NICE National Institute for Health and Care Excellence

NICE guidance

Personalised external aortic root support (PEARS) using mesh to prevent aortic root expansion and aortic dissection in people with Marfan syndrome

HealthTech guidance
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www.nice.org.uk/guidance/htg623

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG394 and IPG724.

1 Recommendations

1.1 Evidence is adequate on the short-term safety and efficacy of personalised external aortic root support (PEARS) using mesh to prevent aortic root expansion and aortic dissection in people with Marfan syndrome. Evidence on long-term outcomes is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE guidance page.

1.2 Clinicians wanting to do PEARS using mesh to prevent aortic root expansion and aortic dissection in people with Marfan syndrome should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team.

1.5 The procedure should only be done in specialist centres with experience of managing this condition, by surgeons trained and experienced in aortic root surgery.

1.6 Further research should report details of patient selection, including aortic diameter, and long-term outcomes, including evidence of disease progression, such as dilation and dissection of the aortic root.

2 The condition, current treatments and procedure

The condition

2.1 Marfan syndrome is a genetic disorder of the connective tissues. One effect of it is that the wall of the aorta can weaken and progressively widen. The wall can tear (dissection) and possibly rupture, which is often fatal. The strongest predictors of dissection are the aortic root size and the rate of change in size over time.

Current treatments

2.2 Conventional treatment involves pre-emptive surgery to replace the ascending aorta with an artificial fabric graft. Some clinicians recommend this when the aortic diameter is 45 mm or more. The aortic valve is also usually replaced but may be conserved. People can experience considerable anxiety waiting for their aorta to reach the size threshold recommended for surgery.

2.3 If the person has a mechanical valve implanted, they need lifelong anticoagulation. If a bioprosthetic valve is used, it is likely to eventually fail, and the person will need another operation. Valve-sparing root replacement surgery, in which the aorta is replaced with a tube graft and the native aortic valve is conserved, is also suitable for some people with normal valve function. This is technically more challenging, and people may need further surgery to replace the aortic valve at a later date.

The procedure

2.4 The aim of personalised external aortic root support (PEARS) using mesh in people with Marfan syndrome is to reinforce the aortic root and ascending aorta

to prevent enlargement and subsequent dissection or rupture. The native aortic valve is left intact so there is no need for lifelong anticoagulation after the procedure. This is a particular advantage for young women considering future conception. Cardiopulmonary bypass is usually not needed, and the operative time is shorter than for traditional aortic root replacement.

2.5 The first step of the procedure is to do imaging studies of the ascending aorta and aortic root. Computer-aided design is used to create a 3-dimensional model of the aorta, which is then used to make a bespoke external polymer mesh support. The mesh is soft, flexible and porous. Openings for the coronary arteries are fashioned into the mesh support.

2.6 Under general anaesthesia, a median sternotomy is done, and the aorta is dissected away from adjacent structures and proximal to the coronary arteries. The mesh support is passed behind the aorta, sutured up the front and secured to the aortoventricular junction. It fully encircles the aortic root and extends from the region of the valve annulus to the origin of the brachiocephalic artery.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 3 cohort studies, 2 non-randomised comparative studies, 2 case series and 1 case report. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: aortic-related pathology (including dissection and dilation), need for aortic valve replacement, and anxiety about progressive aortic disease.

3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, infection and atrial fibrillation.

3.4 Thirteen commentaries from people who have had this procedure were discussed by the committee. Everyone who responded said that they would recommend the procedure to someone else with their condition. Several noted the benefit of not having to take anticoagulants for the rest of their lives.

Committee comments

3.5 The committee was informed that surgeons receive proctoring for their first few procedures.

3.6 The committee encourages the establishment of a registry for this procedure.

3.7 The procedure is used for other aortopathies as well as Marfan syndrome.

3.8 The committee was informed that, in common with valve-sparing aortic root replacement, patients may need further surgery on the aortic valve at a later date.

3.9 The committee was informed that the procedure can be used alongside other procedures.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 724 has been migrated to HealthTech guidance 623. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.