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EluNIR™ Coronary Stent System: From Design to Practice

The inventor's perspective on the manufacturing process and enhanced features of the EluNIR™ device and the intended effects on performance and outcomes.

WITH YORAM RICHTER, PHD

Can you describe the unique factors offered by the delivery system and stent design of the EluNIR™ ridaforolimus-eluting coronary stent system (Medinol Ltd., distributed by Cordis, a Cardinal Health company) and how these have translated into successful procedural outcomes?

Starting at the tip, the EluNIR™ stent system is unique because the catheter tip has been reinvented. Catheter tips have always been made in the same way by heating up a plastic tube and then pulling and stretching it so that it becomes progressively thinner. We asked ourselves if there is a better way and decided to replace the thin plastic tube with a metal coil. The metal coil provides several important advantages over plastic tubes.

First, the coil provides flexibility. For the plastic tube to bend, it needs to crumple or buckle. The metal coil, however, just needs to open on the outside in order to pivot on the inside, making it more flexible. Another factor is pushability. Once a plastic tip gets caught—whether on a lesion, calcification, or strut of another stent—it begins to deform, distort, and crumple. This is not an issue with the metal tip because the coils compress on each other. The most important property of this metallic tip is that it avoids the "fish mouthing" phenomena (where the tip pulls away from the wire at a bend) because the metal coil is welded shut at the tip and is completely closed. Lastly, because the tip is metallic, it becomes radiopaque so that, for the first time ever, you can see your own tip. This helps in navigation and crossing of complex anatomies, where tips tend to get hung up.

The balloon in the EluNIR™ system has been engineered to provide noncompliance. All stents are mounted on "noncompliant" balloons, but not all noncompliant balloons are created equal. If you look at the growth between the nominal and rated burst pressure, EluNIR™ is very low, which is important for safety. Most stents nowadays are implanted with pressure that is higher than the nominal pressure.

In terms of catheter design, we have utilized a new hypotube technology that makes the shaft of the catheter stiffer, allowing a greater force transfer.

What other attributes specific to the stent itself do you think will make it an attractive option?

The two main features are cell design and strut dimensions. Nowadays, all contemporary drug-eluting stent (DES) designs are based on an open-cell geometry. With EluNIR™, we had to come up with a design that is neither open- nor closed-cell but marries the advantages of both. Our design borrowed from both concepts. On one hand, you have cells of a fixed size without interconnecting members, which is an attribute of closed-cell designs that provide very good scaffolding, support, and angiographic results. At the end of the procedure, you see a very smooth border to the blood vessel on angiography, which comes from uniform support. On the other hand, the concept of alternating narrow and ultra-narrow rings allows excellent longitudinal flexibility and conformability, as you normally see with open-cell designs. We call this concept a dynamic-cell design, and it is meant to combine the benefits from both open- and closed-cell designs.

In terms of strut dimension and overall metal content, the EluNIR™ has very narrow struts that are 70 µm wide and ultra-narrow struts that are 40 µm wide. The unique design and strength of EluNIR™ allows these narrow strut dimensions without the need to add more struts and, thus, metal. This lowest possible metal-to-artery ratio is intended to offer improved healing.

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What aspects of the stent's manufacturing and proprietary processes do you believe will lend themselves to delivering optimal results? Do you find the unique manufacturing process confers an advantage you can appreciate during or after the procedure?

The key difference between how EluNIR™ is made compared with all other contemporary stents is the issue of flat manufacturing technology. The EluNIR™ stent is manufactured and coated while still flat, which offers several key advantages. For instance, a flat surface can be easily inspected both inside and out simply by flipping the flat surface over, whereas the inside of a round tube is difficult to inspect.

However, the key difference comes in during the coating process. Coating a flat surface is much easier than coating a round surface. There are multiple reasons for this, most of which are intuitive, including having one working distance, a stationary surface instead of a moving target, covering one angle versus several angles, having to only coat one side at a time, and that the stent doesn't need to dry while it's being coated. All of these make the coating much easier to perform. The truth is that coating is inherently a nonperfect process, as irregularities happen in every single stent in hundreds of locations in that stent, and by making the process easier these defects should be minimized. This in turn results in a high-quality product that resists cracking, flaking, and peeling.

A round stent has to dry while you are coating it, otherwise it drips and/or distorts from the bottom of the cross-section, which limits the ability to control drug release. With our coating process, we can tailor the drug release from the stent, as well as drug deposition inside the blood vessel. EluNIR™ produces a uniform band of drug concentration inside the vessel wall throughout the drug release.

Can you tell us about the combination of polymer and drug used in this device and how they work together?

The drug itself is a rapamycin analog as is used with all contemporary DES, but EluNIR™ uses ridaforolimus in particular. All rapamycin analogs function very similarly. However, there are some small nuances that cause them to vary in how they perform. The purpose of rapamycin is to act as an inhibitor of cellular proliferation. There are two cell types of interest in terms of DES: smooth muscle cells and endothelial cells. Smooth muscle cells undergo phenotypic transformation and migrate into the intima where they begin to proliferate. Proliferation then ultimately leads to restenosis, so the aim is to inhibit smooth muscle proliferation as much as possible. Endothelial cells are damaged by the initial angioplasty procedure, which basically scrapes off the endothelial layer, which then needs to regenerate. Ridaforolimus has a wide therapeutic window for a rapamycin analog in the context of a DES—the ratio of the dose required to inhibit endothelial cells to the dose required to inhibit smooth muscle cells.

The polymer is a very interesting material called CarboSil® (DSM Biomedical) and belongs to a novel class of polymer called elastomers due to their elastic properties. The reason for this goes back to the manufacturing process. If the surface is not flat, then the device is rotating during coating and it has to dry very quickly. Things that dry very quickly tend to crack because they become brittle. With the flat manufacturing, we have been freed from those constraints and can use the elastomer. The EluNIR™ coating thus remains intact, and this attribute, along with the drug, is designed to provide good healing and vascular compatibility, with low rates of vascular inflammation and trauma.

Based on the aforementioned physical properties included in the device's design, how is the healing process intended to progress once the device has been implanted?

Uniform dosing to the vessel wall allows for good healing. Rapamycin and all of its analogs are intensely hydrophobic compounds. Because of this, a nonuniform concentration of stent struts will lead to a nonuniform concentration of drug. The dynamic-cell design of EluNIR™ maintains nearly identical strut spacing per unit area on the inside and the outside curvature of a blood vessel, and as a result, there are nearly identical doses throughout the vessel wall and thus uniform dosing of the drug, which promotes better healing. This, in combination with the lowest metal-to-artery ratio of any available DES, is designed to enable outstanding healing with the EluNIR™ stent. ■

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