

Experimental Studies

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Index terms:

Experimental study
 Magnetic resonance (MR), guidance,
 761.121419
 Phantoms
 Test objects

Published online before print

10.1148/radiol.2322030533
 Radiology 2004; 232:475–481

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Guarantors of integrity of entire study, M.S., R.K., T.J.V.; study concepts, M.S., R.K., J.F.; study design, M.S., R.K., T.J.V.; literature research, M.S., J.F.; experimental studies, M.S., R.K., M.K.; data acquisition, M.S., R.K., M.K.; data analysis/interpretation, M.S., R.K., M.K., N.A.; statistical analysis, M.S.; manuscript preparation, M.S., R.K., M.K., N.A., J.F.; manuscript definition of intellectual content, M.S., R.K., M.K., N.A., T.J.V.; manuscript editing, M.S., R.K., M.K.; manuscript revision/review, R.K., M.K., N.A., J.F., T.J.V.; manuscript final version approval, all authors

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Vascular Guide Wire Navigation with a Magnetic Guidance System: Experimental Results in a Phantom¹

PURPOSE: To investigate the efficacy of a second-generation prototype magnetic guidance system in complex vessel phantoms versus conventional navigation in simulated interventional radiology procedures and to analyze procedure and fluoroscopy times.

MATERIALS AND METHODS: The magnetic guidance system consists of two focused-field permanent magnets on each side of the body that create a 0.1-T navigation field and is integrated with a modified C-arm single-planar digital angiography system. Forty-nine navigations in a glass phantom and 80 navigations in a three-dimensional liver phantom were performed with a magnetically tipped floppy 0.014-inch guide wire and a conventional 0.014-inch microcatheter system. Rates of success and fluoroscopy and procedure times were quantified for both techniques. For the liver phantom experiment, the Mann-Whitney *U* test was used. For the glass phantom experiment, the Wilcoxon matched pair test was used with the Hodges-Lehmann estimator.

RESULTS: In the glass phantom experiments, 42 of 49 turns were successfully performed with both methods. Procedure time to reach a target did not differ significantly between methods, while fluoroscopy time was significantly different when compared with that of the magnetic guidance system ($P < .01$). Navigation in the liver phantom was successful in 80 of 80 turns with the magnetic guidance system and in 76 of 80 turns with conventional navigation. With the support of the magnetic guidance system, procedure time and fluoroscopy time were significantly different from those with conventional navigation ($P < .001$).

CONCLUSION: The magnetic guidance system allows the precise navigation of a magnetic guide wire in complex vessel phantoms with significantly shorter fluoroscopy and procedure times.

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Minimally invasive intravascular interventions are performed by using guide wires and specific catheters. The offending vascular lesion is accessed from remote sites, usually with fluoroscopic guidance (1). Even experienced interventionalists occasionally encounter difficulties in reaching the target site, especially when vessel configurations are complex. Furthermore, the radiation dose during long-lasting procedures may be a limiting factor (2–6).

With rapid advances in high-speed computation, the task of assembling and depicting image data has been greatly facilitated, creating new opportunities for real-time interactive computer applications during interventional procedures (7–11). These highly technical interventions are designed to precisely use the therapeutic modality at a specific point within the patient's body. Image-guided surgical navigation systems have already become the standard for cranial neurosurgical procedures; currently the use of these systems is expanding into other disciplines, such as orthopedic and head-and-neck surgery (12,13).

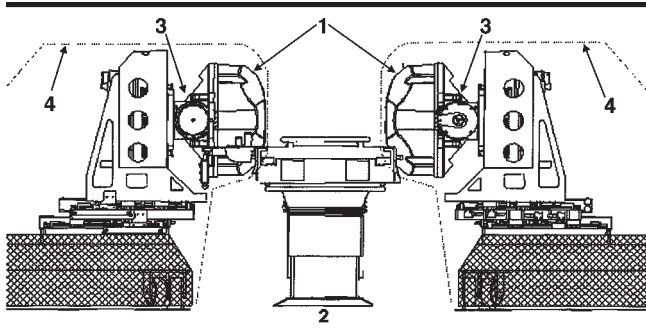


Figure 1. Diagram of the magnet system. This system contains two 0.1-T permanent magnets (1) located on opposite sides of the patient table (2). Each magnet and its respective positioner (3) are contained in a fiberglass cover (4), which is sized to allow movement of the magnets within the stationary cover during navigation. The magnets may be retracted via semicircular tracks permanently installed in the floor.

Navigation in interventional radiology is performed with visually interactive targeting based on the simultaneous display of instrument position and the corresponding two-dimensional image data sets. All current stereotactic procedures hinge on the establishment of a reference volume by using an external mechanical frame or landmarks to provide reference points for these procedures. The technique of magnetic navigation, however, uses externally controlled magnetic fields to control the movement of magnetically tipped instruments without stereotactic frames or registration procedures (14). Earlier generations of the magnetic guidance system, which used arrays of superconducting magnets, were successfully evaluated with neurosurgical and electrophysiologic cardiac catheter procedures (15–17). A prototype has been developed for interventional cardiology and electrophysiology procedures. The aim of this study was to investigate the efficacy of a second-generation prototype magnetic guidance system in complex vessel phantoms versus conventional navigation in simulated interventional radiology procedures and to analyze procedure and fluoroscopy times.

MATERIALS AND METHODS

Magnetic Navigation System

The magnetic guidance system (MGS; Stereotaxis, St Louis, Mo) consists of two focused-field permanent magnets, one on each side of the body, that create a 0.1-T navigation field (Figs 1, 2). It is integrated with a modified C-arm single-planar digital angiography system (AXIOM Artis dFC; Siemens, Forchheim, Germany). The angiography system has

been specifically adapted to enable it to operate in the magnetic field of the magnetic guidance system; it has been equipped with a specially adapted flat panel detector (size, 20×20 cm), a magnetically shielded tube, and flat screen monitors for display.

Magnet Positioners

The rare-earth permanent magnets are mounted on mechanical positioners (Fig 1). The positioners rotate and translate the magnets to generate the specified field direction at the tip of the magnetic device. Each magnet and its respective positioner are contained in a fiberglass cover, which allows the magnets to move within the stationary cover during navigation. When not in use, each magnet may be retracted via semicircular tracks that are permanently installed in the floor. The magnet moves in three different coordinates (Fig 3) and can rotate about the z axis, move toward or away from the navigation volume along the z axis, and tilt about an axis located right behind the magnet. In the magnet position shown in Figure 3, tilting would occur in a vertical fashion; however, tilting of the magnet may occur in a horizontal fashion or any intermediate fashion depending on the rotational position about the z axis. The combination of rotation, translation, and tilting provides a navigation volume resembling a sphere, with a 20-cm diameter between the magnets in which the magnetic field can be adjusted to have any desired orientation.



Figure 2. Photograph of the magnetic navigation system. Experimental setup with silicone liver phantom (1) and engaged magnet positioners. The tableside magnet controller (2) enables the movement of the magnet positioners. The vector tablet (3) and pen (4) are used to enter the desired orientation for the tip of the magnetic guide wire displayed on the interface screens.

The magnet system has three predefined positions. The first is the stowed position, in which the magnets are retracted 90° from the patient. In this position, the magnetic field in the operating area is less than 0.0005 T. The second position is the semistowed position, in which the magnets and their covers are pointed toward the patient, but the magnets and the upper part of the covers are pulled backward relative to the navigation position. In this position, the magnet covers are 31.5 inches (80.0 cm) apart. The third position is the navigation position. At their closest position, magnets and covers are pointed toward the patient, and the covers are 23.5 inches (59.7 cm) apart. The maximum x-ray imaging angles are limited to 30° left anterior oblique and right anterior oblique.

User Interface

The user interface (Fig 2) includes system controls and indicators for the magnetic guidance system. A tableside magnet controller is used for physical movement of the magnet positioners, and to transfer image data to the navigation system. A pen-driven vector tablet is used to enter the desired orientation for the tip of the magnetic device.

Magnetic Guide Wire

Navigation is accomplished with a combination of magnetically driven deflection of the distal tip of a newly devel-

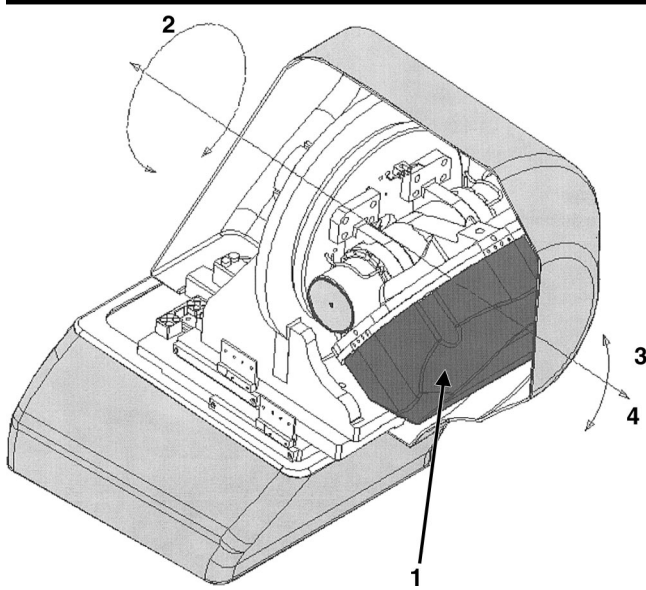


Figure 3. Diagram of the magnet articulation axes. The magnet (1) articulates along three articulation axes by mechanical positioning mechanisms rotating (2) about the z axis, tilting about an axis located behind the magnet (3), and moving toward or away from the navigation volume along the z axis (4). The combination of rotating, translating, and tilting provides a magnetic field of a given strength in any direction at any location within the navigation volume.

oped 0.014-inch guide wire (Cronus; Stereotaxis, St Louis, Mo) and linear manual advancement. The distal tip of the guide wire (Fig 4) contains a magnet that allows the guide wire to be deflected and steered within the vessel. A gold tube is welded to the distal paddle of the wire core, forming the distal tip and marker. Within the gold tube, a single 2-mm long neodymium iron boron magnet is encased or potted.

Magnetic Navigation Procedure

The magnetic endovascular device is introduced by using conventional techniques. Two reference images of the target navigational region are obtained with an angular difference of at least 41°. The physician defines the orientation of the magnetic guide wire by using a pen tablet indicating the magnetic field by using direction on the two reference images. The magnetic guide wire is advanced to the target position and guided by means of the x-ray system and user interface monitors. The physician uses both real-time and saved images to determine the appropriate orientation of the device. The necessary orientation of the tip, as determined with fluoroscopy, is defined by means of the pen tablet at the table-side on two reference radiographs of the target site. When applying the field, mag-

netic field-induced torque orients the device in the appropriate direction. When magnetic navigation is no longer required, the magnetic guidance system is withdrawn.

Guide Wire Forces

The force applied by the magnetic guide wire consists of two parts, the deflection force and the push force, whereas only the push force applies for standard guide wires.

The deflection force is only relevant for magnetic guide wires, because forces exerted on the permanent magnet cause deflection of the magnetic guide wire in the direction of the magnetic field vector. The calculation of the maximum endovascular deflection force applied by the guide wire in the presence of a 0.1-T magnetic field is performed with the following procedure (Fig 5).

The magnitude of torque (τ) exerted on the tip of the wire is equal to the product of the magnetization vector (M , measured in amperes per meter) of the magnet in the tip of the wire, cross-sectional area (A , measured in square meters) of the magnet in the tip of the wire, magnet length (L , measured in meters), external magnetic field vector (B , measured in teslas), and the sine of the angle between the field and magnetization vectors (θ):

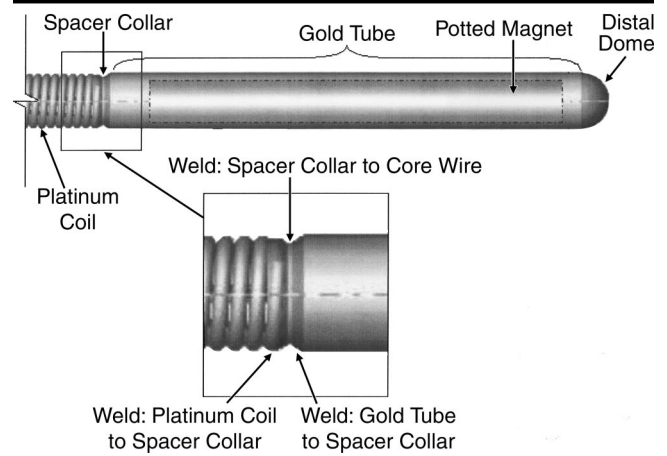


Figure 4. Diagram of guide wire tip configuration. A gold tube is welded to the distal paddle of the wire core, forming the distal tip and marker. A spacer collar is located between the platinum coil and the gold tube. Within the gold tube, a single 2-mm-long neodymium iron boron magnet is encased or potted. The distal tip is rounded to minimize trauma to the surrounding tissue during navigation.

$$\tau = MALB \cdot \sin(\theta). \quad (1)$$

Torque is also described by two identical forces (F , measured in grams) acting in opposite directions on two poles of the permanent magnet through the moment arm:

$$\tau = 2(L/2)F. \quad (2)$$

Combining equations (1) and (2) yields a description of the force exerted by the magnetic field on the distal end of the guide wire:

$$F = MAB \cdot \sin(\theta). \quad (3)$$

This force is maximal when the wire is perpendicular to the magnetic field (ie, $\sin(\theta) = 1$) and zero when the wire is parallel to the magnetic field.

The mechanical force exerted by the physician to advance the wire to the point of prolapse of the tip is defined as push force; this value was measured for both magnetic and conventional guide wires.

The test setup involved fixing the proximal end of the guide wire with the force gauge and placing the distal end in a simulated vessel (4-mm tube) to restrict its movement. Axial force was then applied to the guide wire until prolapse occurred, and the maximum force was applied before prolapse was recorded. For comparison purposes, measurements were obtained with 15 magnetic and conventional 0.014-inch wires.

Navigation in the Glass Phantom

A glass vessel phantom was continuously perfused with warm water (temper-

ature, 37.5°C) while a 90-cm-long 5-F sheath was inserted into the system via a Y connector.

A total of 49 different target turns were performed with the magnetic navigation guide wire and a standard manually navigable nitinol guide wire (Boston Scientific, Natick, Mass). In the glass phantom, the 49 different turns were achieved by performing seven procedures consisting of seven turns; an example procedure is shown in Figure 6. After the guide wires had been pushed beyond a predefined turn, a commercially available microcatheter was advanced over the guide wire to the target site, and then the guide wire was removed. A turn was considered successfully completed if both the guide wire and the microcatheter had been navigated all the way around the phantom vessel curvature and the guide wire had been withdrawn at least 5 cm. All navigations were started with the guide wire inside the catheter for standardized timing. For magnetic navigation, total navigation time was measured from vector drawing for the first turn. For conventional procedures, total navigation time was measured from the first manual manipulation of the guide wire. The end point for each navigation was successful completion of all seven turns or if fluoroscopy time for a single turn exceeded 3 minutes. All experiments in the glass phantom and the liver phantom were performed by an interventionalist with 5 years of experience in conventional procedures and 6 months of nonclinical training in magnetic navigation.

Navigation in the Liver Phantom

The liver phantom was made by using a lost-wax process, in which the aortic trunk with celiac arteries and hepatic branches was modeled of wax and embedded in silicone. After curing and melting out the wax, the resulting tube model was cleaned in an ultrasonic bath. A 5-F cobra configured catheter (Terumo; Frankfort, Germany) was placed in the model of the common hepatic artery, and the above-mentioned microcatheter systems for conventional or magnetic navigation were inserted (Fig 2). Within the liver phantom, eight selected turns exploring segmental branches were tested for both methods and repeated 10 times each to apply statistical evaluation (Fig 7).

Statistical Analysis

To compare the measurements in the deflection force experiment, the mini-

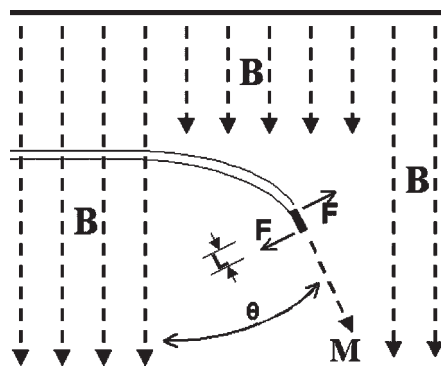


Figure 5. Diagram of magnetic guide wire deflection. The force (F) exerted on the tip of a guide wire equipped with a small permanent magnet inside a magnetic field (B) depends on the magnitude of the external magnetic field, sine (θ) of the angle between the external field and the axis of the permanent magnet, magnetization (M) of the magnet, length (L) of the magnet, and cross-sectional area of the magnet (not shown).

imum, maximum, and mean force and SD for magnetic and standard guide wires were calculated.

To estimate the differences between both techniques concerning rate of success, median fluoroscopy and procedure times, as well as minimum, maximum, range, lower and upper boundaries, and first and third quartiles were calculated.

For the glass phantom experiment, the Wilcoxon matched pair test with Hodges-Lehmann estimator was performed, because there were 49 paired measurements. The Hodges-Lehmann estimator is a measure for the magnitude of difference between two groups. It is defined as the median of the set of all possible differences between values of either group. For the liver phantom experiment, the Mann-Whitney U test was applied, because the median values of turns 1–8 for each method did not differ considerably. A P value of less than .05 indicated a statistically significant difference.

RESULTS

Guide Wire Deflection Forces

Applying an external magnetic field of 0.1 T, the calculated maximum mechanical force the guide wire can exert on the vessel wall as a result of magnetic deflection of the tip at 90° is 0.56 g. The mean and SD of push force applied to the tip of the magnetic guide wire was 5.9 g \pm 0.59 (range, 4.99–7.26 g), compared with 3.18 g \pm 1.90 (range, 1.81–6.35 g) with a conventional wire.

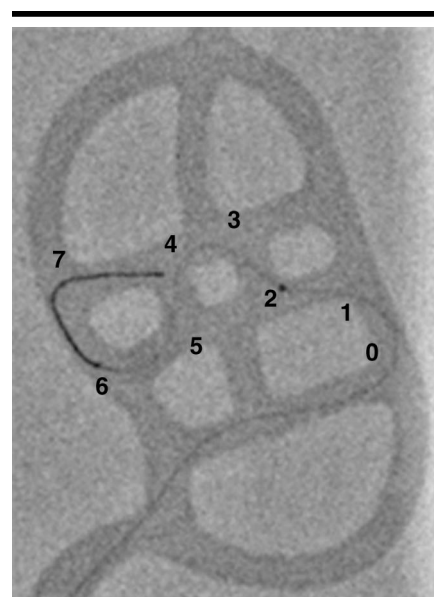


Figure 6. Radiograph of glass phantom shows an example navigation procedure, with the starting point (0) and seven target turns (1–7). In this image, the microcatheter is located at turn 6, and the magnetic guide wire has just been pushed past turn 7. Navigation with the conventional guide wire system was not successful beyond turn 5 (not shown).

Magnetic Navigation Procedure

The magnetic guidance system presented no visual obstacle for the physician in operating the guide wire, even though the magnets represent relatively large bulks close to the patient table (Fig 2). Since the magnetic guide wire may be oriented in any direction in three-dimensional space, it was not necessary to twist the shaft of the guide wire or remove it to reshape the tip.

Glass Phantom

The magnetic navigation guide wire was clearly visible with fluoroscopy (Fig 6). Forty-two (86%) of 49 turns were successfully completed with the magnetic guidance system. Forty-two turns were also successfully completed with the conventional method.

The procedure time for reaching a target did not differ significantly between the magnetic (median, 32 seconds; first and third quartile, 21 and 50 seconds, respectively) and conventional method (median, 35 seconds; first and third quartile, 12 and 68 seconds, respectively) (Fig 8). Fluoroscopy time was significantly different ($P < .01$) with magnetic guidance (median, 24 seconds; first and third quartile, 13 and 40 seconds, respectively) and conventional navigation (median,

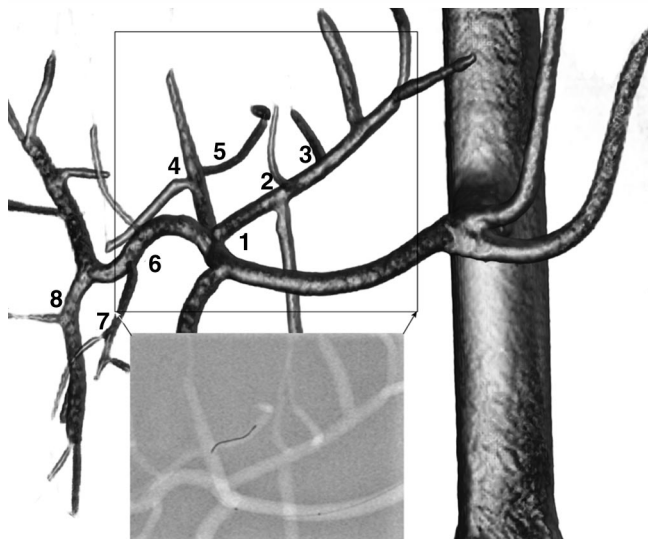


Figure 7. Surface-shaded display of the liver phantom. Volume rendering of rotational angiography is shown. Turns for wires are marked (1–8). The fluoroscopic image shows the tip of the magnetic guide wire inserted past turn 5.

32 seconds; first and third quartile, 12 and 68 seconds, respectively) (Fig 8). The mean difference, as calculated with the Hodges-Lehmann estimator, was 14 seconds (95% CI: 5, 24 seconds).

Liver Phantom

Navigation was successful in all 80 turns with the magnetic guidance system and in 76 of 80 turns with conventional navigation. Mean fluoroscopy and procedure times for all eight procedures performed with magnetic navigation were significantly different from the corresponding mean fluoroscopy and procedure times for the procedures performed with conventional guide wire manipulation ($P < .001$) (Figs 9, 10). The mean difference in procedure time, as calculated with the Hodges-Lehmann estimator, was 19 seconds (95% CI: 11, 25 seconds). The mean difference in fluoroscopy time for each turn between conventional and magnetic navigation, as calculated with the Hodges-Lehmann estimator was 18 seconds (95% CI: 11, 24 seconds). Fluoroscopy and procedure times varied to a much greater extent for the conventional guide wire navigation (median fluoroscopy time, 27 seconds; first and third quartile, 11 and 53 seconds, respectively) (median procedure time, 29 seconds; first and third quartile, 12 and 53 seconds, respectively) than for the magnetic navigation (median fluoroscopy time, 4 seconds; first and third quartile, 4 and 8 seconds, respectively) (me-

dian procedure time, 5 seconds; first and third quartile, 4 and 8 seconds, respectively) (Figs 9, 10).

DISCUSSION

The ability to steer or navigate a device toward the precise location requiring treatment is crucial for the success of interventional treatments. Currently, the steering of interventional devices is accomplished by mechanically manipulating the catheter, using a guide wire, or both. For example, guiding the tip of an intravascular device through intracranial vessels or into the coronary arteries or the vasculature of the liver or the intestine requires the physician to manually twist or torque the shaft of the device. The more turns that are to be traversed, the greater the loss of control of the device will be. For guide wires, steering control is managed by a combination of tip shapes and manual manipulation. Guide wire tips can be shaped by the physician during use or are supplied preshaped by the vendors. In general, the physician cannot alter the bend in the tip of the guide wire while it is in the body with nonmagnetic catheters; exceptions to this include moveable core wires and Disposable Reuter Tip Deflecting Wire Guides (Cook, Bloomington, Ind), but these are only available as 0.035-inch or larger wires. With the exception of these wires, standard guide wires generally

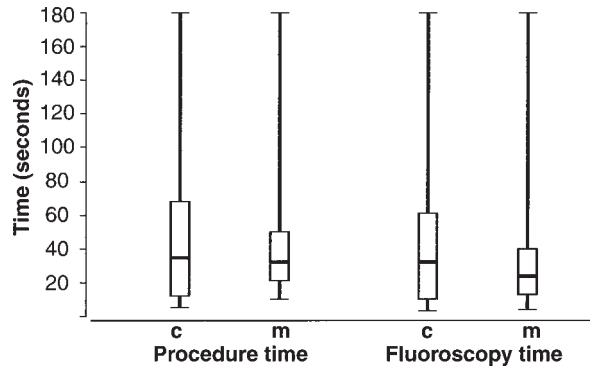


Figure 8. Box plots show that procedure and fluoroscopy times averaged more than 42 turns each. Center lines denote the median, the bounds of the boxes represent first and third quartiles, and the ends of the lines indicate maximum and minimum observed values. *c* = conventional navigation, *m* = magnetic navigation. The procedure time to reach a target did not differ significantly between methods, although fluoroscopy time was lower with the magnetic guidance system ($P < .01$).

must be removed for reshaping and reinserted thereafter.

Magnetic navigation is the interaction between an external magnetic field of a specified direction and magnitude and a tiny magnet embedded in the tip of an endovascular device. The result of this approach is that the tip of the catheter or guide wire can be magnetically oriented in any direction, without articulation wires in catheters, manual reshaping in guide wires, multiple-tip angle configurations, or manual application of rotational torque to the shaft. The magnetic field has a specified uniformity, such that the tip aligns with the field but is not pushed, pulled, repelled, or attracted by the magnet to any marked degree.

The tips of conventional endovascular devices are designed to undergo prolapse when the mechanical push force exceeds a specified value. For magnetically navigable electrophysiology catheters, this force is much larger than the small magnetic force exerted on the guide wires by the magnetic guidance system (17). It may be assumed that the force exerted by the tip of magnetically navigable guide wires is also markedly lower than that of conventional guide wires (18).

When a turn must be made with conventional navigation, the physician torques or twists the shaft of the guide wire to orient the tip in the desired direction. This is an iterative process, with the guide wire being advanced and retracted repeatedly to make the turn. By using a magnetic guidance system, the physician defines the desired orientation of the tip on the pen tablet, and the magnetic field direction is adjusted accordingly. The tip

of the catheter aligns with the magnetic field. The physician then advances the device in the new direction, without having to twist or torque the shaft.

To maintain control of the manually steered guide wire, the physician must keep continuous pressure and torque on the wire, whereas the position of the catheter tip is held stable by the magnetic field with the magnetic guidance system.

Because of the reshaping of the conventional guide wire, the wire tends to prolapse and scrape on the wall of a vessel during withdrawal. In our experiments, this prolapsing was not seen during navigation with the magnetic guidance system. Thus, it may be safer to use magnetic navigation as far as danger of damage to vessel walls is concerned.

The physician who performed the experiments was trained for 6 months in the use of the magnetic guidance system. Despite the larger amount of experience in manual maneuvering of catheters, fluoroscopy time was less with magnetic guidance than with manual steering. Gaining more experience in magnetic guidance might result in further reduction of fluoroscopy and procedure time because of less need to exchange guide wires and catheters (19). At the start of the procedure, however, it is necessary to acquire additional images in two views, which is not required with the conventional guide wire technique. After the initial views are transferred to the navigation system, the physician can obtain images as usual for the rest of the procedure.

In the relatively simple two-dimensional geometry of the glass phantom, magnetic navigation has already resulted in significant reduction of fluoroscopy time but only slight reduction of procedure time when compared with conventional steering. Magnetic navigation resulted in significant reduction in both fluoroscopy and procedure time in a more realistic three-dimensional model of the vessel anatomy of a human liver. These results indicate that magnetic navigation may provide advantages, especially during navigation in complex three-dimensional structures that may be encountered in the body. In addition, the time required for the same turn in the liver phantom varied to a much greater extent for the conventional guide wire navigation. This could indicate that procedure times with magnetic navigation may become more predictable and less dependent on the experience and skill of the operator.

Another promise of the magnetic guid-

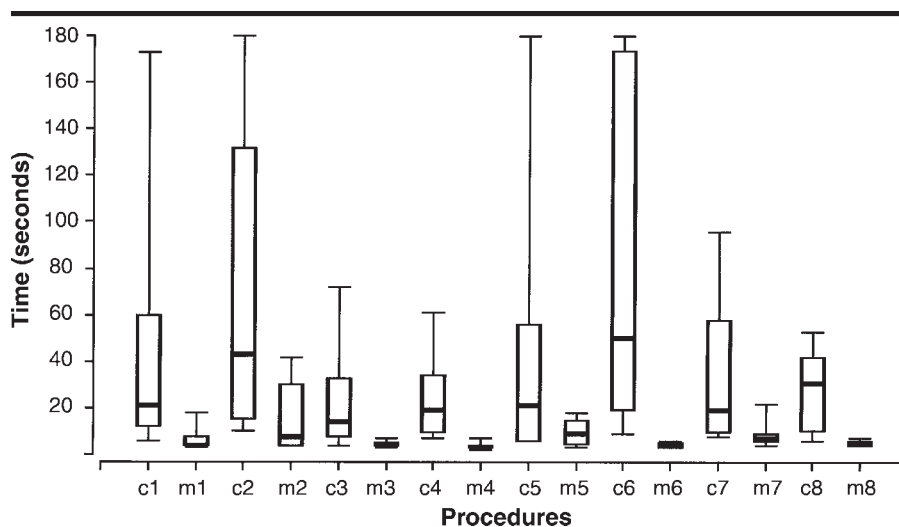


Figure 9. Box plots show fluoroscopy times averaged over 10 procedures each. Center lines denote the median, the bounds of the boxes represent first and third quartiles, and the ends of the lines indicate maximum and minimum observed values. *c* = conventional navigation (*c1*–*c8*), *m* = magnetic navigation (*m1*–*m8*). The differences between *c* and *m* were highly significant ($P < .001$).

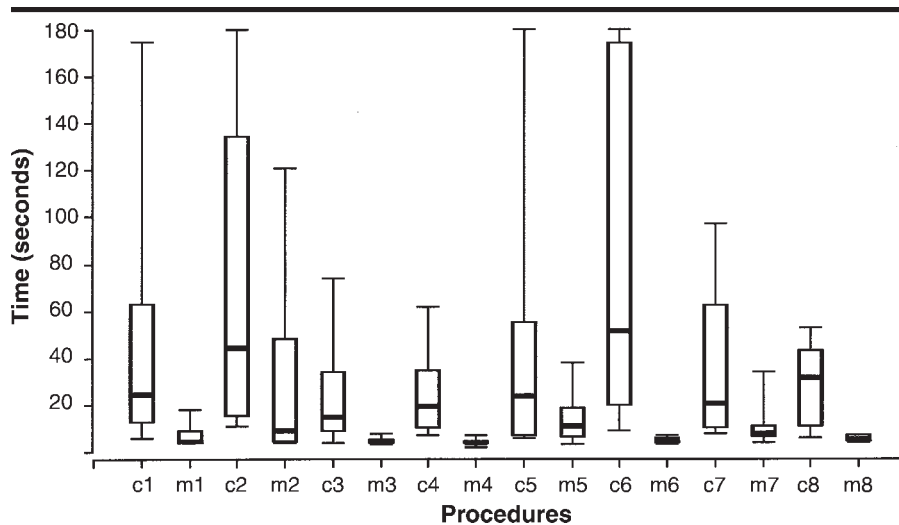


Figure 10. Box plots show procedure times averaged over 10 procedures each. Center lines denote the median, the bounds of the boxes represent first and third quartiles, and the ends of the lines indicate maximum and minimum observed values. *c* = conventional navigation (*c1*–*c8*), *m* = magnetic navigation (*m1*–*m8*). The differences between *c* and *m* were highly significant ($P < .001$).

ance system lies in the precision of movement of magnetically enhanced devices and in the ability to steer the flexible distal portion of such devices in any direction in three-dimensional space. In interventional radiology, clinically relevant indications have to be identified, but we see potential benefits in procedures performed in the pelvic and intestinal vessel area, the external carotid system, the bronchial arteries, or the venous system. The magnetic guidance system would also support the interventionalist in performing complex

superselective catheterizations for local tumor treatments and embolizations in the brain, head and neck, lung, and liver regions (20,21).

Current limitations of the magnetic guidance system are the small size of the flat panel detector and the lack of a larger variety of steerable magnetic devices. Additional limitations include the cost of the magnet system and the size of the magnet enclosures, which limits the maximum x-ray imaging angle to 30° left or right anterior oblique when the mag-

net enclosures are in position for magnetic navigation.

In this study, it was shown that the application of this navigation system may offer potential benefits for vascular interventions. However, the study was performed only with vessel phantoms in a laboratory environment and not in a clinical setting.

Clinical studies are needed to evaluate the benefits of the magnetic guidance system in a routine clinical interventional environment. It is expected that the measured advantages of the navigation system will not be as high when this system is applied in patients as the results described here. Phantoms can neither replicate biologic variation nor display voluntary or involuntary movement by the patient. Experienced interventional radiologists are very familiar with vascular anatomy in patients. Even with exclusive use of the navigation system, it is not obvious if the lifetime radiation dose for the interventional radiologist is substantially reduced.

Practical applications: The relevance of magnetically tipped devices that may be developed, such as 0.035-inch guide wires, transjugular intrahepatic portosystemic shunt canules, endoscopes, and laser catheters, has to be evaluated in further studies. Even though the magnetic guidance system was primarily designed for use in cardiology and electrophysiology, further applications might be possible. The system provides a statistically significant reduction in fluoroscopy times and should be at least equal to conventional guide wire navigation as far as procedure times are concerned.

Acknowledgments: The authors thank Steve Ferry, BS, Mike Sabo, BS, and Jessica

Schafersman, BS, Stereotaxis, St Louis, Mo, for their support in manufacturing the phantoms and the magnetic guide wires. The authors also thank Klaus Ackermann, PhD, Institute of Biomathematics, University Frankfurt am Main, Germany, for advice regarding the analysis of the results.

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