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The consequences of incomplete covering of the critical part of the aortic root in Personalised External Aortic Root Support (PEARS)

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We here inform the Journal and its readers of one case in which an operation was not done as reported in the paper on Personalised External Aortic Root Support (PEARS) in 2016.(1) The Directions for Use for the ExoVasc® implant require that the aorta is dissected, proximal to the coronary arteries, and the mesh sleeve is anchored at the aortoventricular junction.(2) In a patient operated on in 2015 this was not done. The surgeon cut off and discarded the portion of the mesh, custom manufactured to fit the aortic sinuses, and tethered the cut end of the remaining implant to the adventitia above the coronary arteries. This is shown in the video.

The operation note was falsified. The patient and the PEARS data reporter were told that the operation had been carried out as planned. The falsification of the record and the lack of candour with the patient were confirmed in an investigation by the "General Medical Council" which licenses medical practitioners in the UK.

The other doctors involved in the patient's care were "blind" to what was, effectively a sham operation. The aortic diameter at the level of leaflet closure increased from 49 mm to 62 mm over 18 months with worsening aortic regurgitation. With an experience of 380 PEARS operations, we have never seen any failure of a properly positioned ExoVasc® device to stabilise the dimensions of the aortic root. After thorough discussion with the patient, reoperation was put in the hands of the surgeon with the largest and widest experience of surgery with PEARS. The patient was prepared for the possibility of root replacement with whatever approach, valve replacement or conservation, judged appropriate.

The surgeon found that there had been no previous dissection proximal to the coronary arteries and in that area there was virgin tissue. The dissection was no more challenging than for a first operation and was accomplished without cardiopulmonary bypass. A further personalised mesh had been manufactured and was fitted. Size reduction was achieved down to 46 mm on the post-operative measurement. The patient made a good recovery and remains well but with mild residual aortic valve regurgitation. The situation is being monitored.

In the paper published in 2016 there had been one re-operation six years after the mesh was partly released over the non-coronary sinus in the post-operative period. While the rest of the aorta was stable, this portion enlarged progressively. In the absence of a controlled trial,(3) we referred to the occurrence as a "natural experiment" confirming the efficacy of the mesh, where it was correctly applied and incorporated, compared with the continued dilatation of the part of the aorta with no mesh covering.(1) The case reported here, in which the protocol was not followed, is an inadvertent "double blind" trial of a sham operation after which the aortic root continued to expand.

References

1. Treasure T, Petrou M, Rosendahl U, Austin C, Rega F, Pirk J, et al. Personalized external aortic root support: a review of the current status. Eur J Cardiothorac Surg. 2016;50(3):400-4.
2. Pepper J, Golesworthy T, Izgi C, Takkenberg J, Treasure T. Personalised external aortic root support (PEARS) to stabilise an aortic root aneurysm. British Journal of Cardiology. 2020;27:1-13.
3. Nienaber CA, Yuan X, Ernst S. PEARS procedure and the difficulty to provide evidence for its benefits. Eur Heart J. 2020;41:4086-8.