Conclusions: The MFM integrated into the vessel wall while maintaining branch patency over the course of the study. The 56 thread devices were well tolerated locally and yielded fewer signs of inflammation and neointimal hyperplasia. Further preclinical and clinical studies will extend assessment of the long-term safety and effectiveness of the MFM.

TCT-440

Further Evolution In Aortic Arch Endografting

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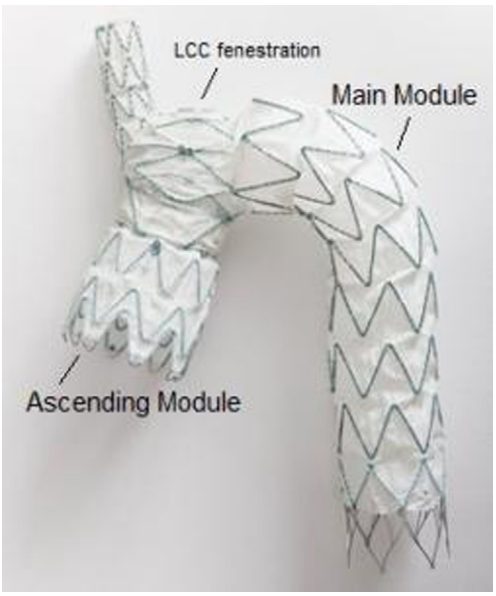
Background: Conventional surgical or hybrid repair of aortic arch aneurysms carries substantial risk of mortality and morbidity. Early experience with custom made branched arch endografts showed promising results, although availability and production time limit their widespread use. Consequently, many patients remain untreated.This preclinical study is the first report of an off-the-shelf modular aortic arch endograft, with a novel Z shape design addresses the unique procedural and long term challenges with complete endovascular therapy for aortic arch pathologies.



Methods: Sixteen pigs (7 acute, 9 chronic) underwent endovascular implantation of the Nexus™ arch endograft over a brachio-iliac through & through wire technique, with modular extensions to ascending aorta and LCC. Aggregate follow-up period was 481 days.
Results: Successful implantation of the modular graft was achieved in 100% of animals. Mean procedural time was 90±30 Min. Mean pressure gradient between ascending aorta and cranial vessels was 0±2 mmHg. All chronic animals recovered well. Long term follow up demonstrated no graft migration or side branch occlusion/stenosis.
Conclusions: The novel designed arch endograft (see Figure) has the potential to provide the next evolutionary step towards an off-the-shelf, pure endovascular solution as a first-line intervention for major aortic arch lesions. The integrated brachial intra-procedural latching and Brachiocephalic artery placement of a proximal (cranial) end of the main prosthesis provides the cornerstone for increased intra-procedural and long term endograft fixation. Initial clinical work due Q3 2014.

TCT-441

Assessing Iatrogenic Atrial Septal Defect Formation with Novel Transseptal Puncture Device

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Background: As ablation and transseptal procedures become more common due to the aging population, transseptal puncture complications become a larger concern. Iatrogenic atrial septal defects (IASDs) are typically considered to close within a year with 7% remaining at 12 months following a puncture with a 12 Fr catheter. Today, IASDs are also attracting attention because cryoablation and MitraClip® procedures that use larger sheaths are common. The purpose of this experimental paradigm was to characterize the biomechanical properties of the fossa ovalis in an animal model commonly used for testing these procedures.
Methods: The atrial septa from Yorkshire Cross swine (n=86) were excised for experimentation. The inferior edge of the fossa ovalis was cut off for catheter tear testing. Samples were randomized to 3 groups, and the transseptal punctures were performed with a: 1) standard Brockenbrough needle, 2) Baylis RF needle, or 3) custom RF 5 Fr needle, which was unique design in this study. More specifically, catheter tear testing allows for the investigation of the resultant effects varying catheter sizes and different transseptal approaches have on inducing trauma.
Results: We observed that the type of needle used for the transseptal puncture had no statistically significant effects on tear forces ($p>0.05$). This suggests that on an acute time scale, the procedure a clinician utilized to cross the septum could be one of personal preference, since no technology demonstrated an increase in tear force and thus a reduction in IASD formation. Yet, there were significant differences in tearing the septum between different size sheaths ($p<0.05$). Noteworthy, the forces required to initiate tearing in this study were within the range of the forces able to be generated by clinically used catheter and sheaths.
Conclusions: Tissue properties and their role in the formation of IASDs have not been previously well studied. This suggests a need to improve our basic understanding in how septa tearing arise and a means to minimize damage created during procedures. This is the one of the first studies performed to investigate a novel transseptal approach in an effort to minimize IASD formation.

TCT-442

Comparison of contemporary DES of different stent geometry and Absorb in a Swine Carotid – Jugular Thrombogenicity Shunt Model

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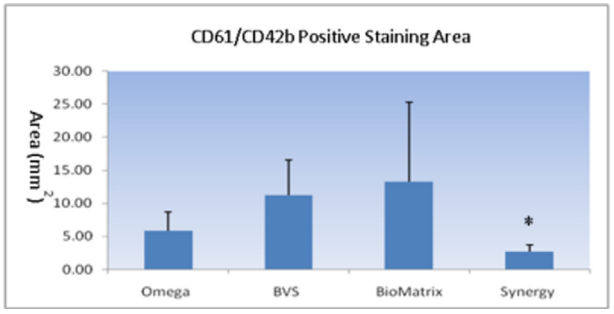
Background: Polymer coatings of drug eluting stents (DES) have been shown to offer a protective barrier against acute thrombus formation compared with bare metal stents (BMS). While this anti-thrombotic function has been assigned to contemporary DES utilizing permanent polymeric coatings, the impact of bioerodible polymeric coatings, strut thickness and fully bioresorbable scaffolds remains to be determined.
Methods: A porcine ex vivo carotid to jugular arterio-venous shunt model involving a test circuit of three in-line stents, was used to test thrombogenicity. The Synergy™ stent (Boston Scientific) (n=6) was compared to 3 different stent types: 1) BioMatrix Flex™ (Biosensors) 2) BVS® (Abbott), and 3) OmegaTM (Boston Scientific) (n=6 each). After 1h of circulation, platelet adherence in whole mount stents was identified by immunofluorescent staining against dual platelet markers (CD61/CD42b) and quantified using confocal microscopy.
Results: Synergy DES showed the least area occupied by thrombus compared to the other 3 stents types, with a significant difference compared to BioMatrix Flex

and BVS ($p< 0.05$)(Figure). The number of platelet aggregation clots was the least in Synergy DES with a borderline significant difference compared to other stents.



Conclusions: The current ex vivo swine shunt model demonstrated decreased acute thrombogenicity in bioerodible polymer thin-strut Synergy as compared to bioerodible thick-strut Biomatrix Flex and fully bioresorbable Absorb, which confirms the acute protective function of bioerodible stent coatings and emphasizes the relevance of stent geometry in acute thrombogenicity.

TCT-443

Multiplug Paravalvular Leak Closure Using Amplatzer Vascular Plug III – Prospective Registry (Wizzard I)

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Background: Transcatheter paravalvular leak closure (TPVLC) has become a viable alternative to reoperation but optimal technical strategy is still to be defined. We present a prospective TPVLC registry in which safety and efficacy of multi-plug, single-stage approach were assessed.
Methods: All subjects presented with hemodynamically significant PVL and symptomatic heart failure (HF). Decision on performing TPVLC was made by the Heart Team and procedures were executed in hybrid operating room. Ante- or retrograde access was employed for mitral while retrograde only for aortic PVLs. 2 to 4 AVP 3 devices (size and number based on PVL channel cross-sectional area by real-time three-dimensional transesophageal echocardiography) were simultaneously implanted into a single PVL channel. Endpoints were defined according to VARC-2 and modified if demanded by TPVLC specificity.
Results: Enrollment started in 2010 and reported data is complete as of December 2013. From 64 referred patients 49, with either mechanical valves (n=30) or stented bioprostheses, were found eligible for TPVLC. PVL location was mitral (n=29) or aortic. In the aortic group acute procedural success (APS) ratio was 100% and no MACCEs occurred. In the mitral group, TPVLC was successful on first attempt in 22 cases (4/4 in transapical and 18/25 in transseptal access). Following transseptal failure another transapical procedure was performed in 5 patients. TPVLC ultimately proved efficient in 89.7% of mitral PVLs with APS of 76.5%. Cumulatively, TPVLC was accomplished in 46 subjects (93.9%) with APS of 78%. When successful, it led to significant decrease of NT-proBNP concentration and HF symptoms regression. Safety endpoints were met in 4 patients and included non-disabling stroke (transient aphasia), plug embolization (successfully snared) and 2 access site-related complications. In device failure group 2 deaths occurred (end-stage HF) and 2 other patients were rehospitalized (decompensated HF).
Conclusions: Multi-plug, single-stage TPVLC with use of AVP III devices is effective and safe strategy in patients with hemodynamically significant PVL. It appears exceptionally well suited for aortic PVLs.

TCT-444

Efficacy of Anterograde Interventional Gene Delivery with Different AAV Serotypes in a Pre-Clinical Large Animal Model

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Background: Transduction efficacy, delivery approaches and vector serotypes are representing major challenges for future cardiac gene therapy. The aim of this current study was to test not only the anterograde coronary approach for gene delivery but three different AAV serotypes (6, 7 and 9) in a pre-clinical large animal model.
Methods: The approach was tested in 19 chronically instrumented dogs which received the AAV vectors anterograde intracoronarily. The left main coronary artery was cannulated with a Cobra1 catheter (5F) and a micro-infusion catheter (2.5F) was selectively advanced into LAD and RCX. The solution for infusion was prepared with normal saline, 1x10^13 AAV-(6, 7 or 9)-eGFP particles, SubstanceP (0.25-0.5ng/kg/min) and Adenosine (0.15mg/kg/min) and was injected slowly over 20min. Nitroglycerine was given i.v. (1µg/kg/min) to further enhance endothelial penetration of the virus. The coronary sinus was approached with a custom made balloon in eleven subjects. Hemodynamic data were recorded and infection efficacy was assessed using immunohistochemistry for eGFP after 30days.
Results: Procedure time was significantly longer in the cases with coronary sinus occlusion (60±10 vs. 90±45min, $p< 0.05$). Mean arterial pressure and dP/dtmax dropped in all cases due to the vasodilators (118±15 to 53±21mmHg and 2289±466 to 1421±414mmHg/sec). These effects were enhanced with coronary sinus blockage that infusion had to be discontinued several times due to hypotension. The eGFP-transduction rate with AAV9 was heterogeneous within the myocardial layers (0.3-56%), with a higher transduction in the subendocardial layer (22-45%).There was no significant increase of eGFP-expression caused by the additional coronary sinus blockage ($p=0.07$). Comparing the different serotypes AAV7 and AAV9 have been more effective infecting LV tissue than AAV6 (16±7%, 21±9% vs. 4±2%, $p< 0.05$).
Conclusions: Anterograde cardiac gene delivery is feasible and comparatively effective. The addition of coronary sinus blockage did not increase efficiency significantly. Individual characteristics need to be taken into account selecting the optimal AAV serotype for translatable results.

TCT-445

A Novel 4.5-Fr CoKatte Catheter Facilitating Stent Delivery in Complex Lesion in the Coronary Artery

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Background: The deployment of the stent sometimes associates with difficulty because of the unfavorable lesion characteristics including severe calcification or tortious configuration of the vessel, and insufficient backup support of the guiding catheter. To address this issue, the small-sized straight inner catheter have been developed to access the lesion, where the stent to be implanted. Recently, a novel 4.5-Fr child catheter with hyper lubricity in outer surface to ease advancement of the catheter was developed to improve the success rate in stent delivery.
Methods: We retrospectively evaluated 51 consecutive patients, who underwent primary percutaneous coronary intervention with CoKatte catheter (Asahi Intecc Co.,Ltd, Seto, Japan) after failure in delivering the stents with conventional procedure with 6-Fr guiding catheter between January 2011 and December 2013. CoKatte catheter is a straight catheter with 1.5mm in outer diameter, 120 cm in length, and compatible for 6-Fr guide catheter.
Results: The mean age of the patients was 75.3 years old and 29 male patients were included. Target vessels were comprised of 13 LADs, 7 LCXs, 27 RCAs, and 4 SVGs. Trans-radial approach was performed in 41 patients. Six lesions were chronic total occlusion. Seven lesions required the lesion preparation with Rotablator (Boston Scientific Corp.) before stent delivery. For advancement and subsequent deep intubation of the catheter, anchor balloon technique was needed in 42 patients, otherwise, the catheter could be advanced under support of the guide wire or the shaft of the balloon catheter. In all cases, stent delivery in the intended lesion was achieved. The complication related to deep insertion of the catheter including proximal dissection, air embolism, and severe ischemia were not observed.
Conclusions: This novel 4.5-Fr catheter is considered to contribute for facilitating stent delivery in the complex lesion in the coronary arteries.