“Non-fluoroscopic imaging and navigation will replace our current modalities for endovascular intervention”

Due to its two-dimensional (2D) nature and the high radiation exposure associated with its use, fluoroscopy is an imperfect solution to endovascular surgery’s need for intraoperative imaging. At the 2016 VEITH symposium (15-19 November, New York, USA), Matthew Eagleton, Cleveland Clinic, Cleveland, USA, presented his centre’s initial experiences with the Intraoperative Positioning System (IOPS; Centerline Biomedical), suggesting that it may represent an opportunity to transition away from fluoroscopy.

Eagleton told VEITH symposium delegates that the IOPS system provides interactive enhanced 3D vascular images, as well as “electromagnetic tracking of endovascular tools within the vascular tree, correlating directly with “in vivo localisation”. With the ability to manipulate the images shown, the system also allows operators multiple and ideal views. These imaging and navigation capabilities, Eagleton said, are “superior to standard 2D fluoroscopy”.

The system is based on a mathematical model for vascular image construction from DICOM CT imaging data, and the model was then tested by assessing the relative geometry of the aortic branches. Though the testing was aortic, Eagleton noted that the system “is not limited to the aorta”. Eagleton also explained that the algorithm used is automatic and patient-specific, with an image of the aorta generated using a Dicom-Dicom overlay. This overlay can then be used to create an overlay fusion of the mathematical model.

Once the model was created, Eagleton and colleagues needed to be able to see where on the model they were moving without using fluoroscopy, so began to work on device localisation methods. A navigation system was developed using sensors on sheaths, wire and catheters, in combination with patient sensors, used to overcome patient and table movement. Display systems were developed to allow Eagleton and colleagues to view images in parallel to angiography imaging based on fluoroscopy. Benchtop testing with several aortic models was performed before transitioning to the operating room. Eagleton noted, “The biggest challenge in this transition was overcoming the electromagnetic interference from the C-arm, but we were able to do it.”

A pre-clinical study in a porcine model was conducted, running the IOPS in parallel with standard fluoroscopy. The initial goal was to assess the system’s ability to cannulate visceral vessels, which would be verified with angiography. Showing examples of the imaging, Eagleton reported, “One of the benefits of this was that we were able to re-orient the 3D image to provide optimal views. We were also able to magnify the images without any additional use of radiation.”

Since the pre-clinical test, the system has been transitioned to clinical application and used during the placement of branched endografts for two patients.

Following the initial encouraging experience, Eagleton suggested that there could be refinement of sensorised endovascular tools, including catheters, wires and sheaths. The sensitivity and specificity testing could also be improved, he continued, compared to the gold standard of live fluoroscopy, while the enhancement of vessel deformation predicting should also be explored.

“Non-fluoroscopic imaging and navigation will replace all of our current modalities for endovascular intervention,” Eagleton concluded. “We must strive for improved procedural imaging, improved procedural navigation and limited radiation exposure.”

Automated planning software could lead to wider FEVAR adoption

While the long-term durability of fenestrated endovascular repair (FEVAR) has been established, the need for accurate procedural planning may act as a barrier to widespread adoption. At the 2016 VEITH symposium (15-19 November, New York, USA), Benjamin Starnes, University of Washington, Seattle, USA, suggested that this barrier may be overcome thanks to AortaFit automated planning software.

FEVAR is an established and durable endovascular option for short neck/juxtarenal abdominal aortic aneurysms,” Starnes told delegates, and has shown “low rates of long-term aneurysm-related mortality, sac expansion and rupture, branch vessel occlusion, type Ia endoleak and open conversion.” Despite these advantages, the time, expense and complexity of case planning present a significant challenge, especially in angulated anatomy. Moreover, even when FEVAR is available and a centre is able to complete the required planning, it is still subject to human error.

Aortica’s three-platform technology may offer a solution to these issues, Starnes said. The first stage uses AortaFit software, in which a patient’s computed tomography (CT) scan is analysed to determine fenestration coordinates. In the second stage, the endograft is manufactured via a “precise fenestration alignment” process with patient-specific reinforced and circumferentially radiopaque fenestrations placed on the graft. Third comes the expansion of a unique, purpose-built branch stent (Boulevard stent) that is designed to engage with the fenestration. This can be achieved in one step with fewer catheter and wire exchanges than other fenestrated procedures, Starnes explained. There is no secondary flaring of the proximal end of the branch stent, minimal stent is left in the flow channel, and no secondary bridging stents would be required. “Simplified fenestrated endograft deployment” is thus achieved.

AortaFit software is currently being evaluated in an ongoing US Food and Drug Administration physician-sponsored IDE study at the University of Washington. Starnes presented results from an ongoing trial of the AortaFit in patients with juxtarenal aortic aneurysms deemed unsuitable for open repair. For the first 10 patients treated, technical success was achieved in nine (90%). Graft modification time was “very respectable” at 54.4±5.7 minutes and mean fluoroscopy time was 37±18 minutes. At thirty days, there had been major adverse events in two patients (one non-ST-elevation myocardial infarction and one minor ischaemic stroke). Mortality was 0%, mean length of intensive care unit stay was 1.5±0.9 days and mean total hospital stay length was 2.3±1.4 days. There was no type I or type III endoleak, and branch artery patency was 100%. There were no major adverse device events. A total of 20 patients have been treated to date.

“Until we can seamlessly conduct, running the IOPS in parallel with the C-arm, but we were able to do it.”

The system has been transitioned to clinical application and used during the placement of branched endografts for two patients.

Starnes concluded. “Automated planning software provides an efficient and accurate way to identify fenestration locations for graft design.”

He continued, “Well-planned FEVAR leads to high quality patient outcomes, and simplified FEVAR may benefit the majority of patients harbouring juxtarenal abdominal aortic aneurysms.”

Benjamin Starnes presenting his findings.

Matthew Eagleton at the VEITH symposium.