

CONCLUSIONS We report satisfactory 6-month outcomes of first-in-man (FIM) implants with the Tendyne Bioprosthetic Mitral Valve System. All were living independently at home at 6-months.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

MODERATED POSTERS: VASCULAR

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TCT-160

A Novel Thin Strut (100 μ m) Sirolimus-Eluting Bioresorbable Scaffold With Hybrid Cell Design: Preclinical Evaluation in Porcine Coronary Arteries

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BACKGROUND The first-in-class and most widely commercially available bioresorbable scaffold (BRS) Absorb has strut thickness of 150 microns, far exceeding those of contemporary drug-eluting stents. As such, it has potential for delivery challenges and higher thrombogenicity. As such, decreasing the BRS strut thickness with no adverse effect on its biomechanics seems desirable. The aim of the study was to assess safety and efficacy of a novel thin strut (100 μ m) sirolimus eluting BRS (MeRes100, Meril Life Sciences, Gujarat, India) in porcine coronary arteries.

METHODS A total of 34 coronary segments of 14 healthy swine were implanted with 24 thin strut sirolimus eluting MeRes100 BRS and 10 Absorb scaffolds at 110% overstretch. To date, angiographic and optical coherence tomography (OCT) imaging were performed after 1 and 3 months (MeRes100 n=19 and Absorb n=8 at each time point). Of the entire cohort, 3 animals were euthanized at each time point and coronary segments were harvested for histological evaluation.

RESULTS The animals in both groups were comparable with regard to weight, clinical status, baseline vessel size and procedural characteristics. All procedures were completed with no complications. At the implantation procedure there was no statistical difference in angiographic, minimal lumen diameter (MLD)-based percent acute recoil between MeRes100 and Absorb (respectively: 13% \pm 7% vs. 10% \pm 5% p=0.18). OCT evaluation demonstrated no differences in metrics of neointimal proliferation in MeRes100 when compared to Absorb at 1- and 3-month follow up. Angiographic results corresponded to OCT and showed similar results without statistical differences in MLD and late loss at both time points. OCT and angiographic results are summarized in the table. Histological analysis at 1-month follow up revealed comparable results in MeRes100 and Absorb in % area stenosis (respectively: 28.7 \pm 12.6% vs. 27.3 \pm 2.5% p=0.86), neointimal area (respectively 1.77 \pm 0.82 vs. 1.95 \pm 0.35 mm²; p=0.22) and in qualitative parameters of vascular healing. Three-month histological results will be available by the time of the meeting.

		1 month			3 months		
		MeRes100	Absorb	p	MeRes100	Absorb	p
QCA	Minimal Lumen Diameter(mm)	1.98 \pm 0.32	2.20 \pm 0.22	0.07	2.02 \pm 0.32	2.24 \pm 0.26	0.11
	Late Loss(mm)	0.61 \pm 0.33	0.59 \pm 0.23	0.85	0.62 \pm 0.30	0.64 \pm 0.18	0.80
OCT	% Area Stenosis	22.4 \pm 8.2	22.6 \pm 7.1	0.96	29.2 \pm 11.6	23.6 \pm 5.3	0.11
	Neointimal Thickness(mm)	0.17 \pm 0.06	0.17 \pm 0.05	0.86	0.22 \pm 0.10	0.18 \pm 0.04	0.86

CONCLUSIONS The novel sirolimus-eluting BRS with thinner struts and hybrid cell design showed similar radial strength and equivalent inhibition of neointimal proliferation when compared to the benchmark Absorb BVS up to 90 days in normal porcine coronary arteries.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Animal model, Bioresorbable scaffold, Optical coherence tomography

TCT-161

Development of a new prediction rule for chronic total occlusion recanalization failure: The Prospective Global Registry for the Study of Chronic Total Occlusion Intervention (PROGRESS CTO) score

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BACKGROUND The J-CTO (Multicenter Chronic Total Occlusion [CTO] Registry in Japan) score was developed to predict the probability of successful guidewire crossing within 30 minutes. However, guidewire crossing alone does not ensure final success of CTO PCI. We therefore sought to develop a novel parsimonious scoring system to estimate the likelihood of technical success.

METHODS We examined 781 CTO percutaneous coronary interventions (PCI) performed using the “hybrid” approach and included in the Prospective Global Registry for the Study of Chronic Total Occlusion Intervention (PROGRESS CTO). To develop the “PROGRESS CTO” score we analyzed clinical and angiographic parameters using a derivation and validation cohort (2:1 sampling ratio). Variables with strong association with technical failure in multivariable analysis were assigned 1 point and a 4-point score was developed from summing all points. The PROGRESS CTO score was subsequently compared with the J-CTO score in the validation cohort.

RESULTS Technical success was achieved in 726 lesions (92.9%). Factors associated with technical success on multivariable analysis included proximal cap ambiguity (beta coefficient b=0.88), moderate/severe tortuosity (b=1.18), left circumflex artery CTO PCI (b=0.99), and absence of “interventional” collaterals (b=0.88). The resulting PROGRESS CTO score demonstrated good calibration and discriminatory capacity in the derivation (Hosmer-Lemeshow χ^2 =2.633, p=0.268 and receiver operator characteristic [ROC] area=0.778) and validation subset (Hosmer-Lemeshow χ^2 =5.333, p=0.070 and ROC area=0.720). In the validation cohort, the PROGRESS CTO and J-CTO performed similarly in predicting final procedural success and guidewire crossing at 30 minutes, respectively (ROC area 0.720 vs. 0.746, area under the curve AUC difference=0.026, 95% confidence interval=-0.093 to 0.144).

CONCLUSIONS The PROGRESS CTO score is a novel useful tool for estimating technical success in CTO PCI performed using the hybrid approach.