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Serial Multimodality Imaging and 2-Year Clinical Outcomes of the Novel DESolve Novolimus-Eluting Bioresorbable Coronary Scaffold System for the Treatment of Single De Novo Coronary Lesions

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ABSTRACT

OBJECTIVES This study sought to report the late multimodality imaging and clinical outcomes of the novel poly-L-lactic-acid–based DESolve novolimus-eluting bioresorbable coronary scaffold for the treatment of de novo coronary lesions.

BACKGROUND Bioresorbable scaffolds are an alternative to drug-eluting metallic stents and provide temporary vascular scaffolding, which potentially may allow vessel restoration and reduce the risk of future adverse events.

METHODS Overall, 126 patients were enrolled at 13 international sites between November 2011 and June 2012. The primary endpoint was in-scaffold late lumen loss at 6 months. Major adverse cardiac events, the main safety endpoint, were defined as the composite of cardiac death, target vessel myocardial infarction, or clinically indicated target lesion revascularization. All patients underwent angiography at 6 months. Serial intravascular ultrasound and optical coherence tomography were performed in a subset of patients.

RESULTS The scaffold device success rate was 97% (n = 122 of 126), and procedural success was 100% (n = 122 of 122). The major adverse cardiac event rate was 3.3% (n = 4 of 122) at 6 months and 7.4% (n = 9 of 122) at 24 months, including 1 probable stent thrombosis within the first month. At 6-month angiographic follow-up, in-scaffold late lumen loss was 0.20 ± 0.32 mm. Paired intravascular ultrasound analysis demonstrated a significant increase in vessel, lumen and scaffold dimensions between post-procedure and 6-month follow-up, and strut-level optical coherence tomography analysis showed full strut coverage in 99 ± 1.7%.

CONCLUSIONS Our results showed favorable performance of the DESolve scaffold, effective inhibition of neointimal hyperplasia, and for the first time, early luminal and scaffold growth at 6 months with sustained efficacy and safety through 2 years. (Elixir Medical Clinical Evaluation of the DESolve Novolimus Eluting Bioresorbable Coronary Scaffold System—The DESolve Nx Trial; NCT02086045) (J Am Coll Cardiol Intv 2016;9:565–74) © 2016 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

FIM = first in man

ITT = intention to treat

IVUS = intravascular ultrasound

MACE = major adverse cardiac event(s)

OCT = optical coherence tomography

PLLA = poly-L-lactic-acid

QCA = quantitative coronary angiography

RCA = right coronary artery

Despite the marked efficacy of drug-eluting stents in inhibiting neointimal hyperplasia, late events, including late "catch-up" restenosis and stent thrombosis, still occur (1-3). Conceptually, bioresorbable scaffolds were developed as an alternative to metallic stents to provide temporary vascular support, prevent vessel recoil, and avoid late events such as thrombosis and restenosis, which are thought to be associated with implant site inflammation due to prolonged exposure to the metal and/or drug-carrier components or the antiproliferative agent (4,5). To date, several polymeric and metallic bioresorbable scaffolds have been clinically tested; initial results with poly-L-lactic-acid (PLLA) scaffolds appear promising (4-8). Still, the impact of device design, materials, drug, degradation, and resorption kinetics on lumen remodeling and long-term outcomes remains unclear.

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The DESolve novolimus-eluting bioresorbable coronary scaffold (Elixir Medical Corporation, Sunnyvale, California) is a novel PLLA-based bioresorbable scaffold that has demonstrated short bioresorption time (degradation within 1 year and bioresorption within 2 years) and high-expansion capacity without strut fracture (8). In the first-in-man (FIM) evaluation, the DESolve scaffold with myolimus—a sirolimus analog—as the antiproliferative agent, demonstrated feasibility in a small patient sample with single, noncomplex coronary lesions (8). Our objective is to report the procedural, serial multimodality imaging, analysis, and 24-month clinical outcomes of the DESolve scaffold with novolimus—a new sirolimus metabolite compound—in the treatment of diseased coronary vessels.

METHODS

STUDY DESIGN AND POPULATION. The DESolve Nx (Elixir Medical Clinical Evaluation of the DESolve Novolimus Eluting Bioresorbable Coronary Scaffold System—The DESolve Nx Trial) trial was a prospective, multicenter, nonrandomized study evaluating the performance, safety, and efficacy of the DESolve scaffold in the treatment of patients with native coronary lesions. Inclusion and exclusion criteria are listed in the Online Appendix. The study complied with the Declaration of Helsinki, and was approved by the local ethics committee at all participating institutions. All patients provided written informed consent before enrollment, and the trial was registered at NCT02086045.

STUDY DEVICE. The design and specifics of the DESolve scaffold have been detailed elsewhere (8). In brief, the DESolve scaffold is composed of a PLLA-based polymer with 150-μm strut thickness, coated with a matrix of the drug novolimus and a polylactide-based polymer. The drug is contained in a proprietary bioresorbable PLLA-based polymer, which is from the same polymer family as that of the scaffold backbone. The device thickness and width, including the polymer coating, are 150 μm and 165 μm, respectively. Novolimus, a metabolite of sirolimus, belongs to the family of antiproliferative compounds of macrocyclic lactones and has a similar mechanism of action to sirolimus. Novolimus is applied to the scaffold at a dose of approximately 5 μg per mm of scaffold length; 80% of the drug is eluted over 4 weeks. The polymer coating degrades within 6 to 9 months, and the scaffold degrades within 12 months and resorbs within 24 months (8). There are 2 platinum-iridium markers located on both ends of the scaffold to aide in angiographic placement. The DESolve scaffold uses a balloon-expandable delivery system that is 0.014-inch diameter guidewire and 6-F guide catheter compatible. The device should be stored at 0°C to 8°C.

PROCEDURE. By protocol, treatment of up to 2 de novo coronary lesions in separate major epicardial vessels was allowed; only 1 target lesion was considered for treatment with the study device. When applicable, the first lesion, designated as non-target, was treated with an approved "limus" drug-eluting stent. If optimally treated, the target lesion was approached. Pre-dilation was mandatory. The DESolve scaffold was available in the 3.0-, 3.25-, and 3.5-mm diameters, and 14- and 18-mm lengths. After lesion access and cross, the scaffold was slowly deployed with 10-s intervals per atm up to 2 atm and then inflated at 2-s intervals per additional atmosphere of pressure until the desired expansion

Medical. Ms. Morrison, Ms. Toyloy, Dr. Bhat, and Mr. Yan are employees of Elixir Medical. Dr. Verheye has received consulting fees from Elixir Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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