

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

Aortic arch remodelling-graft insertion during surgical repair of an acute aortic dissection IP1847

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	Cliff Grover
2. Name of organisation	Aortic Dissection Awareness UK & Ireland
3. Job title or position	NICE Focal Point
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	We are the national Patient Association for those affected by aortic dissection. We have 700+ members, mostly survivors of aortic dissection, plus family members affected and professional members. We are voluntarily-funded by donation.
<p>5. How did you gather the information about the experiences of patients and carers to help your submission?</p> <p>The device is very new and probably only in use in highly specialist centres. We have asked in our support forum (500+ members) and are unaware of any of our members with the device.</p> <p>Comments below are therefore given in the context of procedures where this device might give theoretical advantages or disadvantages.</p>	
Living with the condition	
<p>6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?</p> <p>Living with the aftermath of an aortic dissection is usually life-changing, with a larger or smaller but continuous reduction in capability, both physical and often mental. This affects both the patient and their family/carers.</p> <p>Some of this is unavoidable once the dissection has occurred, some is due to the procedures necessary and some to the medications required afterwards. These issues can arise due to the surgery necessary to save the person's life, and because the surgery may be sub-optimal due to pressure of time, facilities, or deferred diagnosis.</p> <p>Any advance in surgical techniques and procedural options which can benefit patients' outcomes is welcome.</p> <p>See 7.</p>	

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are?

Type A aortic dissections are statistically most often (90%) in the ascending aorta but some dissections progress into the arch and some start within the arch itself. With any dissection involving the arch, treatment is difficult due to the need to protect the brain's blood supply and for this reason arch replacement is usually only considered practicable in major aortic centres. In these cases, two general approaches have developed: 1. "First save the patient's life" i.e. repair the ascending aorta, avert the immediate threat to the patient's life, and defer arch repair to a later, elective, operation at a major centre, or 2. in centres with the capability, carry out a combined ascending and arch repair such as an ascending and arch graft with or without Frozen Elephant's Trunk (FET). These procedures require top-level expertise to protect the brain in particular and is acknowledged to be one of the most challenging surgical procedures done. If there is an "optimal surgical approach for type A dissection" this remains controversial [typical discussion in ref. 1]. In some cases, an ascending repair can be extended to include a hemi-arch repair. As this does not intervene in the head arterial vessels, it does not require the specialist techniques and can also usually be done in any centre where ascending aortic repairs are done. However, hemi-arch repairs have some potential longevity issues if any of the diseased aorta remains partially untreated.

The advantages of this new device may be that it could provide a further option between the two main options outlined, or an alternative to the hemi-arch approach. The graft evidently allows blood to flow through it to the head and arm vessels off the arch, thus avoiding the cerebral perfusion techniques needed and the risks present with a more conventional arch repair. A non-specialist centre might be able to perform an ascending aortic repair plus deploy the device to stabilise and thrombose any dissection which has progressed to the arch.

In some cases, this could produce a total repair within one operation and avoid the need for a later operation. It may be possible to treat a greater number of patients and/or to a greater degree in centres which have traditionally done only ascending and hemi-arch aortic repairs. There could be a reduction in the number of second operations required, reducing trauma for the patient, and freeing resources in key tertiary centres.

Major aortic centres would also have another option open to them.

If a long device were to be used, stretching into the descending aorta, the fact of the open weave should help prevent spinal neurological complications such as can happen with long FETs.

Whilst the above discussion is based around emergency dissections, it is possible the device can be used similarly for elective operations

Disadvantages of the procedure or operation

8. What do patients (or carers) think the disadvantages of the procedure or operation are?

The disadvantages may be that depending on case selection and nature and extent of the dissection (or elective procedure), the device might not achieve the aim of enabling a more complete repair, thus requiring re-operation anyway. Complications such as arch branch dissections or PAU (Penetrating atherosclerotic ulcer), might be found and require a different approach.

Once the stent is in position it may limit the options available for later re-operation.

The initial benefit and potential increase in safety through avoiding a conventional arch repair may be reduced or offset by any need to carry out a later and possibly more extensive repair. If it were ever necessary to remove the device, access to the whole device (particularly if a “long” device were used) and endothelialisation may make removal difficult.

The risk of inducing clotting / embolism / stroke such as by displacement of plaques needs to be assessed and experience gained.

Patient Population

9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.

Yes. The suitable cohort will be those patients who have a dissection involving the ascending aorta and aortic arch, who need an ascending aortic repair plus stabilisation of the arch. A “long” device may prove to be an alternative to an FET.

It seems unsuitable if the dissection tear (or a PAU) is in the arch itself, also if the dissection extends to within any of the arch vessels.

It might be the case that the device could be used prophylactically in a marginal case involving the ascending aorta, where stability of the arch is unclear.

The device may also expand the options available for elective surgery, similarly avoiding the need to detach head vessels.

Equality

10. Are there any potential [equality issues](#) that should be taken into account when considering this topic?

Where there is an aortic dissection associated with pregnancy, options for treating the mother may be particularly restricted by location, the pregnancy itself, available facilities and skills. In a suitable cohort, this device might provide an extra option for non-specialist centres in particular.

Other issues

11. Are there any other issues that you would like the Committee to consider?

There is already an unwarranted variation in accurate and timely diagnosis of aortic dissection in emergency departments and subsequent treatment [refs. 2, 3]. This includes inconsistencies in transfer of critical patients to a centre able to carry out the necessary surgery.

If this device is to realise its full potential, it will be necessary to ensure that EDs diagnose and confirm aortic dissection quickly. A CT scan of sufficient detail is needed (e.g. CT whole aorta, ECG-gated where possible) to allow the clinical team decide the treatment necessary. Centres will then have to make a decision on whether the new device is an option for the patient in their centre, what alternatives might exist, or whether transfer to a major centres is necessary.

Additionally, what a surgeon discovers on opening the patient may present challenges unseen on CT images. It could be envisaged that a decision to use one of these devices may ultimately prove to be one that cannot be followed through, thus creating a difficult situation. Therefore, there needs to be a high level of confidence in making a decision to use one of these devices.

These issues will become clearer as experience is gained of using the device, as has happened for every other advancement in aortic surgery.

Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. Opportunity to carry out a more complete repair in non-major aortic centres, providing a third option between save-the-patients-life vs. conventional arch repair
2. If successful, avoids a re-operation for the patient (reduced trauma, resources)
3. Need to understand any limitations on future surgery or future TEVAR use associated with the device's presence.
4. Case selection is crucial which needs rapid diagnosis and high quality surgical planning vs. transfer to another centre
5. Standards for diagnosis and care of AD need to be improved generally in order to realise any potential in this device.

References

1. Dib, B., Seppelt, P.C., Arif, R. et al. Extensive aortic surgery in acute aortic dissection type A on outcome – insights from 25 years single center experience. *J Cardiothorac Surg* 14, 187 (2019). <https://doi.org/10.1186/s13019-019-1007-7>
2. Bottle A, Mariscalco G, Shaw MA, Benedetto U, Saratzis A, Mariani S, Bashir M, Aylin P, Jenkins D, Oo AY, Murphy GJ; UK Aortic Forum. Unwarranted Variation in the Quality of Care for Patients With Diseases of the Thoracic Aorta. *J Am Heart Assoc.* 2017 Mar 14;6(3):e004913. doi: 10.1161/JAHA.116.004913. PMID: 28292748; PMCID: PMC5524021.
3. Bashir M, Harky A, Howard C, Bartram T. Type A Aortic Dissection in the United Kingdom: The Untold Facts. *Semin Thorac Cardiovasc Surg.* 2019 Winter;31(4):664-667. doi: 10.1053/j.semtcvs.2019.06.011. Epub 2019 Jul 5. PMID: 31283988.

Thank you for your time.

Please return your completed submission to jp@nice.org.uk