Development of a 0.014-inch Magnetic Resonance Imaging Guidewire

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The purpose of this study was to develop a standard 0.014-inch intravascular magnetic resonance imaging guidewire (MRIG), a coaxial cable with an extension of the inner conductor, specifically designed for use in the small vessels. After a theoretical analysis, the 0.014-inch MRIG was built by plating/cladding highly electrically conductive materials, silver or gold, over the inside and outside of the coaxial conductors. The conductors were made of superelastic, nonmagnetic, biocompatible materials, Nitinol or MP35N. Then, in comparison with a previously designed 0.032-inch MRIG, the performance of the new 0.014-inch MRIG in vitro and in vivo was successfully evaluated. This study represents the initial work to confirm the critical role of highly conductive and superelastic materials in building such small-size MRIGs, which are expected to generate high-resolution MR imaging of vessel walls/plaques and guide endovascular interventional procedures in the small vessels, such as the coronary arteries. Magn Reson Med 53:986–990, 2005. © 2005 Wiley-Liss, Inc.

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Atherosclerotic cardiovascular disease remains the leading cause of death in the United States. X-ray technology is the primary imaging modality used to diagnose and treat atherosclerotic cardiovascular disease. However, this imaging technique enables us to see only the stenotic vessel lumen and does not allow visualization of the atherosclerotic plaques of the vessel walls.

Magnetic resonance (MR) imaging has been considered a useful imaging tool for characterizing atherosclerotic plaques of the vessel wall with multiple planes and imaging parameters (1). However, this advantage of MR technology is limited to the imaging of superficially seated arteries, such as the carotid and femoral arteries, when using surface coils. For surface-coil-mediated MR imaging of deeply seated arteries, such as the iliac and renal arteries, as well as the aorta, the signal-to-noise ratio (SNR) dramatically decreases with the distance from the surface coil. To solve this problem, different intravascular MR imaging techniques have been developed (2). Among the different designs for intravascular MR receiver probes is a loopless antenna (3). The loopless antenna can be constructed with thin diameters and thus placed inside either vessels or endovascular interventional devices, providing two primary functions: (a) an intravascular MR receiver to generate high-resolution MR imaging of the vessel wall/plaque; and (b) a conventional guidewire to guide endovascular interventions, such as balloon angioplasty and stent placement (4).

Currently, the MR imaging-guidewire is made of Nitinol, 0.032-inch in diameter, which has been successfully tested and used in the middle- and large-size peripheral arteries (5). The final goal of the development of this technique is to diagnose and treat atherosclerosis in the small-size arteries, such as the coronary arteries, which requires a much thinner magnetic resonance imaging guidewire (MRIG), 0.014 inch in diameter, as a standard size for both imaging and guiding (6). We can construct a 0.014-inch MRIG with superelastic materials, such as Nitinol and MP35N, similar to the 0.032-inch MRIG, because these superelastic materials offer excellent flexibility and maneuverability for the MRIG. This study involved: (a) mathematical calculation of the electrical resistance of these materials is high, which results in high electrical attenuation, decreases the efficiency of receiving MR signal, and reduces the SNR of MR imaging. To date, there are no available materials that offer both superelastic and highly conductive properties.

In this study, we developed a 0.014-inch MRIG by plating and cladding highly electrically conductive materials on the inner and outer conductors of a superelastic MR-compatible coaxial cable, which was specifically designed to maintain both the electrical conductivity and the mechanical properties necessary for an ideal MRIG. This study involved: (a) mathematical calculation of the electrical resistance for different diameter configurations of the 0.014-inch coaxial cables; (b) production of a silver/gold coated, Nitinol/MP35-based, 0.014-inch MRIG; and (c) validation of the newly designed 0.014-inch MRIG in vitro and in vivo in the arteries of living animals.

METHODS
Mathematical Simulation to Design the 0.014-inch MRIG

Similar to a previously designed 0.032-inch MRIG, the design of the new 0.014-inch MRIG was based on a coaxial cable, with an 8-cm extension of its inner conductor. The combination of the extended inner conductor and the outer conductor enabled MR signal reception (Fig. 1). When transmitted through the MRIG, the MR signal was attenuated due to the electrical resistance of the thin coaxial cable. The electrical resistance of a Nitinol-based 0.014-inch MRIG is too high to achieve high-quality MR imaging. To solve this problem, the MRIG can be modified.
by plating and cladding highly electrically conductive materials, such as silver ($\sigma = 6.28 \times 10^7 \text{ S/m}$), copper ($\sigma = 5.8 \times 10^7 \text{ S/m}$), or gold ($\sigma = 4.26 \times 10^7 \text{ S/m}$), on the surface of the inner conductors and the inner surface of the outer conductors. These conductors are made of superelastic MR-compatible materials, such as Nitinol ($\sigma = 1 \times 10^6 \text{ S/m}$) or MP35N ($\sigma = 1.03 \times 10^6 \text{ S/m}$). The MRIG can also be optimized by adjusting the configuration between the outer diameter of the inner conductor (ODIC) and the inner diameter of the outer conductor (IDOC) of a coaxial cable. Because the MR signal is a radiofrequency (RF) signal operated at 64 MHz (for a 1.5-T magnet), it is transmitted only along the surface of the inner conductor and the inner surface of the outer conductor of a coaxial cable. The depth of RF penetration on the surface of the inner conductor and the inner surface of the outer conductor depends on RF frequency and the electrical conductivity of the materials to be used, and is limited to a few microns. Using the same method as in reference (7), the depth of RF penetration at 64 MHz was calculated to be 7.93 $\mu$m when the RF is transmitted along a silver coaxial cable. Thus, we can decrease the electrical resistance by plating highly conductive metal, such as silver, on the outer surface of an inner conductor and the inner surface of an outer conductor made of superelastic materials. The new MRIG with this combination should retain the desired mechanical properties of the MRIG as a conventional guidewire for guiding endovascular interventions. To achieve an optimal design, we calculated the electrical attenuation and character impedance of a 0.014-inch coaxial cable with various ODIC, from 0.003 inch (76 $\mu$m) to 0.005 inch (127 $\mu$m), and IDOC from 0.007 inch (177.8 $\mu$m) to 0.010 inch (254 $\mu$m), with polymer insulator materials ($\varepsilon_r = 3.45$) (7), assuming that the superelastic outer and inner conductors were plated with silver and the thickness of the silver was larger than or equal to the depth of the RF penetration.

Production of the 0.014-inch MRIG

Based on the calculations, the optimal configuration of the IDOC/ODIC was 0.009 inch/0.004 inch as the diameter configuration. With this configuration, the calculated electrical attenuation was 1.49 dB/m, and the correspondent character impedance was 26.5 $\Omega$, close to the electrical load of the human body for the loopless antenna ($\approx 32 \Omega$), which does not cause severe RF signal reflection along the MRIG.

We first manufactured a silver tube, 0.0005 inch (12.7 $\mu$m) in thickness, and then clad an MP35N alloy tube over the silver tube. MP35N is a nonmagnetic, anticorrosive, and biocompatible alloy, which is specifically suitable for our purposes of producing the 0.014-inch MRIGs. Similar to Nitinol, the elasticity modulus and electrical conductivity of MP35N are $3.3 \times 10^7 \text{ S/m}$ and 1033 $\mu\Omega\text{-mm}$, respectively.

The inner conductor was made by plating a silver layer on an 0.004-inch (101 $\mu$m) Nitinol wire (Nitinol Devices & Components, Inc., Fremont, CA). Similar to a previously designed 0.032-inch MRIG, a very thin, 0.00001-inch (0.245 $\mu$m) gold layer was first coated on the surface of the Nitinol wire, and then the 0.00032-inch (8.13 $\mu$m)-thick silver layer was plated on the gold layer. After this, the second 0.00001-inch (0.245 $\mu$m)-thick gold layer was coated again on the surface of the silver layer. The two gold layers ensured the stable plating of the silver layer on the surface of the Nitinol wire. Thus, we achieved a total thickness of 0.00034 inch (8.62 $\mu$m) for the gold/silver/gold layers. Subsequently, we inserted manually the gold/silver/gold-coated inner conductor into a 0.0005-inch (12.7 $\mu$m)-thick heat shrink polymer tube ($\varepsilon_r = 3.45$) (Advanced Polymers, Inc., Salem, NH) to construct the polymer-insulated inner conductor. Then, we inserted the polymer-insulated inner conductor into the silver-clad, MP35N-based outer conductor built above. Although a low dielectrical constant material, such as polytetrafluoroethylene (PTFE) ($\varepsilon_r = 2$ or less), would be preferred as an insulator for optimum electrical performance, construction of the MRIG was much simpler with the heat-shrink polymer tube. Figure 2a shows the scheme of the newly designed, silver/gold coated, Nitinol/MP35N-based 0.014-inch MRIG compared to a commercial 0.032-inch MRIG (Surgi-Vision, Inc., N. Chelmsford, MA). The newly designed 0.014-inch MRIG was built at the same length, 0.63 m, as a 0.032-inch MRIG, with an 8-cm-long extension of the inner conductor (Fig. 2b). The extension of the inner conductor was installed with a spring coil, which made for easy placement of the thin MRIG into a vessel. In addition,
a tuning/decoupling box was installed at the other end of the 0.014-inch MRIG.

In Vitro Experiment

To compare the SNRs between the new 0.014-inch MRIG and the previous 0.032-inch MRIG, we generated SNR maps for the two MRIGs using a GE 1.5-T CV/I MRI scanner (General Electric Medical System, Milwaukee, WI). Both the 0.014-inch MRIG and the 0.032-inch MRIG were placed in a 15-liter saline bath (0.35% NaCl, $\varepsilon_\text{g} = 77, \sigma = 0.6$ S/m), which simulated the electronic loading conditions of the human body. We then performed MR imaging using: (a) a fast spin echo (FSE) sequence with 1400/15 ms TR/TE, 10-cm FOV, 256 x 256 matrix, 1.0-mm slice thickness, 32 ETL, 64-kHz bandwidth, and 1 NEX; and (b) a spin echo sequence with 2000/13 ms TR/TE, 10-cm FOV, 256 x 256 matrix, 1.0-mm slice thickness, 64-kHz bandwidth, and 1 NEX. The images were transferred to a laptop for the SNR analysis of the two MRIGs using Matlab (The Mathworks, Inc., Natick, MA). The SNR maps and contours were obtained by dividing the signal intensity by the SD of the background noise corrected using the methods in (8), and the ratio of the average radius of both contours at 50 was calculated in order to compare the performances of the 0.014-inch and 0.032-inch MRIGs.

In Vivo Experiments

To validate the new 0.014-inch MRIG, we used two New Zealand white rabbits, approximately 4.5 kg in weight, with an aorta of approximately 4 mm in diameter. All animals were treated according to the Principles of Laboratory Animal Care of the National Society for Medical Research and the Guide for the Care and Use of Laboratory Animals (NIH Publication No. 80–23, revised 1985). The Animal Care and Use Committee at our institution approved the experimental protocol.

Through a surgical cut-down, we first positioned a 4F introducer into the right carotid artery and placed the 0.014-inch MRIG into the abdominal aorta through the introducer. Along with the MRIG, we positioned a 3.2F balloon catheter, with a balloon portion of 4-mm diameter and 2-cm length (Boston Scientific, Boston, MA), into the rabbit aorta at a level 5 cm above the bifurcation of the abdominal aorta. In vivo MR imaging was performed on the GE 1.5-T CV/I MRI scanner. We acquired high-resolution axial and sagittal images of the balloon-inflated target vessel wall using: (a) proton-weighted imaging with an FSE sequence with 1400/15 ms TR/TE, 64-kHz bandwidth, 32 ETL, 1 NEX, 6-cm FOV (axial) and 10-cm FOV (sagittal), 3-mm thickness, and 256 x 256 matrix; (b) $T_1$-weighted imaging using an SE sequence with 500/11 ms TR/TE, 6-cm FOV (axial) and 10-cm FOV (sagittal), 3-mm thickness, and 256 x 256 matrix; and (c) $T_2$-weighted imaging using an FSE sequence with 2000/85 ms TR/TE, 64-kHz bandwidth, 32 ETL, 6-cm FOV (axial) and 10-cm FOV (sagittal), 3-mm thickness, and 256 x 256 matrix.

To compare the new 0.014-inch MRIG with the previous 0.032-inch MRIG, we subsequently replaced the 0.014-inch MRIG with the 0.032-inch MRIG in the same experimental setup and performed MR scanning with the same
imaging parameters to compare the imaging qualities between the two MRIGs. Upon the completion of the experiments, the animals were euthanized.

RESULTS

In the in vitro experiments, the SNR contours of both the 0.032-inch and the 0.014-inch MRIGs were as shown in Fig. 2c. The calculated ratio of the average radius was approximately 1.09, indicating 9% higher SNR for the 0.032-inch MRIG than for the 0.014-inch MRIG. For the in vivo studies, we were able to use the new 0.014-inch MRIG to guide the positioning of the balloon catheter into the rabbit aorta and to monitor the inflation/deflation of the balloon under MR imaging. On MR images, we could visualize the balloon-inflated target aortic wall at a resolution of 157 μm with both the 0.014-inch MRIG and the 0.032-inch MRIG (Fig. 2d and e).

DISCUSSION

The present study demonstrates a new, clinical-size, Nitinol/MP35N-based, silver/gold-coated MR imaging guidewire. This combination of different materials should offer both the necessary mechanical property and the electrical conductivity that are required for a very thin coaxial cable. This new MRIG provides a potential intravascular tool for both MR imaging and guidance in small-size vessels, such as the coronary arteries, and thus, it is expected to be a useful device for MRI-guided interventional procedures, such as percutaneous transluminal coronary angioplasty and gene therapy in the coronary arteries in the future.

As we expected, the electrical attenuation of the current Nitinol/MP35N-based, silver/gold-coated, 0.014-inch MRIG was decreased, while the attenuation of the same-size Nitinol-based MRIG was calculated to be 10.7 dB/m using the same method as in Ref. (7). The primary reason for this difference is that MR signal is only transmitted along the coated gold/silver/gold layers. Rather than the traditional electroplating method, we produced the outer conductor of the new MRIG by cladding MP35N over a silver tubing. In order to increase the efficiency of RF transmission, coating with a silver layer thicker than the depth of penetration would be preferred. In our design, the thickness of plated gold/silver/gold layers of the inner conductor was 0.00034 inch (8.6 μm) while the thickness of the silver layer of the outer conductor was 0.0005 inch (12.7 μm), which satisfied the requirement for RF transmission (i.e., thicker than 7.93 μm). It is relatively easy to coat gold/silver/gold on the inner conductor, but extremely difficult to coat a silver layer on the inner surface of the outer tubing. We developed a dedicated method of producing the outer conductor by cladding MP35N over the silver tubing. This design makes the new 0.014-inch MRIG close to a pure silver coaxial cable, offering excellent electrical conductivity for transmitting MR signal from the tip of the coaxial cable to the MR scanner. This method is expected to improve the electrical performance of the 0.018-inch MRIGs as well.

On the other hand, the coated 8.62-μm-thick gold/silver/gold layer makes up less than 10% of the 101-μm-diameter inner conductor, which then retains the elastic mechanical property of the modified Nitinol inner conductor. Similarly, compared to the total 64-μm-thick tube wall of the outer conductor, the 12.7-μm-thick silver layer of the outer conductor should not affect the mechanical performance of the MP35N-based outer conductor (tube) either. Thus, this diameter configuration of the inner conductor and outer conductor coated with highly conductive materials should benefit RF transmission, without affecting significantly the mechanical properties of the MRIG. In this study, this 0.014-inch MRIG has shown the elastic capability necessary to guide the balloon catheter into target vessels. However, these mechanical properties in clinical use as conventional guidewire need to be evaluated and confirmed further. Compared to the optimal IDOC/ODIC configuration (0.011 inch/0.003 inch), the electrical attenuation of the selected IDOC/ODIC configuration (0.009 inch/0.004 inch) was not too high. To further decrease the electrical attenuation and increase the impedance, we may use PTFE (εr = 2 or less), rather than polymer tubing (εr = 3.45), as the insulator material between the inner and outer conductors of the new 0.014-inch MRIG. Our calculation indicates that production of the 0.014-inch MRIG with PTFE should offer a lower attenuation and higher characteristic impedance, close to the electrical load of the human body, and would thus enable us to make the new 0.014-inch MRIG more suitable for MR imaging of small-size vessels. Our in vitro study has demonstrated that this new 0.014-inch MRIG provides an SNR performance comparable to the 0.032-inch MRIG, and the in vivo experiment has shown that the 0.014-inch MRIG can generate MR images of the vessel walls that are similar in quality to the 0.032-inch MRIG. Further work is necessary to quantitatively validate the feasibility of the new 0.014-inch MRIG for clinical use.

CONCLUSIONS

We believe that this is the first study to analyze the materials used in a small-size internal MRI antenna. To build the small-size MRIG, such as the one described in this paper, the tradeoff of highly conductive and superelastic materials is an essential issue. This study demonstrates a Nitinol/MP35N-based, silver/gold-coated, clinical-size 0.014-inch MR imaging guidewire, which should offer the expected electrical conductivity for high-resolution MR imaging of the vessel walls and the mechanical properties for guidance of endovascular interventional devices under MR imaging. The development of this new MRIG is expected to be a step toward the management of cardiovascular atherosclerotic diseases using intracoronary MR imaging-based interventional therapies.

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