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Technical Feasibility and Performance Studies of a Doppler Guide Wire for Potential Neuroendovascular Applications

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PURPOSE: To conduct technical feasibility and performance studies on a new Doppler-tipped, 0.014-inch micro-guide wire for potential neuroendovascular applications. **METHODS:** In vivo microcatheterizations of brachiocephalic arteries were performed in two swine using the 0.014-inch Doppler guide wire and a commonly used microcatheter. A standardized, bench-top method of evaluating basic mechanical properties of micro-guide wires was also used to compare the 0.014-inch Doppler guide wire with a commonly used micro-guide wire. **RESULTS:** The 0.014-inch Doppler guide wire had similar steerability, tractability, torque control, and distal tip flexibility to the commonly used micro-guide wire in the in vivo simulations. Frequent micro-guide wire exchanges were possible without loss of superselective positioning of the microcatheter. Bench-top testing showed the 0.014-inch Doppler guide wire to have comparable distal tip flexibility and stiffness to the commonly used micro-guide wire. **CONCLUSION:** The comparable subjective and objective mechanical properties of the 0.014-inch Doppler guide wire to that of a commonly used micro-guide wire further establishes the possibility of clinical implementation of the device.

Index terms: Interventional instrumentation, guide wires; Interventional neuroradiology, experimental; Ultrasound, Doppler; Animal studies

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Intravascular monitoring of blood flow parameters with a Doppler guide wire has been shown to be useful in the diagnosis and treatment of coronary and peripheral vascular disease (1–7). Such monitoring also may be very useful for more precise and detailed characterization of high-flow cerebrovascular lesions, such as cerebral arteriovenous malformations and fistulas, dural arteriovenous fistulas, and Galenic malformations. Furthermore, the ability to perform such intravascular blood flow monitoring during an embolization procedure can potentially provide a means of more objectively assessing therapeutic efficacy.

Previous validation studies for interventional coronary applications of the 0.018-inch version of the Doppler guide wire (Cardiometrics) have shown this device to provide intravascular Doppler blood flow data reliably and accurately (1, 2). We recently conducted in vivo validation studies for potential neuroendovascular applications with the 0.018-inch Doppler guide wire, which showed that the time-averaged mean velocities (ie, average peak velocity) measured by the Doppler guide wire maintained a linear relationship with measured volumetric blood flow within a given vessel over a wide range of physiologic and superphysiologic blood flow conditions (8). The size and stiffness of the 0.018-inch Doppler guide wire, however, limits its overall utility for neuroendovascular techniques.

Laboratory testing of the 0.014-inch Doppler guide wire was conducted for the following purposes: 1) to characterize and compare its mechanical properties with another commercially available micro-guide wire; 2) to evaluate its compatibility with a commonly used neurovascular microcatheter; and 3) to assess the feasibility of

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making intravascular Doppler velocity measurements in small vessels that have been superselectively catheterized.

Materials and Methods

The 0.014-inch Doppler guide wire consists of a 15-MHz piezoelectric ultrasonic transducer mounted on the tip of a 175-cm-long flexible and steerable 0.014-inch (0.46-mm) guide wire (Fig 1). The distal flexible coil portion of the guide wire is available in 30- and 45-cm lengths. The ultrasonic beam diverges 14° each way from the axis of the transducer with a range gate of 5 mm and gate integration distance of 1 mm. These specifications produce an estimated axial sample diameter of 2.5 mm and sample volume of 5 mm^3. The pulse repetition frequency varies between 12 and 96 kHz with a burst length of 1 μsec. The Doppler signals are processed by a real-time spectrum analyzer (FloMap), using a fast Fourier transform at a rate of 100 spectra per second. The data are displayed on a scrolling gray-scale monitor in standard spectral waveform format. On-line computation of time-averaged spectral peak velocity, instantaneous maximal peak velocity, pulsitility index, and other spectral-derived parameters are also available.

The 0.014-inch Doppler guide wire and FloMap system was used in superselective microcatheterization simulations of brachiocephalic arteries in anesthetized swine. The swine was chosen as a model because its brachiocephalic vasculature shares many anatomic and geometric similarities to humans and is readily amendable to standard percutaneous, neuroendovascular techniques (9).

The experiments were performed in accordance with guidelines for the use of laboratory animal subjects in research by the UCLA Chancellor's Animal Research Committee and the National Institutes of Health. Two red Duroc swine were first sedated with intramuscular diazepam (0.5 mg/kg) and ketamine (20 mg/kg). After intubation, general anesthesia was induced and maintained with continuous inhalation of 1% to 1.5% halothane. Each swine underwent percutaneous femoral puncture by the Seldinger technique.

The simulations were performed in the same manner as is commonly done in patients for superselectively accessing brachiocephalic and cerebral vasculature. A 2.7-F microcatheter (Tracker 18; Target Therapeutics, Fremont, Calif) was placed coaxially through a tapering 5.5- to 4.0-F guiding catheter (Vinuela; Cook, Bloomington, Ind) that was positioned in the common carotid artery. The 0.014-inch Doppler guide wire or a commonly used micro-guide wire (Seeker 14; Target Therapeutics) was used for positioning the microcatheter into various branches of the external carotid artery.

To evaluate some of its practical mechanical characteristics, such as steerability, tractability, torque control, and stiffness/flexibility, the 0.014-inch Doppler guide wire was first used as the primary micro-guide wire in place of the usual torque-controlled micro-guide wires mentioned above. Several external carotid branches were targeted for access, including the the ascending pharyngeal artery, internal maxillary artery, middle meningeal artery, deep temporal artery, and lateral nasal artery. Subsequently, the same superselective catheterizations were repeated with a Seeker 14 for comparison of technical difficulty and for evaluation of ability to exchange the 0.014-inch Doppler guide wire for the Seeker 14 once a superselective cannulation was achieved.

A standardized, bench-top method of evaluating the mechanical properties of micro-guide wires was also performed with a 1-inch-pound stiffness tester (Tinius Olson, Willow Grove, Pa). This apparatus is an industry standard used for objectively testing and quantifying the following two mechanical properties of micro-guide wires. First, the apparatus measures flexibility by the force (pounds) required to produce bending along various lengths of a guide wire. Each measurement of bending force was made along arbitrary lengths of a given guide wire, which were repeated five times and averaged.

The apparatus also measures the stiffness of a guide wire by the tension (inches-pounds) required to maintain a certain angle of bending. Each measurement of stiffness was similarly made along arbitrary lengths of a guide wire and additionally at three different angles of deflection (5°, 10°, and 25°). These measurements were also repeated five times and averaged. All mechanical testing experiments were performed on the 0.014-inch Doppler guide wire and Seeker 14.

Results

The 0.014-inch Doppler guide wire was able to access the ascending pharyngeal, internal maxillary, deep temporal, and lateral nasal arteries

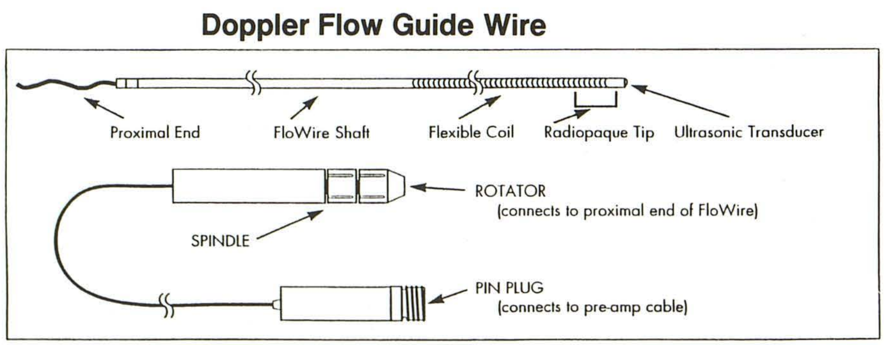

Fig. 1. The 0.014-inch Doppler guide wire (SmartWire; Cardiometrics).

easily. These arteries ranged in diameter from smaller than 1 mm to 3.5 mm. The overall degree of difficulty in accessing each vessel varied according to its combination of size, tortuosity, and angle of branch origin. For example, difficulty in accessing the internal maxillary artery was considered minor, because it is a relatively large-caliber vessel (3 mm), has no angle of branch origin (ie, it is a continuation of the external carotid trunk), and is only somewhat tortuous (Fig 2). In contrast, the middle meningeal artery was considered moderate to severe in difficulty of access because it is a small vessel (1 mm), has a 90° angle of branch origin, and originates from the somewhat tortuous internal maxillary artery. Unfortunately, it was not possible to simulate in the swine the most difficult (severe) vascular configurations encountered in humans (ie, a 360° turn in a vessel), because complete vascular loops do not naturally exist in this animal.

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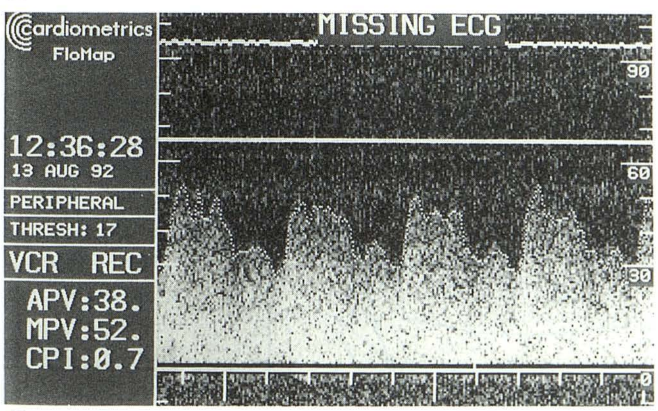

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Fig. 2. Superselective angiogram of the swine internal maxillary artery.

Fig. 3. Intravascular Doppler spectra of the swine internal maxillary artery.

On all but one occasion, the Tracker 18 could be advanced over the 0.014-inch Doppler guide wire into a superselective position. The one exception occurred when we attempted to advance the microcatheter after the 0.014-inch Doppler guide wire had superselectively accessed the anterior division of the middle meningeal artery. This vessel was the most difficult branch we attempted to enter, becuase it is only approximately 0.5 mm in diameter, has an obtuse angle of branch origin, and can be reached only after navigating several turns. This same branch, however, could not be successfully entered using a Tracker 18/Seeker 14 combination.

The floppy distal portion of the 0.014-inch Doppler guiude wire easily could be shaped into various curves, which were found to have retained their memory after use. During the catheterization simulations, the 0.014-inch Doppler guide wire subjectively had similar steerability and torquability to the Seeker 14.

The subjective performance of the 0.014-inch Doppler guide wire with the Tracker 18 microcatheter was also very favorable with regard to ease of making frequent guide wire exchanges. Mild friction was encountered only when advancing the 0.014-inch Doppler guide wire through a Tracker 18 placed superselectively in the middle meningeal artery. There was never loss of superselective positioning of the microcatheter when the 0.014-inch Doppler guide wire was exchanged for another micro-guide wire.

No complications were encountered during any of these laboratory simulations. Specifically, no vasospasm, dissection, or vascular perforation occurred when the 0.014-inch Doppler guide wire was used as either the primary guide wire or was exchanged.

Blood flow velocity measurements from the 0.014-inch Doppler guide wire were easily obtained in many small vessels, including the ascending pharyngeal, internal maxillary, and proximal middle meningeal arteries (Fig 3). As expected, however, Doppler velocity measurements could not be reliably obtained when the Tracker 18 was near occlusive in an artery less than 1 mm in diameter (eg, such as the distal trunk of the middle meningeal artery).

Standardized bench-top studies of the mechanical properties of the 0.014-inch Doppler guide wire and Seeker 14 were comparable. The flexibility of the 0.014-inch Doppler guide wire, as defined by distal tip bending forces, was very close to the Seeker 14 (Fig 4). In fact, slightly lower bending forces were encountered with the 0.014-inch Doppler guide wire except at the very distal portion of the micro-guide wire. The stiffness of the Doppler guide wire, as defined by the amount of developed tension at arbitrary angles of deflection, was always lower than the Seeker 14 at comparable lengths of the distal floppy segments (Fig 5). The shaft portion of the 0.014-inch Doppler guide wire, however, was stiffer than the comparable portion of the Seeker 14.

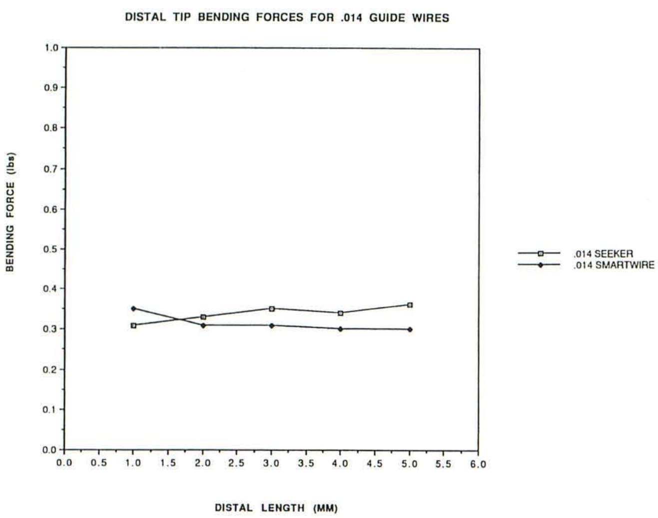


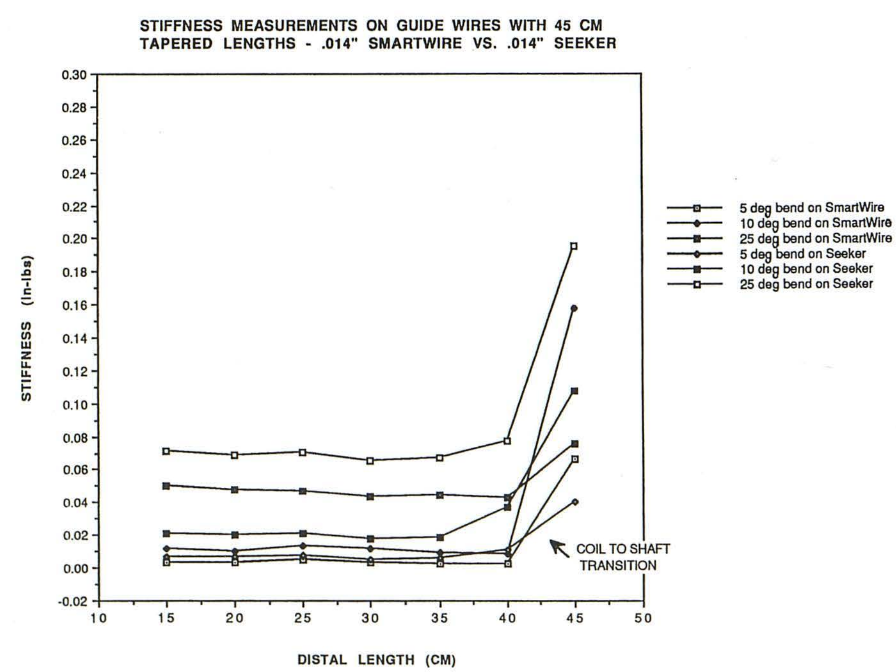
Fig. 4. Bench-top study of flexibility of 0.014-inch Doppler guide wire and Seeker 14 (see text for explanation).

Discussion

Any micro-guide wire intended for use in the cerebral vasculature must possess special characteristics with regard to size, flexibility, and stiffness in order to minimize the risk of vessel injury. Such micro-guide wires also at the same time must possess excellent torque control, steerability, and tractability to enable successful superselective navigation into intracranial vessels. The in vivo catheterization simulations and bench-top studies of the 0.014-inch Doppler guide wire suggest that this micro-guide wire fulfills these requirements. Overall, the 0.014-inch Doppler guide wire compared very favorably with a commercially available micro-guide wire (Seeker 14) that has been proved safe and effective for cerebral neurovascular work.

Because of the similar subjective and objective mechanical features of the 0.014-inch Doppler guide wire with the Seeker 14, we believe that there should be no additional safety-related concerns regarding its compatibility with commonly used microcatheters for intracerebral use. Additional testing of the 0.014-inch Doppler guide wire in complete vascular loops and extremely tortuous vessels may be useful to further assess its performance and durability, becuase the relatively increased stiffness of the shaft of 0.014-inch Doppler guide wire over the Seeker 14 may impede its ability to navigate adequately vessels with such unfavorable catheterization geometry.

Fig. 5. Bench-top study of stiffness of 0.014-inch Doppler guide wire and Seeker 14 (see text for explanation).



The currently available 0.018-inch Doppler guide wire has been successfully used and developed for coronary and peripheral vascular applications (1–7) but is only in the early phases of clinical evaluation for neuroendovascular applications. Our preliminary clinical experience with the 0.018-inch Doppler guide wire indicates that the device can be used safely and effectively only in the extracranial circulation because of its caliber and stiffness. Thus, it is likely that only a relatively small number of useful neuroendovascular applications of the 0.018-inch Doppler guide wire will be possible.

Far broader neuroendovascular applications for the 0.014-inch Doppler guide wire may be possible, because it is compatible with commonly used 0.018-inch microcatheters and possesses the necessary mechanical characteristics for safe intracerebral use. For the first time it will be possible to make selective intravascular Doppler blood flow measurements in individual feeding arteries and venous outlets of various neurovascular malformations.

It is our hope that intravascular blood flow velocity monitoring with the 0.014-inch Doppler guide wire will provide valuable and otherwise unobtainable hemodynamic information about various neurovascular malformations. This information may enable more precise and detailed pretreatment characterization of these lesions and possibly provide additional objective assessment of endovascular therapeutic efficacy (particularly when staged embolization is indicated).

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