Medical, Mountain View, CA) with thinner strut thickness (120 micron) in a porcine coronary artery model.

METHODS Fifty-four coronary arteries of 18 Yucatan mini-swine received either sirolimus-eluting BRS with regular strut thickness (150 μm, n=16), lower strut thickness (120 μm, n=16) or BVS (Absorb, n=16) were harvested for histopathology following imaging with angiography and optical coherence tomography (OCT) at 28 (n=8 for each group) and 90 days (n=8 for each group).

RESULTS At 28 days, 120μm-BRS showed less % diameter stenosis (12±8%) by angiography compared to 150μm-BRS (19±13%) and BVS (27±12%, p<0.05). Histopathology revealed smaller neointimal area (1.68±0.30 mm^2 vs. 150μm-BRS 2.08±0.50 mm^2, and BVS 2.57±0.66mm^2, p=0.007) and % Area Stenosis (AS) in 120μm-BRS group as well; both BRS groups had lower peri-strut inflammation score compared to the BVS group (150μm-BRS: 0±0, 120μm-BRS: 0.17±0.36 vs. BVS: 0.42±0.39, p=0.04). At 90 days, OCT and histological evaluation showed comparable neointimal formation (%AS: 150μm-BRS: 36±6%, 120μm-BRS: 31±10% vs. BVS: 38±14%, p=0.40) and comparable qualitative features of arterial healing between both BRS groups and BVS.

CONCLUSIONS The novel sirolimus-eluting BRS with thinner (120 μm) struts showed adequate acute and chronic biomechanical behavior and durability when compared to regular strut BRS and BVS, and a favorable effect on neointimal inhibition and healing response up to 90 days after implantation.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Histopathologic examination, OCT

TCT-531

Safety of upsizing up to 0.8 mm beyond nominal compliance chart diameters of a novel sirolimus eluting bioresorbable scaffold in porcine coronary artery model

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BACKGROUND Due to the inherent limitations of bioabsorbable polymeric materials, overexpansion may be very limited for some bioresorbable scaffolds (BRS) such as the benchmark Absorb BVS. The unique biomechanical properties of the novel sirolimus eluting BRS (Amaranth Medical, Mountain View, CA) may allow it to be safely upsized. The aim of the study was to evaluate the biomechanical properties and healing of the sirolimus eluting BRS that have been postdilated by 0.55 and 0.8mm beyond the nominal diameters within the pressure-diameter compliance chart range.

METHODS Twenty eight coronary arteries of 8 healthy Yucatan miniswine underwent implantation of novel sirolimus eluting BRS. Upsizing by postdilation was performed up to 0.55 mm (PLUS 0.55, n=6) or up to 0.8 mm (PLUS 0.8 n=6) in a manner maintaining consistent stent-to-artery ratio of average 110%, thus ensuring only overexpansion of the scaffold but consistent level of arterial injury. Non postdilated segments served as control (Control, n= 16). OCT and angiographic follow up were performed at 28 and 90 days follow up.

RESULTS There was no statistical difference between tested groups in terms of acute recoil (PLUS 0.55: 9.5±5.5%, PLUS 0.8: 9.7±7.6%, Control 5±9.5%, p=0.45). QCA analysis after 28 days showed similar late lumen loss (PLUS 0.55: 0.48±0.17, PLUS 0.8: 0.29±0.29, Control: 0.65±0.50 mm, p=0.22), % diameter stenosis was smaller in PLUS 0.8 compared to Control group (PLUS 0.55: 18.6±9.15%, PLUS 0.8: 10±2.02%, Control: 24.6±5.69, p<0.01). 90-day angiographic outcomes were comparable in terms of late lumen loss (PLUS 0.55: 0.58±0.29, PLUS 0.8: 0.38±0.2, Control: 0.43±0.43 mm, p=0.42) and % diameter stenosis (PLUS 0.55: 17±9.3%, PLUS 0.8: 17.1±7.1%, Control: 18.2±12.5, p=0.97). OCT analysis showed comparable neoinitmal area (PLUS 0.55: 2.2±0.89, PLUS 0.8: 1.32±0.57, Control: 2.11±0.87 mm2, p=0.13) and neointimal thickness (PLUS 0.55: 0.25±0.1, PLUS 0.8: 0.14±0.06, Control: 0.25±0.1 mm, p=0.06) at 90 days follow up. No scaffold fractures were observed in any of the studied groups.

CONCLUSIONS Overexpansion up to 0.8mm of novel, high strength sirolimus eluting BRS is not associated with worse angiographic outcomes, neointimal formation or biomechanical issues such as stent deformation or fracture, neither acutely nor chronically.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Animal model, Bioabsorbable scaffolds, Optical coherence tomography

TCT-532

Implantation Of Bioresorbable Vascular Scaffolds After Acute Coronary Syndrome Is Associated With Reduced Early Neointimal Growth And Strut Coverage

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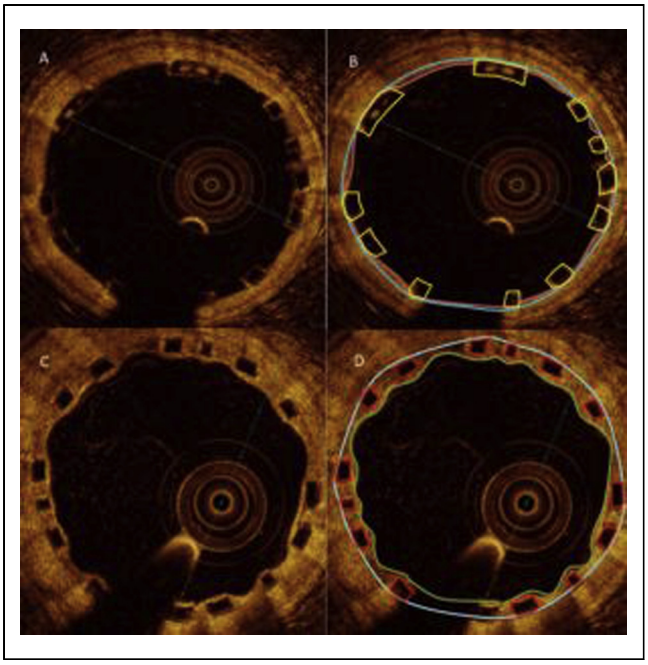
BACKGROUND Previous studies have suggested that neointimal growth and strut coverage is reduced in patients with acute coronary syndrome (ACS) that receive metallic stents. The BVS is a novel technology and use of more biocompatible devices may facilitate early neointimal growth and subsequent earlier strut coverage. We aimed to assess whether neointimal growth is affected by clinical presentation, in a population of patients undergoing bioresorbable vascular scaffold (BVS) implantation.

METHODS BVS were implanted in patients either for stable angina (SA) or ACS using optical coherence tomography (OCT) guidance. Repeat OCT was performed at follow-up (median 74 days), and BVS analyzed at 1mm longitudinal intervals. OCT analysis (Figure) included measures of scaffold, luminal and flow area, as well as assessment of strut apposition, coverage and neointimal growth.

RESULTS In total, 29 BVS were included in the analysis (62% following ACS). There were no differences between procedural or lesion characteristics between groups. Post-deployment, all BVS achieved >90% predicted scaffold area with only 1.64% struts classified as incompletely apposed at baseline, compared with 0.47% at follow-up (p=0.006). Reductions in mean scaffold (-4.0%, p=0.01) and flow (-8.4%, p<0.001) areas were observed at follow-up, with larger reductions in mean flow area for stable patients (SA -14.5±14.2 vs. ACS -4.9±7.9%, p=0.03). ACS patients had reduced neointimal growth (0.51±0.18 vs. 0.87±0.37mm2, p=0.002), and increased percentage of uncovered struts (2.68±1.67% vs. 1.43±0.87%, p=0.015).

CONCLUSIONS Neointimal growth and strut coverage is reduced following ACS in patients receiving BVS at an earlier timepoint than previously studied. This is consistent with studies in metallic stents and suggest use of more biocompatible devices may not necessarily improve early strut coverage.



CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds