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Further Evolution In Aortic Arch Endografting

Sagi Raz, Marcel Goodman, Daniel Silverberg, David Planer

1Endospan, Hertzelia, Israel, 2University of Western Australia, Perth, Australia, 3The Chaim Sheba Medical Center, Tel Hashomer, Israel, 4Hebrew University-Hadassah Medical Center, Jerusalem, Israel

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 0.1±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 prostheses provides the cornerstone for increased intra-procedural and long term endograft fixation. Initial clinical work due Q3 2014.

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Assessing Iatrogenic Atrial Septal Defect Formation with Novel Transseptal Puncture Device

Stephen G. Qualllich1, Mark A. Bentscoter2, Lars M. Mattisson2, Megan M. Schmidt1, Salah J. El Haddad1, Paul A. Itzko2

1University of Minnesota, Minneapolis, MN

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 ovallis 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 is the one of the first studies performed to investigate a novel transseptal approach in an effort to minimize IASD formation.

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

OSCAR D. SANCHEZ2, Qi Cheng1, Kazuyuki Yahagi1, Fumiyuki Otsuka1, Kenitchi Sakakura1, Julia Feygin2, Frank D. Kolodgie1, Renu Virmani1, Michael Joner2

1CVPath Institute Inc., Gaithersburg, MD, United States, 2Boston Scientific, Maple Grove, MN, 3CVPath Institute Inc., Gaithersburg, MD, United States

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® (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 stent types, with a significant difference compared to BioMatrix Flex