New Catheter Tip Concept Providing Both Flexibility And Pushability *NIRxcell™* CoCr Coronary Stent System

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Background:

Crossing tight lesions remains one of the major challenges in percutaneous coronary interventions (PCI) today. It requires a stent system and PTCA balloon catheters that have a highly flexible and pushable tip with good resistance to buckling that may deform the tip and prevent its performance and its repeat use. In the past, small-diameter devices were developed in order to meet these challenges. All these devices, however, use a polymer tip that is prone to deformations such as flare-out and buckling during PCI, particularly in challenging anatomies and when crossing tight, calcified lesions and previously stented segments. Tip buckling may prevent a second attempt with the same system due to the damaged tip that has to be assumed even if we do not see it with our naked eyes.

A new stent system, the NIRxcell™ by Medinol®, offers a new concept in coronary delivery systems by featuring a metallic spring tip instead of the standard polymer tip used with all other systems. The spring tip provides supreme flexibility (Figure 1), together with high pushability and excellent resistance to buckling at tight and calcified lesions. This as can be seen in a bench trial (Figure 2) demonstrating the buckling resistance of the spring tip as compared with that of a conventional tip.

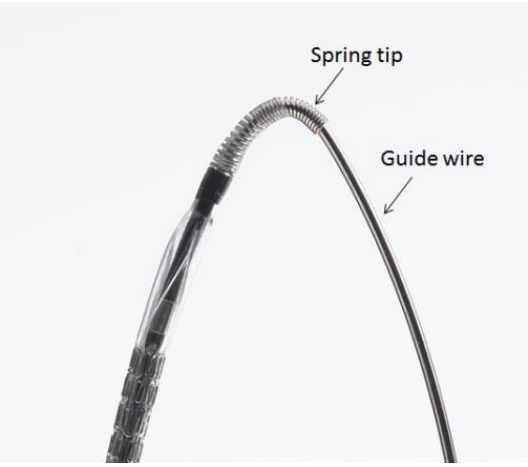

Figure 1: The Metallic Spring Tip

Figure 2: The Spring Tip (left) of the NIRxcell Stent System pushed against a conventional polymer tip

In this paper, I report a case of a tight calcified lesion which presented a good opportunity to evaluate the pushability and structural integrity of the new spring-tip based delivery system of the NIRxcell™ stent.

Case Report:

A 66 year-old male patient with a tight, heavily calcified lesion at the proximal RCA was treated at Clinique Louis Pasteur, Nancy, France. A guide wire was placed at the RCA (Figure 3).

There were multiple attempts to cross the tight lesion with the following devices:

1. Trek (Abbott) dilatation catheter (9 attempts with 9 different systems).
2. Emerge (Boston Scientific) dilatation catheter (1 attempt).
3. Sprinter (Medtronic) dilatation catheter (2 attempts with 2 different systems).
4. NIRxcell (Medinol) delivery system used as a PTCA balloon after removal of the stent from the balloon (not optimal as a PTCA balloon in crossing profile and without hydrophilic coating on the balloon), 3 attempts with the same catheter, the third of which succeeded.
5. Two Integrity (Medtronic) stents were finally implanted in the proximal RCA following the successful crossing by the NIRxcell catheter.

The resulting angiography showed good revascularization of the proximal segment of the RCA with a non flow-limiting dissection at the mid segment and improved flow to the distal RCA (Figure 4).

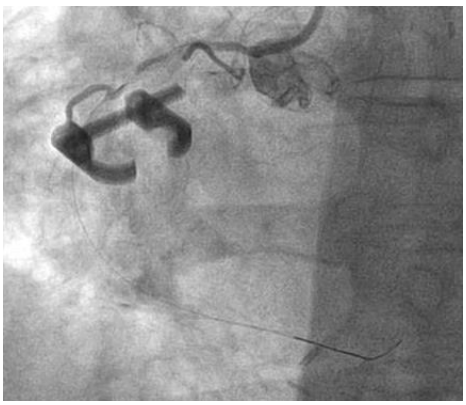

Figure 3: Placing a guide wire in the RCA

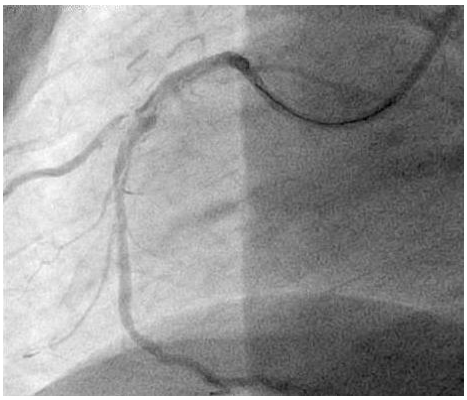

Figure 4: Revascularization in the RCA

Discussion:

Multiple devices were used in an attempt to cross the lesion. Each of the systems was used only once, except for the NIRxcell catheter that was used three times and actually crossed the lesion in the third attempt. Following the procedure, the balloon catheter tips were visualized under low magnification light microscopy with the following findings: all the polymer tips (except for one) were deformed (Figure 5) in a way that would prevent them from crossing in a subsequent attempt. This finding supports our usual assumption that catheters after a failed attempt to cross a tight lesion should not be reused. The metallic spring tip of the NIRxcell delivery system showed no sign of deformation and the tip maintained its shape, even though the system was used three times while each of the other systems was used only once. Additionally, the visibility of NIRxcell's metallic spring tip under fluoroscopy helped in visualizing the distal part of the catheter in the artery and pointed out the exact location of tip entry to the tight stenosis (Figure 6).

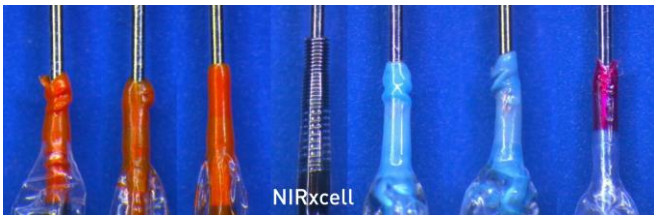

Figure 5: Deformed tips of standard PTCA balloon delivery systems vs. the spring tip of NIRxcell

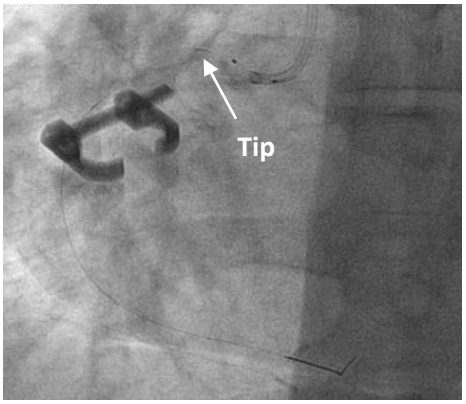

Figure 6: Visible Spring Tip

The notion that polymer tips are subject to flare-out and buckle did not receive enough attention, probably because until now only polymer tips were available and they in turn had to compromise between flexibility and buckle resistance, as mentioned above. Yet, most operators would not use a catheter that failed a challenging crossing attempt for a second attempt assuming it might be damaged.

The potential advantages of a delivery system with a flexible tip that does not buckle, such as the NIRxcell with the metallic spring tip, are apparent from this case. It could lead to stent and balloon-catheter systems with superior crossability and deliverability and could present a saving on equipment by using it in multiple crossing attempts without fear of tip buckling.

Disclosure of Commercial Conflict of Interest: Nothing to disclose

