Title
CLINICAL FEASIBILITY OF AN 0.018-INCH INTRAVASCULAR ULTRASOUND IMAGING DEVICE

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Clinical feasibility of 0.018-inch intravascular ultrasound imaging device

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Objectives Intravascular ultrasound imaging (IVUS) is limited by the size of the imaging catheter. To facilitate imaging before and during interventions, a 30-MHz ultrasonic imaging device was developed that is the same dimension as a 0.018-inch guide wire. The purpose of this study was to evaluate the clinical feasibility of this device.

Methods and Results The imaging core was tested in 8 patients with the use of a monorail guiding sheath that was advanced through a 7F catheter. In addition, after coronary interventions, the standard guide wire was removed, the imaging core was placed inside a compatible balloon, and imaging was performed. In 4 patients, imaging was also performed with a standard 3.2F IVUS catheter. The lumen-plaque interface and the media-plaque interface were clearly visualized in all patients. There was no detectable loss in image quality between the new imaging device and the larger IVUS catheter, and measurements of lumen cross-sectional area were not statistically different.

Conclusions Improvements in manufacturing technology have permitted the development of a mechanically rotating ultrasound imaging core 0.018 inches in diameter. It is compatible with current balloon catheters without degradation of image quality. (Am Heart J 1998;136:1017-20.)

Intravascular ultrasound (IVUS) is useful as a diagnostic device and as a guide during interventional procedures.[1-8] However, IVUS is time consuming and requires exchanges between interventional devices and imaging catheters. The development of a smaller imaging device that could be exchanged with a guide wire could facilitate the use of intracoronary ultrasound imaging. To meet this requirement, a 30-MHz ultrasonic imaging core was developed that is the same dimension as a 0.018-inch guide wire.

The purpose of this study was to test the clinical feasibility of this imaging core that can be exchanged for a 0.018 inch guide wire and can fit through the shaft of existing balloon catheters.

Methods

0.018-Inch imaging core

A magnified view and a structure diagram of a 2.9F imaging catheter and of the 0.018-inch-diameter, 30-MHz imaging core (CVIS, Inc, Sunnyvale, Calif) are shown in Figs 1 and 2. The 2.9F imaging catheter has a 0.029-inch imaging core, which is the smallest commercially available catheter (MicroView, CVIS). The entire shaft of the catheter rotates within a protective plastic sheath and can be advanced or withdrawn along the long axis of the sheath. The transducer is placed at a 5 degree angle to the long axis of the catheter to diminish near-field artifact. The distal end of the imaging device has an 8-mm-long flexible tip, but this wire does not extend beyond the distal end of the protective sheath.

The transducer of the 0.018-inch-diameter imaging core is also displaced 5 degrees off the longitudinal axis to prevent near-field artifact. Although the diameter of the imaging core is the same as a 0.018-inch guide wire, the characteristics of this imaging core are significantly different from a guide wire, and it is not meant to extend beyond the sheath or be used as a guide wire.

Clinical studies

The 0.018-inch imaging core was tested in 8 patients who underwent interventional procedures at The Clinica Cuore Columbus, Milan, Italy. All patients gave informed consent. The study was approved by the Human Research Committee at the hospital.

During interventional procedures, the standard guide wire was removed and the 0.018-inch imaging core was directly advanced through the central lumen to image through the angioplasty balloon. After the balloon was removed, these patients were also studied with the 0.018-inch imaging core

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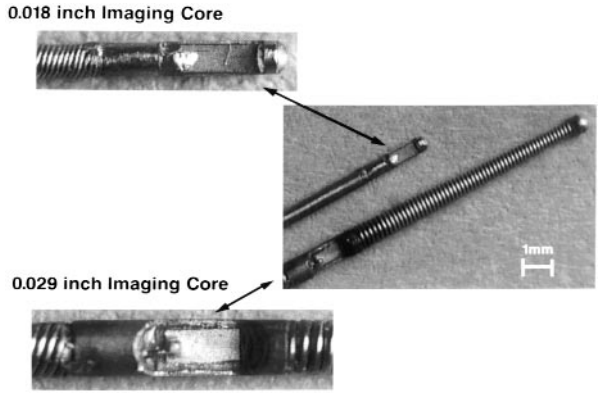
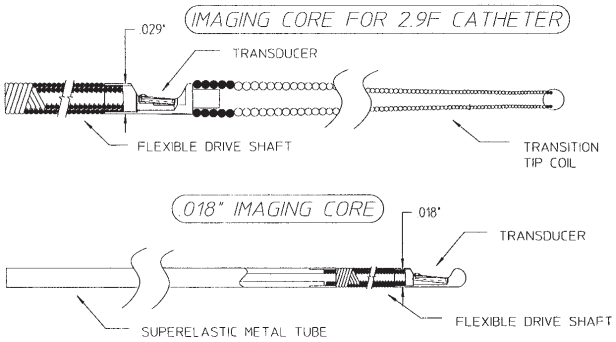
Figure 1



Magnified view of 0.018-inch imaging core compared with 0.029-inch imaging core.

Figure 2



Structure diagram of 0.018-inch imaging core compared with 0.029-inch imaging core.

Table I. Comparison of 0.018-inch imaging core and standard 3.2F imaging device

	0.018-Inch imaging core	3.2F Imaging device
Mean lumen cross-sectional area	6.8 ± 3.2 mm^2	6.7 ± 3.3 mm^2
Lumen/plaque interface visibility	8/8	4/4
Plaque/media interface visibility	8/8	4/4

by passing it down the lumen of the standard monorail-type 3.2F ultrasound catheter from which the standard IVUS imaging core (0.029 inches) had been removed. After the intervention, 4 of these patients were also imaged with a standard 3.2F IVUS device (MicroRail, CVIS).

Data analysis and statistics

The analysis of these preliminary in vivo tests in patients undergoing interventional procedures was performed by qualitative and quantitative interpretations of the images and by comparing these images with a standard 3.2F imaging device from the same company. Measurements of lumen cross-sectional area were expressed as mean ± standard deviation. A value of $P < .05$ was considered statistically significant. Mean values were compared by analysis of variance.

Results

Fig 3 shows an ultrasound image obtained by the 0.018-inch imaging core through a 3.0-mm angioplasty balloon during inflation at 8 atm. The first intense reflection is from the inflated balloon, which is pressed against the plaque. Although the dimensions of the balloon are clearly defined, the morphology and layers of the plaque have lost their distinction. The second intense line is produced by ultrasound reverberations between the ultrasound transducer and the balloon edge. These observations were limited to less than 10 atm of pressure because of compression of the shaft and resistance to the motor drive chain as the pressure was increased above 10 atm.

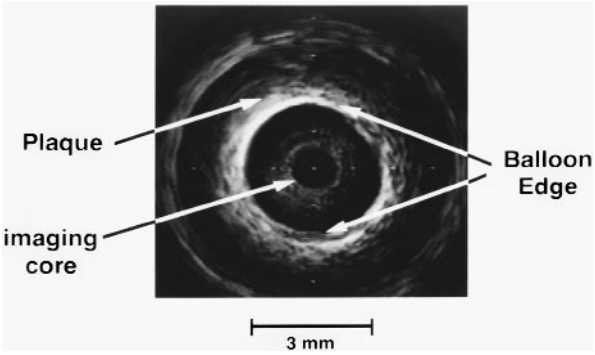
Compared with an image obtained through an inflated balloon, Fig 4 demonstrates the image quality obtained with the 0.018-inch imaging core after it was placed down the lumen of a standard 3.2F ultrasound imaging catheter. The lumen and plaque boundaries are well visualized in the images before treatment (Fig 4, *A*, *B*, and *C*) and in the interrogation of a stent after deployment (Fig 4, *D*). Although the lumen size of the 3.2F catheter was larger than the dimension of the 0.018-inch imaging core, there was no evidence of either nonuniform rotation artifact nor pendulum motion of the transducer inside the lumen.

Table I demonstrates that the mean lumen cross-sectional area was similar for both devices and that both the lumen-plaque interface and the plaque-media interface were clearly visualized in all cases with the imaging core and in the 4 patients who had imaging performed with the standard 3.2F ultrasound device.

Discussion

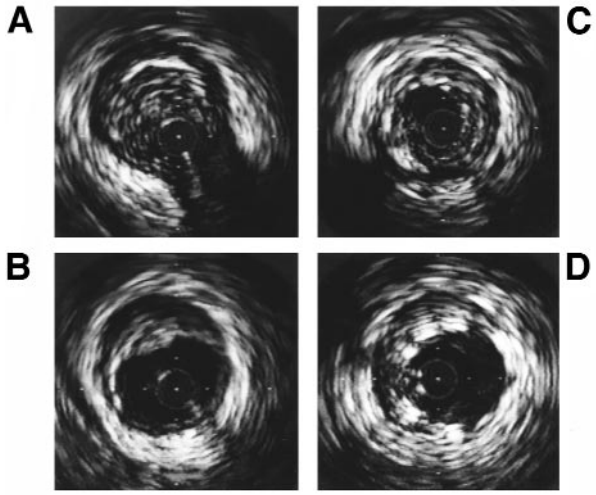
Improvements in manufacturing technology have permitted the development of a mechanically rotating imaging core 0.018 inches in diameter. This imaging core is compatible with the lumen size of current bal-

Figure 3



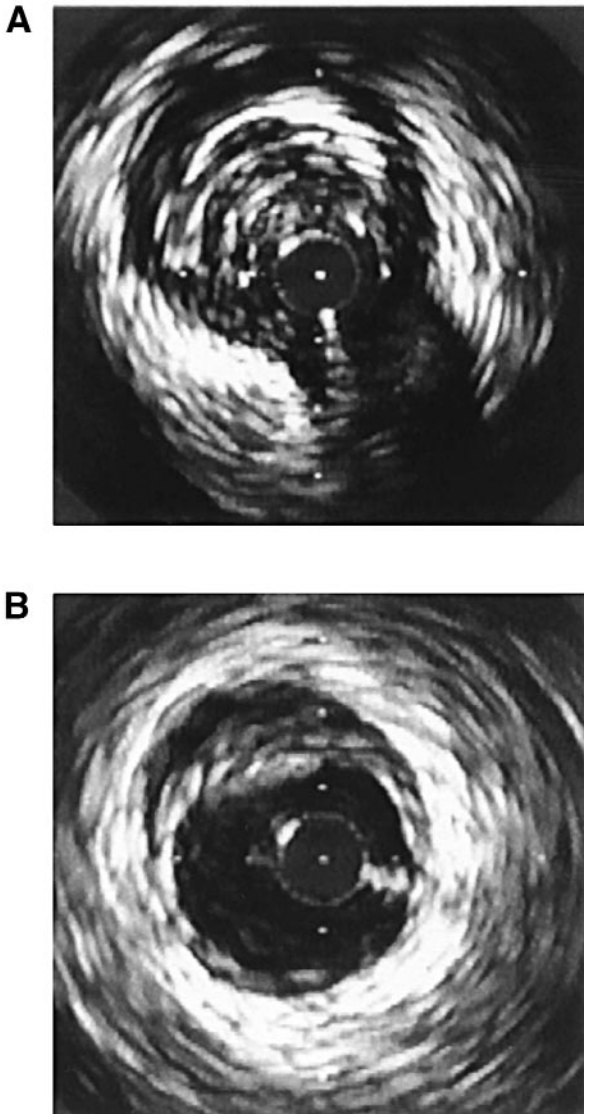
Ultrasound image by 0.018-inch imaging core through 3.0-mm angioplasty balloon during inflation in patient.

Figure 4



Representative ultrasound images of coronary arteries by 0.018-inch imaging core placed down lumen of standard 3.2F ultrasound imaging catheter sheath. **A**, Lesion with tight stenosis at bifurcation (5 o'clock position). **B**, Lesion with mild eccentric plaque. **C**, Lesion with concentric plaque. **D**, Stented coronary lumen with Palmaz-Schatz stent.

Figure 5



Intravascular ultrasound images obtained with a standard 3.2 Fr IVUS catheter. Panel A and B correspond to the same arteries that were shown in Figure 4A and 4B respectively. The images in figure 4 were obtained with the 0.018-inch imaging core.

loon catheters. The major result of this study is that there is no significant degradation of image quality in vivo with the 0.018-inch imaging core compared with the larger standard IVUS imaging devices.

The size of the imaging transducer has a significant impact on image quality. Smaller transducers provide less tissue penetration of the ultrasound beam because of emission of lower energy.[9] Although the lateral resolution in the near field is better with smaller IVUS transducers, the focal zone is shorter compared with larger catheters.[9,10] Despite these limitations, the 0.018-inch imaging core provided similar image quality compared with the 0.029-inch imaging core in terms of plaque boundary recognition and tissue characteristics.

The 0.018-inch imaging core has several advantages compared with larger IVUS devices. First, balloon

inflations can be monitored in real time to examine lumen size and morphology. Second, the imaging core saves time when multiple ultrasound interrogations are performed during coronary interventions because it is not necessary to remove the dilatation balloon. Third, it facilitates obtaining ultrasound images of smaller or more tortuous arteries. It should be noted that this 0.018-inch imaging core represents a work in progress and is not meant as a final product design. There are still technical limitations with this device that will need to be addressed before it can be released. However, this study demonstrates the clinical feasibility and potential utility of an ultrasound imaging device that is as small as a guide wire.

Clinical implications

This device is an intermediary step toward development of a 0.018-inch imaging guide wire that could be used to cross a lesion before an intervention, interrogate it diagnostically, and then remain in place during interventions to help direct therapy. To achieve this goal, a smaller IVUS imaging core and protective sheath would be necessary to avoid interaction between the core and artery.

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