CONCLUSION Even in stable CAD pts, worsening ischemia was highly correlated to the presence of LAP by CTA and evidence of plaque rupture documented by subsequent OCT.

CATEGORIES **IMAGING:** Imaging: Intravascular

NEW POLYMERIC BIORESORBABLE VASCULAR SCAFFOLDS - I

Abstract nos: 388 - 392

TCT-388

Real World Follow- up one year Of The Novel MeRes100.

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BACKGROUND Safety concerns with 1st generation of bioabsorbable vascular scaffolds(BRS) have prompted the development of next generation of these devices, focused on thinner struts and faster resorption time. Recently developed, the MeRes100 (Meril Life Sciences) is a sirolimus-eluting (1.25 mg/mm2) BRS, which is built of a thin-strut (100mm) PLLA polymer with a hybrid cell design (closed cells on the edges and open cells on the center). There are couplets of tri-axial radiopaque markets at either end to facilitate scaffold positioning and post dilation. Bioresorption is expected to occur within 2 years.We sought to evaluate the performance of this device in the treatment of "real-world", less selected patients.

METHODS A propective, single center registry including patients treated between August 2016 and April 2018. Exclusion criteria were: cardiogenic shock, in stent restenosis and target lesions at left main/bypass graft. BRS were available in 2.5 to 3.5m and up to 40mm in length. All procedures were guided by OCT. Primary endpoints included procedure success and one-year MACE rate. Nine-month OCT assessment is part of the secondary endpoints.

RESULTS A total of 65 patients underwent PCI with 81 MeRes100. Most patients were male (86%), with mean age of 66yo and 41% of diabetes. Non ST elevation MI was the initial clinical presentation in 23% of the cases, while LAD was the most frequent target vessel (46%). Device success was achieved in 98% of the cases. In the in-hospital phase, MACE rate was 0%. During the clinical follow-up period, a single case of BRS thrombosis(1.5%) was observed, in a patient who discontinued DAPT in the 1st month after the procedure. At one year, total MACE rate was 4%, with 4% of ischemia-driven TLR.

CONCLUSION Our initial "real-world" experience with the novel MERES 100 showed excellent acute performance with low and acceptable one year MACE and device thrombosis rates. Later clinical follow-up and OCT analysis will shed more light into these preliminary findings.

CATEGORIES **CORONARY:** Stents: Bioresorbable Vascular Scaffolds

TCT-389

Pre-Clinical Evaluation of a Novel Thin Strut (85 μm) Ultra-High Molecular Weight PLLA Sirolimus-Eluting Bioresorbable Scaffold: A Comparative Multi-Modality Imaging-Based Study

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BACKGROUND First generation Bioresorbable Scaffolds (BRS) are more prone to mechanical failure and vascular recoil despite their redundant surface area and wall thickness (~157-microns). The development of DES-like BRS is key for the future of this field. In this study, we tested the biological performance of a highly durable thin strut (85 μm) ultra-high molecular weight PLLA-based sirolimus-eluting BRS (Amaranth Medical, Mountain View, CA) to an equivalent strut thickness sirolimus drug-eluting metal stent (DES) (Ultimaster, Terumo, Tokyo, Japan) in a preclinical swine model.

METHODS A total of 15 coronary segments (5 healthy swine) were implanted with 10 thin-strut sirolimus-eluting BRS and 5 sirolimus DES at 10% overstretch (day 0). At 0 and 28 days mean balloon diameter (MBD), mean scaffold diameter (MSD), and percent diameter stenosis were assessed by angiography. Acute recoil (AR) was calculated as (MBD - MSD) / MBD x 100%). Strut coverage, neointimal thickness, lumen, and device area were examined by OCT. Late recoil (LR) was calculated from OCT as (inner scaffold area at post-procedure - inner scaffold area at follow-up)/inner scaffold area at post-procedure).

RESULTS OCT findings were comparable in both groups showing no statistically significant difference. Likewise, biomechanical features were also statistically equivalent between the BRS and DES groups (Table). Angiographic data such as AR and stenosis at 28 days were comparable in both groups. All devices were embedded and fully covered by neointimal tissue, with no difference in apposition or strut coverage rates.

		BRS (85 microns) n=10	DES (85 microns) n=5	p-value
OCT	Lumen Area (mm2)	4.28 ± 0.92	5.21 ± 1.83	0.20
	Device Area (mm2)	6.19 ± 0.45	6.62 ± 1.47	0.40
	Neointimal Thickness (mm)	0.25 ± 0.12	0.18 ± 0.10	0.28
	Area Stenosis (%)	31.13 ± 12.95	23.34 ± 13.77	0.30
	Late Recoil (%)	7.34 ± 6.82	10.14 ± 1.34	0.39

CONCLUSION This novel thin strut ultra-high molecular weight sirolimus-eluting BRS demonstrated comparable biological and mechanical behavior to a metallic DES after 28 days in normal porcine coronary arteries.

CATEGORIES **OTHER:** Pre-Clinical/First In-Human Studies

TCT-390

Impact of Strut Thickness on Radial Force and Late Vascular Recoil of a Novel Thin-Strut Ultra High Molecular Weight PLLA Sirolimus-Eluting Bioresorbable Coronary Scaffold

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BACKGROUND First generation bioresorbable scaffolds (BRS) achieved stent-like mechanical performance by increasing strut thickness and scaffold's surface area. The future of the BRS field depends on the development of devices with mechanical and biological performance comparable to metallic DES but the development of thin-strut BRS has been challenging. In this study, we compared the mechanical performance of 3 generations of a novel ultra-high molecular weight BRS (150-μm, 115-μm, and 98-μm, Amaranth Medical (AMA), Mountain View, CA) to Absorb (BVS, Abbott, Santa Clara, USA) using serial OCT analysis up to 180 days.

METHODS A total of 182 scaffolds (46 AMA-150; 48 AMA-115; 43 AMA-98; and 45 BVS) were implanted at 10% overstretch in healthy porcine coronary arteries. Percent late recoil (%LR) defined as (inner scaffold area at post-procedure-inner scaffold area at follow-up)/inner scaffold area at post-procedure) was derived from OCT at 28, 90 and 180 days.

RESULTS Late vascular recoil was evident in the BVS group as early as 28 days and remained unchanged over time. None of AMA-BRS groups displayed significant late vascular recoil at 28 days and the scaffold architecture remained stable up to 180 days (Figure). The AMA-98 group displayed a mechanical performance comparable to the AMA-150 BRS and superior to BVS ($p<0.03$)(180d %LR: -2.10±9.4 vs. -2.43±2.6 vs. 5.85±5.67).