EluNIR™ Ridaforolimus Eluting Coronary Stent System by Medinol®

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Background:

This paper outlines the first in-patient implantation of the EluNIR™ ridaforolimus eluting elastomeric stent (Medinol Ltd.). This complex case involved a patient with a flow-limiting lesion in a native coronary artery post bypass surgery.

The new EluNIR stent system includes a stent with a low metal footprint which comprises struts of variable width: ultra-narrow struts having a width of 40µm and narrow supportive struts having a width of 72µm. The combination of different strut widths enables the stent to provide both excellent flexibility and conformability, and at the same time adequate radial strength to support the artery after dilation. The stent geometry enables excellent deliverability even in tortuous and calcified lesions. In addition, the delivery system of EluNIR includes an innovative metallic spring tip that was designed to enhance crossability and buckle resistance. Other stent delivery systems that typically have polymer tips, are prone to flare-out and buckling that may impact deliverability.

Case Report:

A 64-year-old male with prior history of coronary bypass surgery was treated at San Raffaele Hospital in Milan, Italy. His coronary angiography showed a patent Left Internal Mammary Artery (LIMA) bypass graft anastomosed to the mid portion of the native LAD. At the site of the anastomosis, there was a calcified lesion in the native LAD (Figure 1, black arrow). The LIMA bypass was extremely tortuous with a "hair-pin" bend immediately preceding the lesion at the anastomosis with the LAD. The LAD provides collateral flow to the native RCA.

The case was performed via the left radial artery. A guidewire was directed through the LIMA graft across the lesion into the distal LAD. A standard 2.5/15mm PTCA balloon (Figure 2, black arrow) was advanced over the wire but failed to cross the bend in the LIMA (Figure 2, red dotted line) proximal to the LAD anastomosis. A second "buddy" wire was placed in the LIMA graft which enabled pre-dilation of the lesion with the balloon. Following that, a 2.5/15mm EluNIR stent (Medinol Ltd.) was easily advanced around the bend in the LIMA through the anastomotic lesion into the LAD. The stent was inflated at 16 ATM and post-dilated with a non-compliant balloon.

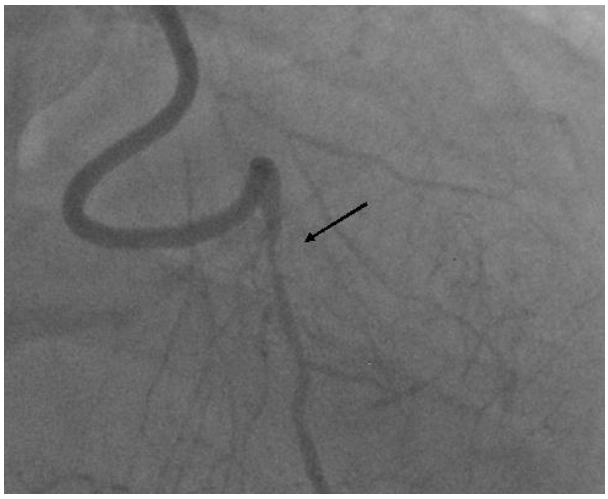

Figure 1

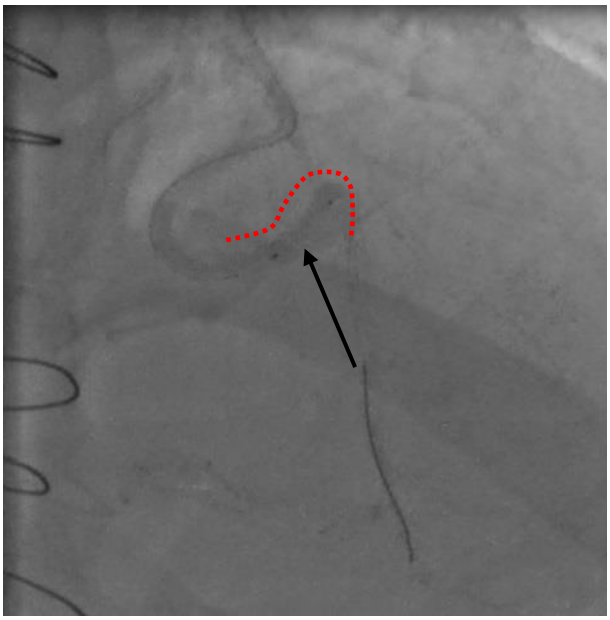

Figure 2

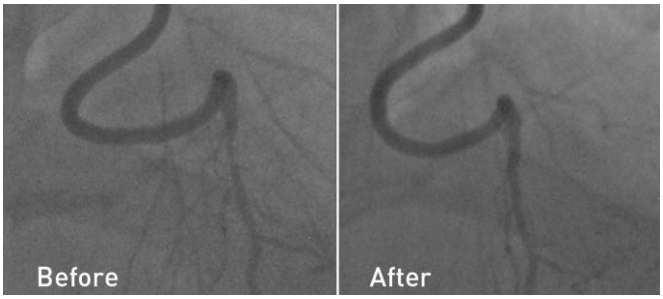

Figure 3

Discussion and Conclusion:

The procedure with the EluNIR stent system (Medinol Ltd.) was successful and the final angiographic result was very good (Figure 3). The EluNIR stent system with the metallic spring tip was highly deliverable; it easily traversed the tight angulations of the LIMA graft and crossed the lesion despite challenging catheter support. Finally, an EluNIR stent was implanted at the native LAD and blood flow was restored.

The new EluNIR stent has been recently approved for use in Europe and the United States. The approval in the United States was granted based on the results of the BIONICS trial*, that included 1,919 patients in the United States, Canada, Europe and Israel and compared between the EluNIR stent and the Resolute stent (Medtronic). The primary endpoint of target lesion failure at 1 year was 5.4% for EluNIR, which was found non-inferior to Resolute. Definite/Probable stent thrombosis rate at 1 year was very low: 0.4%, with 0% late stent thrombosis beyond 30 days.

* Kandzari, David E. et al. Randomized comparison of Ridaforolimus- and Zotarolimus-Eluting Coronary Stents in Patients with Coronary Artery Disease. *Circulation* (2017) 136: 1304-1314

Disclosure of Commercial Conflict of Interest: Nothing to disclose

