

An update on PEARS

Sunday played host to a dedicated session on personalised external aortic root support (PEARS), beginning with an introduction by John Pepper, Professor of cardiothoracic surgery at the National Heart and Lung Institute, Imperial College, London, UK, who gave an overview of research conducted by his group.

The basic concept of PEARS is to create a bespoke personalised polymer sleeve tailored to each patient's individual aortic root morphology. This sleeve is created by using computer-aided design and rapid prototyping. The closeness of the fit allows incorporation of mesh support, stabilisation of the aortic dimensions and maintenance of aortic valve competence. The first man who underwent the procedure, Tal Goleworthy, was also the co-inventor of the technique.

Professor Pepper said that while PEARS research had started off slowly back in 2004, there are now several centres, on several continents, performing the procedure in small numbers. He added that in terms of intention to treat, there were 123 patients operated with intention to implant PEARS, but in fact one had a Florida sleeve, one required a VSSR, and one had a TRR. He added that this was done at a time when the pericardium was open, the aorta was inspected, and the operator felt the tissue was too thin and too fragile to go ahead with the PEARS.

"It was a perfectly reasonable thought, so it wasn't that they were half way through with a PEARS operation and then converted," said Professor Pepper. "There has been a late death – unrelated – at five years. The patient had cardiomyopathy in addition to Marfan which he inherited from his mother, and we think he developed ventricular arrhythmia."

Professor Pepper also noted that they had re-operated on one patient after five years, who developed ventricular arrhythmias early post-operatively. They opened the sleeve completely and the patient recovered, and in fact remained very well for four years after the operation.



"Then between year four and year five there was dilation of the non-coronary sinus so my colleague went back and reoperated," said Professor Pepper. "This was a kind of negative proof of the operation as the non-coronary sinus, which was not protected, did enlarge."

"These patients were followed for 412 patient-years; 11 followed for more than 10 years, 32 for more than five years and we have 120 patients still alive. This is the current status of where we are."

Professor Pepper showed an image of the heart of one patient with Marfan syndrome who sadly died. He said: "It was difficult to fit a finger between the back of the sternum and the front of the vertebrae. So, access is difficult in these patients, although oddly it sometimes makes it easier."

"... this is a new twist on an old idea of placing something around the aorta. But the two main differences are firstly, it's personalised, and secondly the material is completely different from the standard Dacron that we use."

John Pepper

"We initially started using MR scans to analyse the dimensions of the patient and with Warren Thornton's help a computer engineer, we managed to create the former, but it became clear that the resolution of CT scans are better, so we now do CT scans and we follow up the patient with MR to avoid radiation." He said although modern CT scans have less radiation if a patient is having them repetitively, he thought an MR was better.

Professor Pepper showed a slide of the sagittal view of the aorta which showed red tramlines representing the thickness of the former. He explained that sort of image is then reviewed by the individual operating surgeon before work starts to construct the former, which generally takes three to four weeks.

"... this is true precision medicine."

John Pepper

very different. So, this is true precision medicine surgery, personalised surgery and you will hear more about this from my colleague, but essentially we need to carefully dissect down beneath both coronaries to the annulus and we do this mainly without coronary bypass but occasionally we may use it."

Professor Pepper then discussed an example of an individual proof of concept study of a woman who was diagnosed with Marfan syndrome in pregnancy. During the last trimester of her pregnancy her aorta diameter increased in size (as seen on Echo) but she was safely delivered by vaginal delivery. "Then we asked to see her and operated on her to put on a sleeve and she had the second successful pregnancy and you can see that complete control of aortic diameter was achieved," he said.

Professor Pepper acknowledged there were concerns about the PEARS procedure, because it was relatively, moving on to discuss frequently asked questions about it. He said: "But of course there are many concerns this is

"There are now several centres, on several continents, performing the procedure in small numbers."

John Pepper

a new twist on an old idea of placing something around the aorta. But the two main differences are firstly, it's personalised and secondly the material is completely different from the standard Dacron that we use: it's a polyester but it's different because it is a macroporous mesh."

He argued that it was frequently asked whether the arterial wall would become thinner, but explained that follow up annual MR scans had not found this. He added that incorporation makes migration unlikely and hadn't seen it yet in 10 years of follow-up. "People say 'well it could dissect within the sleeve and anything could happen', but we haven't seen it yet and maybe we won't, but I don't think you can ever say that in medicine. But maybe if you follow 100 patients for 10 years and don't see it we can be a little more confident that it won't happen."

He said dilatation beyond the support could happen, but had not been seen on follow-up imaging and there was less likelihood of it happening than with an interposition graft.

The audience heard that PEARS surgery has been applied to the following disease types: 82 ascending aortic dilations associated with Marfan syndrome (five patients with adjunctive mitral valve repair); six patients with BAV; two with transposition late after ASO; five with

Loeys-Dietz syndrome; one with Fallot's tetralogy; two with Turner syndrome; nine with non-syndromic degeneration; and five unspecified.

He summarised by saying that PEARS has maintained the same device manufacture, positioning and incorporation, and that they had used an identical protocol from 2004 to 2017. In total there had been 120 consecutive intention-to-treat cases, 412 patient-years of follow-up. There was one valve or aortic event, one death and three conversions.

