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Accurate Guidance of a Catheter by Ultrasound Imaging and Identification of a Catheter Tip by Pulsed-Wave Doppler

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Abstract

Background—With the advent of numerous minimally invasive medical procedures, accurate catheter guidance has become imperative. We introduce and test an approach for catheter guidance by ultrasound imaging and pulsed-wave (PW) Doppler.

Methods—A steerable catheter is fitted with a small piezoelectric crystal at its tip that actively transmits signals driven by a function generator. We call this an active-tip (AT) catheter. In a water tank, we immersed a "target" crystal and a rectangular matrix of four "reference" crystals. 2D ultrasound imaging was used for initial guidance and visualization of the catheter shaft, and then PW Doppler mode was used to identify the AT catheter tip and guide it to the simulated target, which was also visible in the 2D ultrasound image. Ten guiding trials were performed from random initial positions of the AT catheter, each starting at approximately 8 cm from the target.

Results—After the 10 navigational trials, the average final distance of the catheter tip from the target was 2.4 ± 1.2 mm, and the range of distances from the trials was from a minimum of 1.0 mm to a maximum of 4.5 mm.

Conclusions—Although early in the development process, these quantitative in vitro results show promise for catheter guidance with ultrasound imaging and tip identification by PW Doppler.

Keywords

ultrasound; catheter; acoustic; navigation; Doppler; pulsed-wave

Background

As many medical procedures follow an increasing trend towards being less invasive, the importance of an accurate catheter guidance system becomes increasingly important. Within the field of interventional cardiology, catheters have become widely used for a number of both diagnostic and therapeutic procedures, such as coronary angiograms, cardiac ablation, and percutaneous coronary interventions, including angioplasty, atherectomy, and stent placement. Other medical specialties also use catheters for a variety of both diagnostic and therapeutic purposes, including fluid drainage, injections, and biopsy procedures. Future applications may include targeted delivery of drugs or gene therapy. All of these approaches require navigation of a catheter tip to relatively small, localized anatomic target regions.

Traditionally, cardiac catheterization procedures have been done under the guidance of fluoroscopy. This approach has a number of drawbacks such as exposure to ionizing radiation for both patients and medical personnel, projection of a large 3D imaging field (entire depth of body) onto one 2D plane, and the necessity for using specialized procedure rooms. These limitations have led to recent development of a number of alternative methods for catheter guidance including magnetic navigation (1–10), registration of previously acquired tomographic images with fluoroscopic and/or ablation system images (11–14), electroanatomic voltage gradient guidance (15), non-contact mapping systems (16), remotely-controlled robotic systems (17–24), and other systems employing steerable catheters or sheaths (25; 26). These newer systems do address the issue of ionizing radiation, by either eliminating its use or by removing the medical personnel from the room through remote guidance, but most of these systems add substantial additional costs. Also, many of the newer methods still tie the catheterization procedures down to specialized rooms or equipment.

Systems using ultrasound techniques for guidance of either catheters or needles have been previously proposed. In 1988, investigators reported successful tests of a “transponder” catheter system (Telectronics, Inc.) in a canine animal model (27; 28). The transponder system was designed to first wait passively to receive an ultrasound signal propagating from an imaging system, and then the transponder switched to an actively transmitting ultrasonic mode, which was tied into additional circuitry necessary for synchronization with the ultrasound machine (29). This synchronization with the imaging system allowed for a visual marker to be inserted into a 2D ultrasound image at the location of the transponder.

Other ultrasound-based systems were developed to guide placement of central lines (30) or use vibrating needles to navigate interventions by color Doppler imaging (31). One of these systems, called the Smart Needle (Peripheral Systems Group, Mountain View, CA), uses the Doppler principle to help during venipuncture (32; 33). There is also a transponder needle system for biopsies (34) that works in a similar fashion to the transponder catheter (29), in that it responds to a received signal from an ultrasound machine by sending a signal through an intermediate circuit box that changes the returned echo train for visualization at a synchronized distance within the ultrasound image.

We introduce a method for catheter guidance by pulsed-wave (PW) Doppler ultrasonography based on a prototype of a steerable catheter (Figure 1). We call the prototype an “active-tip” (AT) catheter because it has an actively transmitting miniature piezoelectric crystal attached to its tip. Our goal is to develop a catheter guidance system that is relatively inexpensive by working with Doppler modes already available on commercially available ultrasound systems without the necessity of further adaptation to their hardware. This paper presents our early results toward meeting that goal.

Methods

Physical Principles

The method to be presented is based on the physics of sound scattering by a vibrating surface. It can be shown that when an ultrasound field of a specific frequency interacts with a vibrating surface, the reflected ultrasound field will have two components at different frequencies. Assuming the ultrasound frequency is f_1 and the surface vibration frequency is f_2 , then the reflected signal will have two frequencies, one equal to $f_1 + f_2$ and the other to $f_1 - f_2$ (35; 36). If f_2 is much smaller than f_1 , then the reflected ultrasound field may be interpreted as the Doppler shifted version of the original field. By this principle, the signal produced by the ultrasound transducer (f_1) interacts with a low-frequency signal (f_2) generated by the vibrating crystal at the tip of the catheter. The ultrasound field resulting

from interaction of the two signals is then detected by an ultrasound machine operating in Doppler mode.

Construction of an AT Catheter Prototype

A steerable catheter was fitted with a piezoelectric crystal (2 mm in diameter) at its tip (Figure 1). The connecting wire was permanently attached along the catheter body by a thin layer of glue so that steering function was not affected. The AT crystal is driven to vibrate by using a function generator, set to a sinusoidal signal with its frequency within the audible range. The energy produced by the crystal is detected by an ultrasound transducer working in PW Doppler mode as specific $f_1 + f_2$ and $f_1 - f_2$ frequency shifts and displayed by the ultrasound machine as horizontal lines in the PW velocity graph. Moreover, when the tip of the catheter is located within the relatively small PW sample volume, the ultrasound machine also generates an easy to hear signal (beep). Conventional (B-mode) 2D ultrasound imaging can be first employed to guide the shaft of the catheter to a position within the imaging plane, and then the PW Doppler mode can be used to uniquely identify the active crystal at the catheter tip as opposed to any other part of the catheter shaft or other similarly appearing objects within the 2D image plane.

Experimental Setup

In a water tank (Figure 2), we immersed a soft rubber plate simulating a heart wall with one central target crystal (Figure 2, red) and four surrounding reference crystals (Figure 2, black). The latter were oriented in a rectangular matrix each approximately 3 cm from the center target crystal and each were approximately 2 mm in diameter. This arrangement allowed us to obtain the exact location of the catheter tip by a sonomicrometry system (Sonometrics, London, Ontario, Canada) after each navigation trial, while using only a clinical ultrasound imaging system for navigational purposes. The sonomicrometric system uses the “time-of-flight” principle by timing the arrival of ultrasound pulses between transmitting and receiving crystal pairs and multiplying by the speed of sound within a known medium to calculate distances. Such measurements have been used in cardiac research to characterize heart motions for many years (37; 38), and more recent digital systems allow for precise distances to be saved to a computer for ease of offline analysis (39). The sonomicrometric equipment was used to validate the final distance between the AT crystal at the catheter tip and the target crystal for each navigational trial, but would not normally be part of the AT catheter guidance system.

The center target crystal on the rubber plate was visible by conventional (B-mode) 2D ultrasound and simulated an “anatomical” target, but neither the target nor the surrounding reference crystals were transmitting ultrasound pulses during the guidance portion of each trial. Only at the end of each trial, the crystals on the rubber plate as well as the crystal at the catheter tip were acoustically driven by the sonomicrometry system to obtain the reference distance of the catheter tip from the simulated target. Thus, the crystal at the catheter tip had two distinct and independently performed roles in our studies: firstly, to navigate the catheter tip to the target in conjunction with the ultrasound machine and, secondly, to provide the reference distance of the tip from the target in conjunction with the sonomicrometry system.

During our navigation tests, the catheter with the AT crystal (Figure 2, blue) actively transmitting/vibrating was initially placed ~8 cm away from the target, with the catheter tip somewhere below the imaging plane. The ultrasound machine operator was completely blinded from the actual position of the catheter, 1) within the water tank and 2) with respect to the target or reference crystals. 2D ultrasound imaging was used for initial guidance to get some part of the catheter shaft near the target, and then PW Doppler mode was used to

identify the catheter tip and guide it to the target at its intersection within the 2D imaging plane. Duplex PW Doppler imaging mode allows for simultaneous display of both a 2D B-mode ultrasound image as well as the PW Doppler display of a velocity graph (m/s) through time. Such a graph is used in echocardiography routinely, for example, to measure the velocity of blood flow through a vessel or valve orifice. In our case, the purpose of the velocity graph is to identify the energy produced by the AT crystal within the PW sample volume.

Figure 3B is a 2D ultrasound image showing the culmination of a successfully guided approach to the simulated target. The operator of the ultrasound machine had to rely only on the 2D ultrasound image of the catheter, which appeared as sparse as in “real world” ultrasound imaging of catheters, and then on guidance by the active-tip transmission, identified by using PW Doppler imaging. A Vivid 7 ultrasound system (GE Healthcare, Milwaukee, WI) equipped with a 4-MHz transducer was used for imaging. The operator did not know the reference sonomicrometric distances either, since that system was turned off during each navigational trial.

The ultrasound operator had to first move the transducer into a starting position where the 2D imaging plane clearly contained the target and adjacent reference crystals. Once the “blinded” ultrasound operator could see the catheter shaft somewhere in the 2D ultrasound image, a second person guided the catheter according to basic verbal instructions from the ultrasound operator such as “away from transducer, left, right, up, or down.” Two people were really only necessary so that the ultrasound operator could not directly see the position of the catheter in the tank.

As each trial proceeded, when the ultrasound operator judged that some part of the catheter shaft was close to the target, the ultrasound machine was switched to PW Doppler mode in order to differentiate the active-tip crystal from the catheter shaft and finally guide it precisely to the target (Figure 3A). At the end of each trial, when the ultrasound operator deemed that the AT catheter tip was as close as possible to the target, 1) the AT crystal electronics were switched from its function generator to the sonomicrometric system, 2) reference and target sonomicrometric crystals were also activated, and 3) sonomicrometry data were digitally stored for later analysis by using SonoLab software (Sonometrics, London, Ontario, Canada). These steps were taken at the end of each trial in order to accurately measure the final distance of the AT catheter tip from the simulated target crystal.

Ultrasonography

In preliminary studies, we explored several modes of operation such as pulsed-wave versus continuous wave and a wide range of frequencies and voltages for the AT driving signal, and we found that the catheter tip can actually be detected under several conditions. An interference signal can be produced from the AT crystal in the ultrasound frequency range and its presence detected by a color flow Doppler mode on the ultrasound imaging system. Similar results to those shown here can also be obtained with the AT crystal signal in the kilohertz frequency range using not only PW Doppler, as in this experiment, but also by using a continuous wave Doppler mode.

The results presented here were obtained with the signal to the AT crystal transmitting as a continuous sinusoidal wave with a frequency of 2 kHz and amplitude of 10 V_{p-p}, and the PW Doppler frequency mode on the ultrasound machine was set at 2 MHz. If the AT crystal (catheter tip) was within the 2D ultrasound scan plane (Figure 3B) as well as within the PW sample volume (SV), the acoustic energy produced by AT crystal vibrations was recognized by the ultrasound machine working in PW Doppler mode and created clearly detectable horizontal lines (Figure 3A) on the PW graph. The position of the set of horizontal lines on

the PW velocity scale can be moved by either changing the frequency of the ultrasound transducer on the Vivid 7 or by changing the frequency of the sinusoidal waveform from the function generator which was driving the AT crystal at the catheter tip, but the frequencies were kept constant during these trials.

When we tested the navigational ability of the AT catheter system, 2D imaging was used for rough initial guidance but the final guidance was done while in PW Doppler mode, which clearly demarked the active-tip crystal, even if the tip and/or other parts of the catheter were only partially depicted. The PW sample volume region of interest was used during final navigation to test whether the part of the catheter depicted in the 2D ultrasound image was actually the crystal at the tip or not. The horizontal lines on the PW Doppler display only appeared when the AT crystal was within the PW sample volume and, at the same time, driven by the acoustic signal generator.

Results

Figure 2 illustrates the setup of the tank. Table 1 summarizes the results of 10 guiding trials. The trials were performed from random initial positions, each about 8 cm from the target crystal. The average final distance of the catheter tip from the target was 2.4 ± 1.2 mm. The range of distance values was from a minimum (i.e., 2-mm catheter tip crystal and 2-mm target crystal in direct contact) of 1.0 mm to a maximum of 4.5 mm.

Discussion

We introduce a functional prototype of an active-tip, or AT, catheter for navigation by a clinical ultrasound machine operating in a Doppler mode. We present the results of initial tests in vitro, which suggest accurate navigation to a predetermined target. The method makes a use of a conventional echocardiography system, thus supporting prospective translation to a clinical utility. Except for initial instructions, there is no need for any additional training of an ultrasound machine operator.

Characteristics of the Navigation Method

The governing principle of the presented method is an interaction of a signal generated by a crystal located at the tip of the catheter with an acoustic field produced by the ultrasound imaging probe. Signal interference would typically be considered as an undesired source of ultrasound imaging artifacts (40; 41), but we use it to our advantage. When the acoustic energy of the ultrasound imaging plane interacts with the active tip of our navigation catheter prototype, unique interference signals are produced that are detected by the same ultrasound imaging machine as positive and negative Doppler shift and displayed on a PW graph. In this way, the use of an AT catheter navigation system allows us to employ a routinely available clinical ultrasound system.

One of the problems with using ultrasound alone to guide catheters within the heart is that it can often be difficult to differentiate the actual tip of the catheter from just a bend coming into or going out of the 2D plane, or from a portion of the catheter shaft intersected by the 2D plane. This problem can be exacerbated by artifacts and signal dropouts that are common in ultrasound images. While real-time 3D ultrasound imaging is quickly emerging and will advance spatial orientation during scans, the fundamental limitations and, thus, the potential for the ambiguity in determination and navigation of a catheter by ultrasonography, remain.

Comparison of Our Approach to Other Methods for Ultrasound Navigation

The AT catheter solves a different problem than that addressed in navigating, for example, the venipuncture needles (32; 33). Based on blood flow characteristics, a Doppler-based

venipuncture needle determines by an audible signal when it is inserted into a vessel, and whether the vessel is a vein or artery. Our system does use PW Doppler mode on the ultrasound machine, but it shows an actual visible set of indicator lines when the AT crystal is located within the PW sample volume in the imaging plane and does not rely solely on the acoustic signal. In this way, the AT catheter identifies its tip in order to distinguish it from other portions of a catheter shaft or from other objects of similar appearance in ultrasound images. There is also a transponder needle system for biopsies (34) that works in a similar fashion to the transponder catheter (29).

The transponder systems (27–29) are also conceptually different from our AT catheter. The AT crystal is not transmitting in the ultrasonic frequency range but, rather, in the acoustic range for the purpose of producing a unique Doppler shift signal when the catheter tip is intersected by an ultrasound imaging scan. Moreover, the AT catheter does not require any physical connection with the ultrasound machine, and neither does it require any signal synchronization with the ultrasound machine circuitry.

Navigation Trials

During our tests, the catheter was guided to a predefined target within a mere 1–3 mm in 8 out of 10 trials (Table 1). In the remaining 2 navigation trials, the catheter tip ended 4.1 and 4.5 mm apart from the target. Considering that the operator was completely blinded to the true position of the catheter with respect to the target, the results were highly encouraging and clearly demonstrated that the catheter can be navigated to a target consistently within single-digit mm distances or to a point of direct contact with the target. The method is practical (no special education for a sonographer or cardiologist is needed, except for some practicing) and the operator can be rapidly trained (the method uses standard Doppler ultrasound functions). Interestingly, besides watching for the PW Doppler navigation signal (pair of yellow horizontal lines in Figure 3A), our operator was also alerted to the tip being within the PW sample volume by an audible signal from the ultrasound machine.

Clinical Implications

Our catheter guidance method navigates in 3D space, eliminates exposure to ionizing radiation, and does not require modification to a current clinical echocardiography machine. Although the use of a catheter with an acoustic energy-emitting crystal would have to satisfy the applicable regulatory limits, electrophysiology catheters with internal wiring (potentially suitable also for connecting the AT crystal) are routinely manufactured and support the clinical viability of the AT catheter.

Limitations

Our current study was done with a 2D probe which required us to locate the target first within a 2D imaging plane and then locate the tip of the catheter using the PW Doppler signal. The probe could be rotated to navigate in perpendicular planes, but ideally, the navigation could be done within a 3D volume.

Quantitative results were shown only for an in vitro water tank experiment, and although not shown here, we have done a preliminary successful closed-chest porcine navigational study. Further animal studies are required to investigate the best way to measure accuracy during surgery and to optimize the signal from the function generator to the vibrating piezoelectric crystal in order to overcome attenuation by the chest wall.

Using the PW Doppler mode, reaching the target is indicated by a characteristic signal visible on the velocity graph (and also audible). However, placement of a specific

(superimposed) marker on the catheter tip located within the 2D B-mode image is currently not supported.

Future Directions

We are currently working on an AT catheter prototype, in which the wiring would be internalized, in order to avoid any possible entanglements or movement constraints.

Thus far our studies have used 2D ultrasound images to navigate the prototype active-tip catheter. In the future, we would hope that the PW Doppler mode of operation could be detected simultaneously on several perpendicular planes acquired from 3D volume scans so that the visualization could take place in real-time within 3 dimensions.

Conclusions

A noninvasive method for accurate catheter guidance is presented. The results of initial in vitro tests with an active-tip catheter document excellent navigation accuracy. The method does not require any modifications to a standard PW Doppler ultrasound machine, navigates in 3-dimensional space, and eliminates exposure to ionizing radiation.

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Figure 1.

Right-side) handle of steerable catheter also showing electrical wire from active-tip crystal that could be connected to the function generator or to the Sonometrics computer system, Zoom on Left-side) close-up photo of 2-mm piezoelectric crystal attached to catheter tip with epoxy,

Figure 2.

Experimental set up showing water tank containing ultrasound transducer, scan plane, and rubber plate with target (red) and reference (black) crystals. The AT crystal at the catheter tip is depicted in blue and several sample starting positions are showing how the set up might look at the start of an experimental navigational trial.

Figure 3.

From in vitro water tank experiment, **A)** PW Doppler image showing change in its signal from nothing to a pair of yellow horizontal lines as the PW sample is respectively placed from several centimeters away to including the catheter tip within both the 2D imaging plane and the PW sample volume, **B)** 2D ultrasound (B-mode) image showing crystal on tip of catheter touching the fixed target crystal (middle) with 2 of the 4 reference crystals also shown in the imaging plane on either side. This position in the 2D image corresponds to a successful end of a navigational trial in which the PW Doppler image in 3A) would display the pair of long, yellow horizontal lines indicating that the tip of the catheter is within the PW Doppler sample volume. The yellow dots and short horizontal lines toward the center of the 2D image in 3B) represent the PW scan line and the width of the PW sample volume.

Table 1**Results of Navigation Trials**

Trial Number	1	2	3	4	5	6	7	8	9	10
Final Distance (mm)	2.0	4.5	1.9	4.1	2.7	2.4	2.7	1.8	1.1	1.0
Mean $\pm$ SD	2.4 $\pm$ 1.2 mm									