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EDITORIAL COMMENT

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When does an 'emerging technology' emerge into the therapeutic arena? Should we be offering personalized external aortic root support?

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REVIEW

Treasure *et al.* [1] report the current status of an innovative procedure to provide external support to an enlarged aortic root using a customized flexible mesh: 'personalized external aortic root support' (PEARS). Over 60 patients have undergone the procedure in 5 centres and the maximum follow-up is 10 years (median 7) with a total of 260 patient-years. Most of the patients have Marfan's syndrome and none have had a dissection. In a patient who died of an unrelated cause, the pathologist reported normalization of the histology of the aortic wall with healing of the collagen structure.

In most cases, cardiopulmonary bypass is not required and if it is, the operation is done on the beating heart without having to open the aorta. Assuming the follow-up experience is maintained, it clearly has advantages over the existing procedures of root replacement using a composite graft (with a mechanical valve in these younger patients) or a valve-sparing root with the future uncertainty of needing further surgery. Patients will be attracted by the less invasive, more conservative approach.

The authors describe it as an 'emerging technology' and add that it 'might appropriately be considered as a niche innovation still under evaluation in an observational phase'. They address the anticipated negative responses from surgeons in a Frequently Asked Questions section. They conclude: 'Our current policy is to cautiously extend the use of PEARS with surgeons who wish to adopt this technique'. This begs the question: when/at what stage in the evolution should we offer a new technique/emerging technology to our patients?

It is a fundamental principle of medical ethics that a patient has absolute authority over what is done to their body. We refer to consent for surgery. I do not know how it is treated in other languages, but in English we have adulterated the word 'consent', changing it from a noun to a verb—something we do to patients rather than something they give us. Even worse, we decide what information they should be given in the 'consent' discussion. In English law, the legal test has been the 'Bolam' standard—you were not negligent if a 'responsible body' of other doctors would have given the same information.

However, a recent case in our Supreme Court [2] is set to bring a new paradigm to the consent process. I recognize that each country has its own legal system and approach to clinical negligence, but the courts often refer to cases in other jurisdictions and so I feel it is relevant to practice across Europe. Medical ethics transcend boundaries.

The Irish writer W.B. Yeats began his famous poem 'Easter 1916' with 'all changed, changed utterly'. This neatly summarizes the effect of the Montgomery case. UK law now demands a new approach. The details of the case are not important—it is what the Judges say in their judgement which directs practice. They made it very clear that it should be a process of 'supported decision making' by the patient. The surgeon has a responsibility to give the appropriate information and it has to be tailored to that particular patient. Importantly, one of the Judges specifically said [3]: '... it is not possible to consider a particular medical procedure in isolation from its alternatives.' So, in the UK, we must now (we probably should have done so in the past) tell our patient about other options—even if we do not do the operation, it is not done in our unit or we do not think it is the, in our view, best option. It is for the patient to decide. Has PEARS reached the threshold?

Imagine for a moment that you have Marfan's syndrome and your ascending aorta is beginning to enlarge. Your cardiologist has mentioned surgery in the future and so you have asked to meet your surgeon for an initial discussion. You are in the clinic. You will be told that you should wait until your aorta is really big and then you will have a major operation—and you can either take warfarin for the rest of your life or you might need further major surgery. Would you want to be told about 'PEARS'? I know I would.

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;50:400–4.
[2] Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) [2015] UKSC 11.
[3] Ibid. Lady Hale at paragraph 109.