods

Balloons Injury Model

Animal protocols were approved by the National Heart, Lung, and

Blood Institute Animal Care and Use Committee. National Institutes

of Health miniswine (mean weight, 50±12 kg) were fed a 2% high-cholesterol diet for 1 week before CTO model creation and

thereafter until recanalization was attempted 6 to 8 weeks later. After transfemoral access, an angioplasty balloon (Agiltron, Guidant) sized

1.5 to 2 times artery diameter was positioned in the mid left carotid

Artery (LCA), inflated to nominal pressure, and rapidly withdrawn up
to 6 times. Contrast-enhanced MR angiography (CEMRA) was

performed at 2 weeks to confirm CTO. If the LCA remained patent

(\(n = 4\)), balloon injury was repeated.

Histology was performed on 2 uninstrumented CTO arteries 8

weeks after balloon injury. Formalin-fixed, paraffin-embedded,

transverse sections (4 \(\mu m\)) were taken at 5-mm intervals along the
artery length and stained with hematoxylin and eosin and Masson’s

Interventional MRI Suite

Procedures were performed in a previously described combined

x-ray/MRI interventional suite (Axiom Artis.1.5-T Sonata, Sie-

mens).

In-room hemodynamics, scan control, and rendered images were

displayed with the use of shielded LCD projectors. Optical

microphones (Phone-Or) and filtered headsets (Magnacoustics) per-

mitted staff communication.

Digital subtraction x-ray and CEMRA of the arch and great

vessels were performed immediately before and after intervention.

Typical parameters (repetition time [TR] [ms]/echo time [TE]

[ms]/flip angle [FA] [degrees]/bandwidth [Hz per pixel]/voxel size

[VOX] [mm]) were as follows: TR/TE/FA/bandwidth/VOX = 3.7/1.4/2/3/0.3×0.5×2, slab 300×244×128 mm. Real-time steady

state free precession (rtSSFP) and 2D TI-weighted (T1w) spin echo

axial images representing key anatomic planes were stored for

interruption during the intervention. Typical parameters were as follows: rtSSFP: TR/TE/FA/bandwidth/VOX = 3.5/1.7/45/975/1.0×1.4×4; T1w: TR/TE/FA/bandwidth/VOX = 130/0.5/0.5×3, 2 averages.

During rapid device manipulation in the aortic arch, rtSSFP frame

rate was accelerated 3:1 with the use of echo sharing, wherein image

data are interleaved over adjacent frames. Saturation prepulses

suppressed background tissue to better visualize inflation of balloons

filled with gadopentetate dimeglumine (0.8% Gd-DTPA, Magnevist,

Berlex) and selective intra-arterial angiography (2.4% Gd-DTPA).

Uninterrupted real-time subtraction angiography was achieved by

displaying the difference between maximum intensity projections in

time before and after the injection. Voxel size was reduced to

increase spatial resolution, and temporal image filtering (averaging)

was applied to improve signal-to-noise ratio (SNR) during slow
device advancement within the CTO. Multiple oblique slices could

be acquired simultaneously, repositioned interactively, and individ-

ually disabled and enabled as desired. Custom scan features allowed

adjustment of pulse sequence, reconstruction, and display parameters

without scan interruption. Finally, signals from separate device

antennae could be independently displayed along their entire length,

color-highlighted, and combined in real time with anatomic images

from surface coils.

Interventional Devices

Active devices were prepared and tested in our laboratory. The intent

was to create devices that were conspicuous along their entire length,

including the tip.

Custom MRI Active CTO Support Catheter

Distal 1-cm microcoils were mounted on 6F ×100-cm angled,
tapered, custom tungsten-braided catheters (Minnesota MedTec).

Figure 1. Custom active CTO guidewire telescoped within custom active CTO support catheter.

Coil signals are transmitted along the catheter shaft under insulating
polyimide. Tuning, matching, and decoupling circuitry were attached
at the proximal hub to prevent heating during MRI. The device was
connected to a separate MR scanner receiver channel so that
device-related images could be displayed in color.

Custom MRI Active CTO Guidewire

Consecutive gold-silver-gold–plated nitinol core wires were inserted

within nitinol hypotubes, separated by polymer insulation. Closely

wound MP35N (cobalt-chromium alloy) microcoils were attached
distally to add wire flexibility, and 2.5-cm distal microcoils enhanced

MRI receiver sensitivity at the tip. The final receiver-coil guidewire

was 0.032 inch×155 cm, straight, and stiff. The proximal end of the
guidewire had detachable connectors, permitting catheter exchange
(Figure 1).

Custom Active Flexible “Workhorse” Guidewire

Flexible-tip nitinol guidewires (Nitrex, ev3, 0.032 inch×155 cm)

were altered to serve as active, “loopless” design21 receiver coils that

were visible along their entire length. These were used as “work-

horse” wires to safely deliver the CTO catheter to the origin of the

occluded carotid artery.

Delivery Sheath

10F delivery sheaths (Fast Cath, St Jude; Brite Tip, Cordis) were

trimmed to 75 cm. Stainless steel MRI markers (1 mm×0.014 inch)

were bonded to the sheath tip, creating passive markers (discrete

signal void) during MRI.

Device Testing

MRI heating tests (Appendix) were performed on CTO support
catheters and guidewires with the use of previously described
methods.22,23

rtMRI-Guided CTO Recanalization

The primary study end point was successful traversal of occluded
arteries from their patent origins to their patent outflow regions. The
secondary study end point was restoration of antegrade flow by
adjunctive balloon angioplasty.
Animals were pretreated with aspirin 325 mg and clopidogrel 300 mg. Intravenous heparin 100 U/kg bolus was given initially and supplemented with 50 U/kg every 2 hours. After sheath insertion, the active CTO support catheter was navigated to the brachiocephalic artery over the active floppy guidewire and positioned proximal to the occluded LCA. The floppy wire was exchanged for the active CTO wire. The CTO guidewire and catheter were steered intraluminally through the CTO with the use of multislice rMRI. Two parallel slices orthogonal to the CTO artery centerline were used to ensure an intraluminal device course. One slice tracked the wire tip, and the second was advanced ahead of the wire tip, providing a target for the operator. Once the CTO was traversed, a 260-cm polytetrafluoroethylene guidewire (Glidewire, Terumo) was used to exchange the CTO guide catheter for a 100-mm-long peripheral angioplasty balloon sized 1:1 to the artery wall. After several balloon inflations with 5 mmol/L Gd-DTPA, selective angiography was performed with the use of 5 mL of 10 mmol/L Gd-DTPA. Intra-arterial nitroglycerin 200 to 400 μg was administered as needed to treat spasm.

**Comparative X-Ray–Guided Recanalization of CTO Model**

X-ray–guided recanalization was attempted in 3 swine by experienced interventionists to assess the suitability and procedural difficulty of the CTO model. Contemporary techniques and devices were used (Shinobi 0.014 inch, Cordis; Cross-It 0.010 to 0.014 inch, Guidant; Glidewire Straight Stiff and Super-Stiff 0.035 inch; 4F Glidecath, Terumo). Each attempt used high-performance x-ray imaging (Artis FC, Siemens) with 13-cm field of view, 15 frames per second, appropriate collimation, and at least 60 minutes of fluoroscopy. In 3 additional swine, after unsuccessful MRI-guided recanalization, x-ray–guided recanalization also was attempted.

**Statistics and Analysis**

Continuous variables were reported as mean±SD and were compared with a 2-tailed Student t test (Excel 2003, Microsoft). Discrete variables (procedure success) were compared by Fisher exact test.24 The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

**Results**

**Device Heating Tests**

No significant heating was observed in phantom experiments during MRI of active CTO support catheters and guidewires (Appendix).

**CTO Model Geometry and Histopathology**

Native LCA diameter by x-ray was 4.6±0.7 mm before balloon injury, measured 70 mm cranial to the carotid bifurcation. Immediate preintervention CTO diameter (T1w) at this level and CTO length (CEMRA) were 4.7±1.3 and 133±16 mm, respectively. By comparison, the contralateral carotid artery diameter (T1w) at this level, the CTO minimal luminal diameter (T1w), and CTO maximal external wall diameter (T1w) were 5.0±0.7, 3.1±1.3, and 6.7±1.2 mm, respectively. These measurements suggest zones of positive (outward) and negative (inward) remodeling in this swine CTO model and are consistent with histology. MRI identified the entire CTO artery wall endoluminal and external boundaries and occasional proximal dissection flaps resulting from initial balloon injury (Figure 2). Histology of the explanted, naive CTO arteries revealed dense luminal collagen deposition, disrupted intima, microchannels, and distal organized thrombus (Figure 3).

**rtMRI-Guided Recanalization**

The primary end point, rtMRI-guided CTO recanalization, was achieved in 11 of 14 animals. The shaft profile and tips of the active devices were conspicuous while navigating the aorta and brachiocephalic arteries (Figure 4). The occluded artery walls and active interventional devices were easily visualized under MRI (Figure 5). Multiplanar imaging facilitated continuous assessment of device-anatomic relationships, enabling intraluminal device traversal. Mean time to wire traversal was 55±22 minutes (spread, 25 to 99 minutes), with an observed learning curve between the first and last third of interventions performed (69±23 versus 34±7 minutes; P=0.048). After balloon angioplasty, real-time selective MRA demonstrated brisk antegrade flow in 6 of 11 of those successfully recanalized with a guidewire (Figure 6). Gross necropsy of all successfully recanalized animals revealed mild artery thickening with no extramural hematoma (Figure 7) and appeared similar to the uninstrumented CTO lesions. In 3 of 14 animals, the active guidewire would not advance beyond the proximal one third of the occluded segment despite an apparently intraluminal trajectory. After careful MRI interrogation to rule out any adverse sequelae such as hematoma, x-ray–guided attempts in all 3 were similarly unsuccessful.

In 2 of 11 successfully recanalized under rtMRI, antegrade blood flow was not achieved despite intra-arterial nitroglycerin and several prolonged balloon inflations because of refractory recoil, spasm, and unavailability of suitable stents. Intraluminal position was confirmed by selective real-time MR and x-ray angiography through the wire port of balloons positioned distal to the lesion.
Homemade active CTO support catheters would not advance over active CTO guidewires that successfully traversed the occlusions in 3 of 11, preventing balloon exchange and subsequent angioplasty. In 1 of these 3 (the very first experimental animal), overaggressive attempts at advancing the active catheter over the wire resulted in clear real-time visualization of extraluminal CTO wire exit followed by extravascular hematoma accumulation. This complication was immediately recognized in rtMRI, and the procedure was aborted.

Comparative X-Ray–Guided Recanalization
Primary x-ray–guided CTO recanalization was successful in only 1 of 3 different animals attempted (requiring 45 minutes of fluoroscopy time). Crossover x-ray recanalization was also attempted in 3 of 14 animals after unsuccessful recanalization under rtMRI; none were successful. When these were combined, 1 of 6 x-ray–guided procedures were successful.

Successful CTO recanalization was more likely (79% versus 17%; \( P=0.02 \)) during rtMRI attempts (11 of 14) compared with all x-ray–guided attempts (1 of 6). During extended primary x-ray recanalization attempts, wire exit caused contrast extravasation in one animal, and dissection was associated with lethal mediastinal hematoma in another.

rtMRI Enhancements
Subtraction real-time MRA improved visibility of intra-arterial Gd-DTPA injections compared with saturation preparation alone (Figure 6E and 6F). We increased spatial resolution by reducing the voxel size, but this degraded the SNR. We used temporal image filtering (averaging) to improve this reduced SNR during periods of slow device motion.

Discussion
Percutaneous peripheral artery CTO intervention can be highly challenging, time-consuming, and risky. Failure rates for iliac and femoropopliteal CTO are 3% to 36%\(^25\)–\(^33\) and 12% to 25%,\(^34\),\(^35\) respectively. Novel alternative devices and techniques have had varied success for coronary and peripheral artery CTO recanalization, although to date none have prevailed clinically.\(^7\),\(^36\)–\(^43\)

This experience demonstrates successful wholly rtMRI-guided endovascular recanalization of long and challenging CTO with the use of custom devices in a suitable animal.
model. In this model, MRI was successful in 79% of attempts with the use of homemade devices and in 17% of all x-ray attempts with the use of higher-performance commercial devices.

The model CTO artery diameter and length resemble long (albeit rigid) human iliofemoral artery occlusions. These lesions would be considered TransAtlantic Inter-Society Consensus (TASC) type D, or best suited for surgical rather than endovascular recanalization.1 Unlike x-ray, MRI delineates the occluded artery walls, permitting truly image-guided wire navigation. Custom “active” MRI CTO devices prove conspicuous and distinct from adjacent tissues. Procedure duration declined throughout this experience because of a “learning” phenomenon.

Device conspicuity, simultaneous display of multiple real-time imaging slices, and uninterrupted interactive features contributed to procedural success. Real-time selective MRA techniques with small volumes of dilute Gd-DTPA confirmed artery patency. This work represents an advance because a broad assortment of imaging and device features are fully integrated to support complex and completely rtMRI-guided vascular interventions.

Long conductive devices may heat significantly during MRI radiofrequency excitation and pose a safety concern. The custom active devices used here are appropriately tuned, matched, and decoupled and do not heat during scanning in a suitable test phantom (Appendix).

Our CTO model differs from tortuous, lipid, and calcium-rich atherosclerotic human iliofemoral disease. Severe arterial recoil and spasm prevented antegrade flow (n=2) or guiding catheter traversal (n=3) despite successful wire recanalization. The lesions were sufficiently long and challenging for a feasibility experiment. Of note, x-ray–guided recanalization attempts were less successful, even though they used higher-performance commercial clinical devices. Indeed, MRI guidance offers the potential to visualize the entire occluded segment and luminal boundaries, particularly in severely tortuous lesions often found in human peripheral CTO.

This experience adds to that of other published reports of rtMRI-guided procedures that traverse anatomic boundaries such as transjugular intrahepatic portosystemic shunt14,44 and...
Metal alloys such as nitinol, platinum-iridium, or nickel-cobalt-chromium have less MRI susceptibility artifact than stainless steel. Numerous reports already have been published of experimental rtMRI-guided deployment of such devices. Nevertheless, our primary end point, rtMRI-guided CTO recanalization, was successfully accomplished with the use of our rudimentary device prototypes. Subsequent therapy to maintain antegrade flow and patency such as stenting could be conducted under x-ray, immediately after successful rtMRI CTO recanalization.

Conclusions
This work demonstrates the feasibility of rtMRI guidance to recanalize arterial CTO with the use of custom active MRI visible devices in a suitably challenging swine model. Future image-guided human peripheral artery CTO interventions may be possible with the use of this technology. However, clinical-grade catheter devices must be manufactured to translate these findings into patients.

Acknowledgments
This study was supported by National Institutes of Health grant Z01-HL005062-03 (Dr Lederman). The authors thank Kathryn Hope, Kathy Lucas, and Joni Taylor for their animal care and support.

Disclosures
None.

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**CLINICAL PERSPECTIVE**

Traditionally, surgical bypass is preferred over x-ray–guided endovascular repair for long, tortuous chronic total occlusion (CTO). Endovascular guidewire traversal under x-ray is conducted almost “blindly” through occluded vessels that are not opacified by contrast. The guidewires and catheters required to reanalyze these lesions risk failure, perforation, and life-threatening hemorrhage. We demonstrate successful real-time MRI-guided recanalization of a long peripheral artery CTO in a suitable pig model. Real-time MRI may offer an advantage in artery visualization during CTO traversal while obviating ionizing radiation and nephrotoxic radiocnast.
APPENDIX: Custom Active Chronic Total Occlusion Device Heat Testing

Device heat tests were performed on the active guidewire and the catheter in a 20 cm diameter, 70 cm long polyacrylamide gel (PAG) phantom according to previously described methods.\textsuperscript{27} PAG has conductivity similar to that of human tissue (0.7 siemens/meter at 64 MHz). The heating tests were performed using a steady state free precession pulse sequence with a peak whole body SAR of 4 W/kg. During 10 to 20 minutes of continuous scanning, local temperature changes at various sections along the device length were recorded using fiberoptic temperature probes (UMI4; FISO Technologies). SAR was calculated by multiplying the slope of temperature rise (dT/dt) with specific heat of the gel (4180 J/kg). Five probes were positioned adjacent to key points along the active device. (Catheter: at the distal catheter tip, middle of loop coil, proximal end of loop coil, the distal end of the braid and 20 cm proximal to the distal end of the catheter; Guidewire: distal tip, middle of loop, proximal end of loop, middle of MP35N coil, proximal end of coil and 20 cm from the distal end. Combination guidewire/catheter was tested with wire extending 1.5 cm outside catheter. Probes were placed at: distal end of wire, distal end of guide (middle of the guidewire loop), middle of catheter loop, proximal end of catheter loop, distal end of catheter braid. For maximum energy deposition, the guidewire and the catheter were placed 2 cm from the phantom edge placed 10 cm off magnet isocenter.

Results: Heat tests for device safety are summarized in the Table. The maximum SAR was observed at the middle of the catheter loop. When guidewire and catheter were combined, the local SAR was close to the sum of the local SARs of the two devices. The minor temperature elevations associated with each device location (<2 °C) would not be expected to result in tissue damage or adverse effects based on these conditions.
**Conclusions:** These custom active guidewires and catheter do not heat significantly under these test conditions.
### Appendix Table: Local temperature changes during 10 minute test scan

<table>
<thead>
<tr>
<th>Guiding catheter</th>
<th>Location</th>
<th>Distal Tip</th>
<th>Mid Loop</th>
<th>Proximal loop</th>
<th>Distal end of braid</th>
<th>20 cm from tip</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR</td>
<td>4.0 W/kg</td>
<td>6.0 W/kg</td>
<td>10.0 W/kg</td>
<td>1.2 W/kg</td>
<td>3.5 W/kg</td>
<td></td>
</tr>
<tr>
<td>Temp rise</td>
<td>0.1 °C</td>
<td>0.4 °C</td>
<td>0.6 °C</td>
<td>0.2 °C</td>
<td>0.2 °C</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>Guidewire</th>
<th>Location</th>
<th>Distal Tip</th>
<th>Mid Loop</th>
<th>Proximal loop</th>
<th>Mid MP35N coil</th>
<th>Proximal end of MP35N coil</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR</td>
<td>11 W/kg</td>
<td>5.0 W/kg</td>
<td>2.0 W/kg</td>
<td>19.0 W/kg</td>
<td>6.0 W/kg</td>
<td></td>
</tr>
<tr>
<td>Temp rise</td>
<td>0.2 °C</td>
<td>0.1 °C</td>
<td>0.1 °C</td>
<td>0.4 °C</td>
<td>0.2 °C</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guidewire Inside Guiding Catheter (Combined)</th>
<th>Location</th>
<th>Distal Tip of wire</th>
<th>Distal Tip of catheter</th>
<th>Mid Loop catheter</th>
<th>Distal end of braid catheter</th>
<th>20 cm proximal from tip of wire</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR</td>
<td>8 W/kg</td>
<td>21 W/kg</td>
<td>26 W/kg</td>
<td>5 W/kg</td>
<td>5 W/kg</td>
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<tr>
<td>Temp rise</td>
<td>0.7 °C</td>
<td>1.3 °C</td>
<td>1.4 °C</td>
<td>0.9 °C</td>
<td>0.4 °C</td>
<td></td>
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