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A New Flexible and Deflectable Tip Guidewire For Coronary Angioplasty and Other Invasive and Interventional Procedures

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In the past decade and a half, there has been a prodigious growth of coronary angioplasty. In large measure, this has occurred because of the evolution and development of angioplasty equipment. In the first coronary angioplasty era (1977-79), the hardware was prototypical, thus limiting the procedure to patients having single vessel disease with stenoses (not occlusions) that were proximal, discrete, concentric and non-calcific that did not involve major side branches nor were located on angulated arterial segments.1-5

In the second angioplasty era (1980-82), two technical advances occurred. The first was the guiding catheter which evolved from an unwieldy 9-10F solid Teflon model to a layered iteration with significantly improved memory and torque control. With the addition of numerous distal configurations, stable and coaxial cannulation of coronary arteries could be obtained.6 The second major advance was the development and introduction of a guidewire7,8 which permitted advancement through tortuous and branching arteries and across lesions with complex morphology and located in distal sites.

Over the past decade, and in particular during the last 4 years, there have been further advancements in angioplasty technology1-5,10-12 with the development of smaller diameter guiding catheters13 and lower profile dilatation catheters, including monorail14,15 and balloon-on-a-wire16,17 devices with balloons that were thinner, more con-
formable, stronger, longer and with lower compliance. In addition, other new devices for coronary intervention were developed.

This current era (1988— ) has witnessed the widening of coronary angioplasty indications, increased procedural success rates and a decreased incidence of complications.

The angioplasty guidewire, introduced a decade ago, has also evolved. The initial models were made of a fine stainless steel wire tightly coiled over a central core. Guidewire diameters were reduced from 0.018" to 0.014" and 0.012" and 0.009", the latter for the fast rotational ablation device. Guidewires were initially coated with Teflon and, more recently, silicone to decrease the coefficient of friction and thus allow improved trackability of the dilatation catheters. Torque control has improved, as well, even through multiple arterial curves. The proximal end of the guidewire can be extended to allow exchange of the dilatation catheter. The guidewire distal tip, in various iterations, was made stiffer or more flexible and could be shaped (by hand) to address various arterial morphology.

Yet, guidewire tip shaping was, at once, its strength and its weakness. When the tip was shaped before introducing it into the guiding and dilatation catheters, it could not be reshaped except by removing it. This limitation resulted in an increase in fluoroscopy and procedure times and also cost, since frequently two or more guidewires were utilized. This limitation of guidewires (especially) compromised the use of monorail and balloon-on-a-wire devices.

In 1988, a guidewire was developed by Buchbinder and marketed by Versaflex Delivery Systems Co., Inc. which was subsequently purchased by Medtronic, Inc. This guidewire had a distal tip that could be deflected while within the coronary arterial system to accommodate variations in anatomy. To achieve this feature, a pull wire was attached to the distal tip and, when pulled would deflect the tip through various angles. However, the construction of this guidewire caused the tip to be quite rigid (stiff), which resulted in instances of arterial dissection. For this reason, this device fell into some disfavor and has been rarely used by interventional cardiologists in the United States.

Nevertheless, the rationale for an in vivo deflectable tip guidewire remains sound. This type of guidewire would permit another dimension of manipulation and control. To that end, a new guidewire has been developed which has a
deflectable tip but, by an ingenious construction, allows distal flexibility as well as excellent torque control.

TECHNOLOGY

The deflectable tip guidewire (Pilot Cardiovascular Systems, Inc., San Clemente, CA) is constructed using a proximal stainless steel tube which is connected to a platinum coil. The outer diameter of the radiopaque guidewire is 0.014" and the (effective usable) length is 165cm. The guidewire is coated to provide the lubricity and facile trackability of the over-the-wire dilatation catheter. The pull-wire, which controls deflection, is anchored to a steering post which is 7mm proximal to the distal tip. Tip deflection can be achieved with a pull pressure of less than 15 grams, causing less tension and therefore, less stiffness. This design permits distal wire tip floppiness. These characteristics ensure atraumatic maneuverability of the guidewire within the coronary arteries.

The tip of this guidewire can be shaped in vivo by using an integral manipulator which is attached at the proximal end. The manipulator grips the proximal outer tip. By turning the rotating knob on the manipulator, retraction or advancement of the inner core relative to the outer stainless steel core is effected. This results in a deflection of 0 to 90° in the distal tip.

Torque control (1:1) is achieved, even through multiple arterial curves, by rotation of the manipulator handle, itself, which directs the orientation of the distal tip. Because the manipulator handle can be easily removed (and reattached), the proximal end of the guidewire can be extended if exchange of the dilatation catheter or new device is desired (Figure 1).

STUDY COHORT

After extensive bench testing and animal studies, clinical trials were initiated in several centers. From the outset, cases were selected that had challenging anatomy and pathology. Coronary arteries with angulated origins (entrance points), tortuosity, numerous branches, and complex and severe lesions were attempted (Figures 2, 3). In addition, the Pilotguidewire was coupled with dilatation catheters of various sizes, lengths and designs from several companies (USCI, ACS, Schneider, SciMed). Certain new devices (atherectomy and laser catheters and ultrasound devices) were also employed with this guidewire.

The Pilot guidewire was utilized in 40 cases with a clinical profile showing an age range of 34-85 years (mean 61); 62% were male. The morphologic profile showed the target vessels included the left anterior descending, left circumflex, and right coronaries and the diagonal, obtuse marginal and
A-V, posterolateral and posterior descending branches as well as the saphenous vein graft and internal mammary artery. Lesions were generally very severe and varied in morphology (eccentric, angulated, bifurcation, calcified, proximal and distal). Some lesions were associated with acute ischemic syndromes, i.e. unstable plaques.

With the exception of a very few (and not unexpected) technical glitches in the initial phase, the Pilot guidewire showed remarkable versatility. A functional Pilot guidewire was uniformly successful, without any complications, in all cases, save one. That one case had an old total occlusion. The Pilot guidewire could not traverse the occlusion, nor (incidentally) could other standard guidewires subsequently utilized. On the other hand, in a few complex vessels in which standard guidewires "struggled" (though were ultimately successful), the Pilot guidewire quickly cannulated the target vessels.

DISCUSSION

Contemporary guidewires for coronary angioplasty are associated with very high success rates. Yet, the use of these guidewires is limited by the inability to reshape the distal tip in vivo (on-line). This has resulted in frequent removal of guidewires to reconfigure the distal tip (or replace the guidewire) to accommodate anatomic and pathologic variations in coronary anatomy.

In a sense, the "art" of coronary angioplasty is the use of a guidewire (in which the tip was shaped to accomodate the initial vessel curve), through the distal arterial transfer (via angulations and by branches and across lesions) in which the distal tip curve is not "correct" (i.e. congruent). For example, to enter a sharply angulated origin (entrance-point) of a left anterior descending or left circumflex coronary artery, one may have to create a severe curve (90° or more) in the distal tip of the guidewire. Once introduced, this curve may subsequently compromise facile distal guidewire passage and encourage (inadvertent) engagement and entrance of side branches. Standard guidewires may also encounter some difficulty traversing complex (eccentric, long, angulated, subtotal) lesions.

With this newly designed guidewire with a flexible (soft) tip, in vivo deflection and straight-

Figure 3. Same patient as in Figure 2. (A) Initial passage of pilot guidewire (GW) into LAD. (B) Further advancement of GW through straight segment. (C) Progress of GW in LAD angulation. (D) Progression of GW into straight segment. (E) GW in diagonal branch. (F) Advancement of GW into LAD. (G-I) Further progression of GW into tortuous distal segments. Note distal tip configurations in all panels (arrows) (A-D: RAO-30°; E-I: RAO-15° CR15°) (The GW passage occurred in < 15 seconds).
ening allows immediate (on-line) change in tip deflection to better accommodate the variations in coronary anatomy. This feature of the Pilot guidewire has had the positive effect of obviating the need for guidewire removal (for tip reshaping) and guidewire exchange. With the monorail catheter design, the Pilot guidewire has proven even more useful, since the catheter, itself, need not be removed (as before) when guidewire removal for tip reshaping is necessary.

FUTURE PLANS

A randomized trial has been planned to test the Pilot guidewire against the standard designs for a) safety, b) effectiveness, c) fluoroscopy and procedure time, d) number of guidewires used, e) versatility and, f) cost.

In addition, the proximal extendible segment will be available soon and a balloon-on-a-wire with a deflectable tip is in prototype form.

SUMMARY AND CONCLUSIONS

A newly designed coronary angioplasty guidewire has been developed and introduced in initial clinical trials. The device shows great promise and adds a new dimension to coronary angioplasty. It is anticipated that this guidewire may find use, as well, in other cardiac and radiologic diagnostic and therapeutic venues in which variable tip deflection may aid guidewire manipulation to allow facile introduction into even more challenging sites.

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