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First experience with imaging core wires

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This study is the first assessment of feasibility and clinical usefulness of an imaging wire. The device used is a 0.018" flexible cable mounting a 30 MHz piezoelectric crystal at the end. The only possible application of the wire in its current configuration is the assessment of balloon expansion with over-the-wire balloon catheters. In this study, 17 lesions were examined in 14 patients. Despite careful removal of the air, no image could be obtained with the balloon deflated or through the shaft of conventional balloon catheters. When the balloon was inflated to 1–4 atm the circular echo-free cross-section of the balloon became visible, surrounded by the dense line of the balloon membrane and by the vessel wall. By examining the stent area at different balloon pressures, it was possible to determine the stent recoil between maximal balloon expansion and lowest balloon pressure allowing a readable ultrasound image. These encouraging preliminary observations confirm the feasibility of the use of an ultrasound guidewire for monitoring balloon expansion during stent implantation. After high pressure inflation, a moderate reduction of the stent lumen was observed during deflation, compatible with the small recoil predicted for the stainless-steel mesh stent used.

Key words: intravascular ultrasound, stent implantation, coronary artery disease

Introduction

Miniaturization of transducers has been the primary goal in the technical development of intracoronary ultrasound. The first prototypes used for intracardiac imaging were developed by the Editor (N. Bom) of this issue and had a diameter of 8 French (1973). Today, for both electronic and mechanical systems there are ultrasound catheters with a diameter equal to or slightly larger than 1 mm, allowing the assessment of severe coronary stenoses before intervention and of small tortuous distal vessels. Despite these advancements, the use of an ultrasound catheter still has clear disadvantages since a separate insertion of the probe is required before and after each treatment with balloons or other interventional devices. Furthermore, ultrasound guidance is unavailable when you need it the most, for on-line monitoring of the effects of treatment on lumen and plaque. A possible alternative is the combination of therapeutic and imaging capabilities on the same catheter [1]. Balloon catheters with 64 to 128 crystals mounted in a ring proximal to the balloon [2–4] and combined ultrasound–atherectomy catheters [5] are available. The use of these catheters, however, assumes that the selection of the type and size of interventional device to be used is already appropriate, and this selection must be based only on angiography, thus limiting the usefulness of these devices [6]. Furthermore, the ultrasound image can be obtained only in one location along the catheter, not always coincident with the area of interest. These limitations have prompted the development of very miniaturized ultrasound transducers, with a diameter equal to the diameter of standard guidewires.

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Technical description

The imaging wires tested in our centre are a modification of the driving cable used in the mechanical 2.9 French ultrasound catheters of CVIS/Scimed-Boston Scientific (Sunnyvale, California). Although these devices have the diameter of regular guidewires (0.018", 0.46 mm in diameter) and are fairly flexible, their mechanical characteristics are still different from the characteristics of a guidewire. The absence of a floppy steerable distal end precludes their use as a rail to insert other devices inside the coronary arteries. On the contrary, they must be protected by being inserted within a protective sheath such as any catheter

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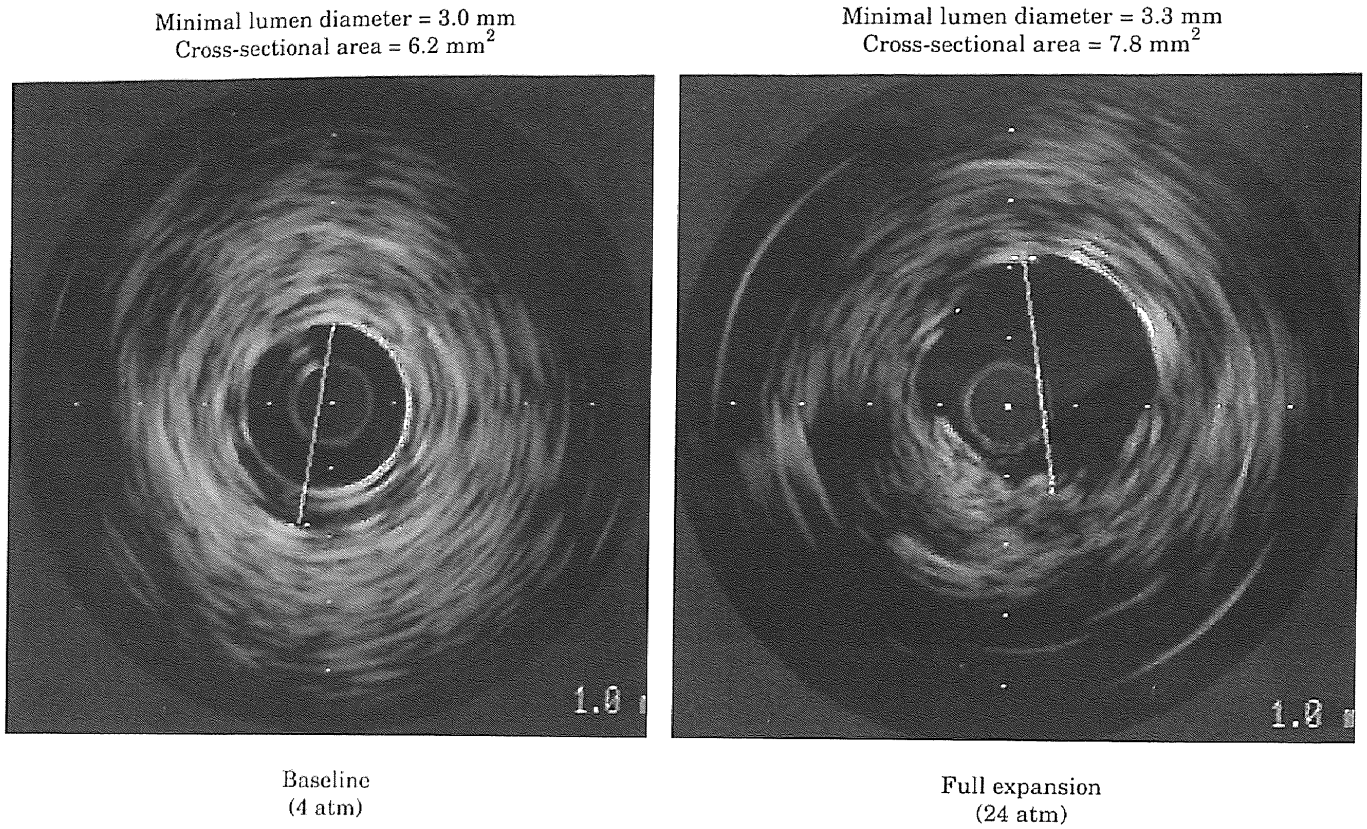

Figure 1. Two cross-sectional images obtained with the imaging wire during inflation of a Titan 3.5 mm balloon within a stent. Note that the maximal stent expansion was achieved at 24 atm (right panel) and that a decrease in stent area due to stent recoil was observed at lower pressures

compatible with an 0.018" guide wire. The initial prototypes tested in our centre [7] consist of metallic interwoven wires forming a flexible cable which is attached to a motor unit and rotated at 1800 rpm. At the distal end of the cable, a 30 MHz piezoelectric crystal is mounted and connected by electrical cables to the central unit (Insight III, ClearView software, CVIS/ Scimed, USA).

Preliminary clinical applications at the Columbus Clinic

The imaging wire was tested in 11 lesions in eight patients, all undergoing stent implantation because of severe coronary artery disease. The arteries treated were the left anterior descending coronary artery (five lesions, 46%), the left circumflex (two lesions, 18%) and the right coronary artery (four lesions, 36%). The lesion location was in the proximal or mid-arterial segment in eight cases (73%) and in the distal artery in three cases (27%). Two protocols of stent implantation and ICUS examination were used. In the first six patients (seven lesions) a Palmaz–Schatz 14 mm stent (Johnson & Johnson, Warren, New Jersey) was deployed with an 0.018" wire compatible over-the-wire catheter (Goldy, Medtronic, USA). After careful removal of the air inside the balloons by repeatedly applying negative pressure, the stent was hand-crimped and positioned at the stenosis site using a regular angioplasty guidewire. The stent was deployed by inflating the balloon at a pressure of 6–8 atm for 30 s and the balloon was deflated and left in place. The guidewire was withdrawn and the imaging core was advanced under fluoroscopy up to the mid-segment of the balloon so that the ultrasonic crystal was positioned within the stent during subsequent balloon expansions. After positioning, the motor unit was activated but no images could be obtained with the balloon deflated because of persistency of air around the crystal. During inflation, the ICUS image appeared at a pressure of 2–4 atm. Occasionally, further application of negative pressure or small changes in the position of the transducer were required. Typically, the image showed a homogeneous black circular area within the balloon, with an echo-dense line representing the balloon membrane. At low pressure, small spaces filled with highly echogenic blood between balloon and vessel wall were observed and interpreted as sluggish flow around the balloon during inflation. The vessel wall was also visible around the balloon, with echo-dense bright spots representing the stent struts. 'Ghost' images of the stent struts and of the balloon membrane were frequently observed. At a balloon pressure of 10 atm, measurements of the area within the stent were obtained. Images could be obtained occasionally at higher pressures but in most cases entrapment of the imaging wire occurred at

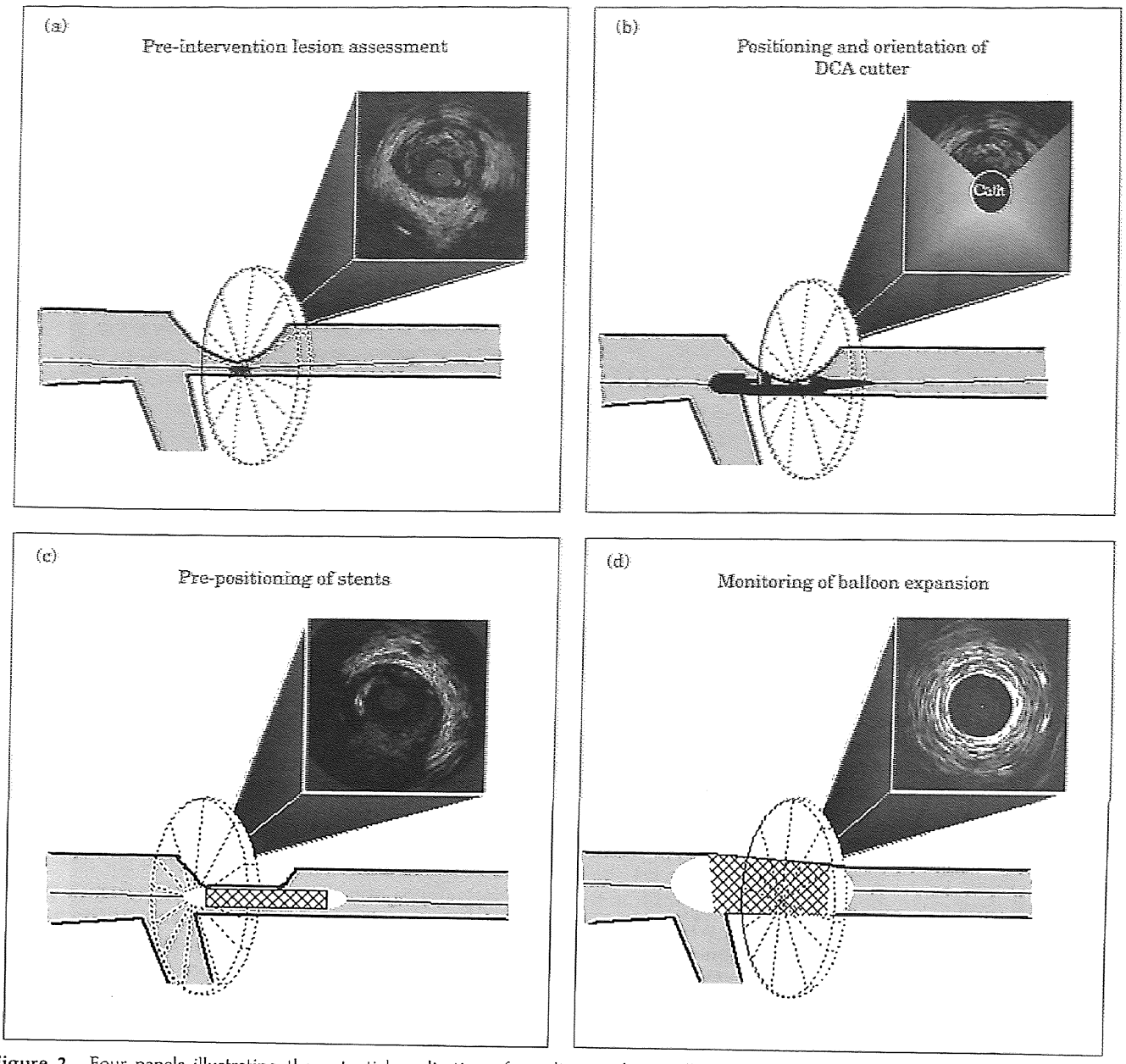

Figure 2. Four panels illustrating the potential application of an ultrasound wire allowing wall imaging also without a partially inflated balloon. (a) Lesion characteristics can be examined before treatment with the imaging core wire without inducing ischaemia; (b) through a window in the housing of the atherectomy catheter the quadrant of the vessel wall in contact or within the cutting chamber can be examined; (c) the stent can be precisely positioned in ostial lesions, avoiding incomplete lesion coverage or stent protrusion into the aorta or, as in this example, the left main coronary artery; (d) the optimal expansion of the balloon throughout the stent length can be controlled during inflation, allowing the use of as much pressure as needed to overcome the resistance of the vessel wall.

pressures higher than 10 atm because of impingement of the wire lumen, resulting in malrotation artefacts and, eventually, wire rupture (three cases, 21%). After 30 s of inflation at 10 atm, the balloon was deflated and imaging was repeated at the minimal balloon pressure at which an interpretable circumferential image was present. Stent lumen cross-sectional areas at 10 atm were compared with the measurements obtained after deflation (residual pressure of 3 atm). The imaging wire was then removed and the regular guidewire inserted, allowing withdrawal of the balloon and insertion of a conventional 2.9 French or 3.2 French ICUS catheter. Since the exact position imaged by the wire was not known, the average of 10 cross-sections in the mid-portion of the balloon at 1 mm intervals was used for comparison. Lumen area was 6.9 ± 4.0 mm^2 at 10 atm and decreased to 6.7 ± 2.5 mm^2 after deflation (average pressure = 3 atm) suggesting a 3% stent recoil for this difference in inflation pressure. The lumen area measured with a conventional ultrasound catheter was 5% smaller (6.4 ± 2.0 mm^2) than the area measured with the imaging wire at the minimal balloon pressure compatible with the use of the imaging core wire.

In the last six lesions, a different balloon was used (Titan, Cordis Corporation, Billerica, Mississippi), characterized by a very low compliance and high resistance to pressure. In these last cases, the stent was deployed with a different low compliant, 0.5–mm smaller balloon at an average pressure of 14–16 atm. In these last cases the imaging wire was advanced after positioning of the Titan balloon within the stent and the measurements were taken at maximal pressure (20–24 atm) and after deflation (at 4 atm) (Fig. 1). An 18% average reduction in stent area from maximal pressure to 4 atm was observed, with a trend to the equalization of maximal and minimal lumen diameter within the stent at high pressure.

Discussion

These preliminary observations confirm the feasibility of an ICUS examination with a miniaturized imaging core wire, compatible with currently available interventional devices. Such a system has many advantages over conventional ultrasound catheters. First, imaging would become available for guidance during the interventional phase of the procedure, allowing lesion interrogation before treatment, ultrasound-directed plaque removal with directional atherectomy and assessment of the optimal position and expansion of the balloon during balloon angioplasty or stent expansion (Fig. 2). Since the first application still requires changes in the design of the atherectomy catheter (0.018" compatibility, ultrasound window), our attention was focused on this second application, feasible also with the presently available prototypes. Intracoronary ultrasound has shown that incomplete stent expansion or apposition to the vessel wall is present in most cases when balloon dilatation is performed at conventional pressure (up to 8–12 atm) [8–10]. In addition, after standard dilatation, the lumen diameter after dilatation is smaller than the balloon diameter. Although this is generally attributed to wall recoil this phenomenon is likely to be caused, in most cases, by an incomplete balloon expansion. There is increased awareness, based on measurements of balloon diameter with quantitative angiography [11], that there are large differences between nominal size of the balloon at a given pressure and true balloon size measured during inflation in stenotic arterial segments. If a stent is present at the site of dilatation, the scaffolding properties and radial force of the stent should limit or prevent wall recoil and prolapse of large dissection flaps inside the vessel lumen but may have little influence in balloon expansion. The rationale of the policy of high pressure balloon inflation is the attempt at overcoming the unpredictable mechanical resistance of the vessel wall to stretching, allowing a more complete expansion of the balloon. Appropriate monitoring of the balloon expansion with accurate ultrasound measurements would avoid unnecessary application of high pressure to all lesions, which potentially increase wall damage and the consequent hyperplastic response [12–13]. Considering the frequent eccentricity and calcification of the stenotic plaque, it is clear that only a tomographic technique such as ultrasound can reliably monitor optimal balloon expansion. Further modifications of the imaging wire are required to facilitate its use during interventions, including improved mechanical resistance of the rotating cable, higher sensitivity of the ultrasound transducer, and the presence of a flexible and ideally steerable distal end. Other modifications are probably required in the balloon used for angioplasty, including a non-deformable wire lumen, resistant to high pressure, and the presence of a shaft material allowing imaging through the balloon shaft.

Conclusions

These encouraging preliminary observations confirm the feasibility of the use of an ultrasound guidewire for monitoring balloon expansion during stent implantation. After high pressure inflation, the reduction in stent lumen observed during deflation was compatible with the recoil predicted for the stainless-steel mesh stent used and was higher after high-pressure dilatation. The measurements of stent lumen obtained with a conventional ultrasound catheter were well correlated with the measurements obtained with the imaging core wire.

Further improvements of the imaging core wire are required to allow more clinically relevant applications such as (a) examination of the lesion before intervention to select type, size and length of the device to be used; (b) guidance of accurate positioning of the device at the stenosis site and orientation of the cutter for directional atherectomy to obtain a more complete selective plaque removal; (c) monitoring of the expansion of the balloon during inflation, especially during stent deployment; and (d) assessment of the adequacy of the final result and the need for further interventions.

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