# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

# Medical technology guidance

# SCOPE

# E-vita open plus for treating complex aneurysms and dissections of the thoracic aorta

## 1 Technology

### *1.1 Description of the technology*

The E-vita open plus (JOTEC GmbH) is an endoluminal stent graft system designed for treating aneurysms and dissections of the thoracic aorta. The device is a one piece polyester fabric tube which combines a conventional vascular graft attached to an endovascular stent graft that allows treatment of the ascending aorta at the same time as the arch and descending aorta, in one procedure. The E-vita open, which has also been marketed in the UK, is the immediate predecessor device, and is superseded by the E-vita open plus. The two are similar in design but the E-vita open plus is blood-tight and does not require the addition of fibrin glue to seal the stent graft.

The E-vita open plus is used in a single stage procedure known as a 'frozen elephant trunk'. The thoracic aorta is surgically opened with access through a median sternotomy approach. The stent graft is deployed distally in the descending aorta and the proximal vascular graft is surgically anastomosed to the ascending aorta. The distal stent graft is a self-expanding device that incorporates nitinol springs into the fabric and is used to treat the descending aorta. The deployment of the distal stent graft is achieved through the retraction of a retaining sheath. The proximal vascular graft is then used to repair the ascending aorta and arch in a standard surgical fashion. The aortic branch vessels are re-attached to the graft using a patch. Radiopaque

markers are integrated into the fabric of the graft to permit radiological imaging.

The E-vita open plus is a single use device with a shelf life of 2 years. It is supplied sterile and is pre-loaded in its delivery system. The device is available in a range of sizes with varying diameters and lengths. The device is deployed within a delivery system which consists of catheters and a positioning aid. A luer connector is also incorporated to permit flushing of the inner guide catheter.

## *1.2 Regulatory status*

E-vita open plus received a CE mark in October 2008 for the repair or replacement of the thoracic aorta in cases of complex aneurysms or dissections which involve the ascending aorta, the aortic arch and the descending aorta.

## *1.3 Claimed benefits*

The benefits to patients claimed by the sponsor are:

- The E-vita open plus permits the ascending aorta, arch and descending aorta to be repaired in a single stage procedure which can lead to:
  - reduced pain and discomfort
  - elimination of the psychological distress associated with the anticipation of a second procedure
  - a reduction in total end organ ischaemia
  - a reduction in incisional complications and infections
  - a reduction in anaesthetic use and the elimination of the need for additional epidural pain management
  - a reduction in both total length of stay and Intensive Care Unit length of stay
  - a reduction in rehabilitation time
  - an earlier return to normal activities and work.

The benefits to the healthcare system claimed by the sponsor are:

- a reduction in treatment times and costs due to the elimination of a second procedure
- a reduction in total length of stay
- a reduction in Intensive Care Unit stay
- reduced rehabilitation time
- fewer wound complications.

## *1.4 Relevant diseases and conditions*

E-vita open plus is intended for use in the treatment of complex aneurysms and dissections of the thoracic aorta which involve the ascending aorta, aortic arch and descending aorta. Based on expert advice, it is estimated that approximately 50-100 people per year in England would be suitable for treatment with the E-vita open plus.

Thoracic aortic aneurysms result from weakening of the aortic wall leading to localized dilatation. They are usually degenerative and often incidentally detected. If left untreated, the aneurysm may continue to enlarge and result in rupture and death. The incidence of thoracic aortic aneurysm is estimated to be approximately 5-10 per 100,000 people.

Aortic dissection results from a tear in the inner layer of the aorta leading to blood entering and separating the layers of the wall. Acute aortic dissections are those that present within the first two weeks of the initial tear, while chronic dissections are those that persist for more than two weeks following the tear. The incidence of aortic dissection is estimated to be approximately 3-4 per 100,000 people with 96% of aortic dissections involving the thoracic aorta. Aortic dissection is classified by its location and the extent of involvement of the thoracic aorta. Stanford Type A dissections affect the ascending thoracic aorta. They may be more extensive and also include the arch and descending thoracic aorta. Stanford Type B dissections do not affect the ascending aorta and typically involve the descending thoracic aorta. Approximately two thirds of aortic dissections are Stanford Type A. Patients

with acute dissections typically present with pain and are classed as an emergency due to the risk of the dissection rupturing the wall of the aorta. If left untreated acute Type A dissection has a 75% mortality rate in the first 2 weeks. Patients with chronic dissections can present with pain but can also be asymptomatic.

## *1.5 Current management*

The management of thoracic aortic aneurysms and dissections is determined by the location, severity and rate of change of the disease, as well as the clinical sequelae. Patients with thoracic aneurysms are often observed carefully with clinical and imaging surveillance. Invasive treatment may be offered depending upon the size and rate of enlargement of the aneurysm. In patients with Type A aortic dissection, emergency surgery is usually offered, while patients with Type B dissections are often managed with conservative medical treatment although elective surgical repair is sometimes undertaken.

There are three main methods of surgically treating complex disease of the thoracic aorta. Two of these methods involve a two stage 'elephant trunk' procedure; both approaches are similar in their first stage but use alternative repair techniques to complete the second stage. During the first stage, the ascending aorta and arch are repaired with a vascular graft through a median sternotomy. This is often combined with aortic root or other cardiac interventions. During this procedure a free-floating extension of the arch prosthesis (the elephant trunk) is left dangling in the proximal descending aorta. In one approach, the second stage of the procedure may be undertaken as an endovascular procedure during which a stent graft is inserted into the proximal descending aorta with arterial access via the femoral artery (endovascular aortic vascular repair – EVAR). In an alternative approach, a second surgical procedure may be scheduled some weeks or months later during which the descending aorta is repaired by extending the 'elephant trunk' through a lateral thoracotomy approach. The third method involves 'debranching' of the head and neck vessels from the aortic arch with the creation of a surgical anastomosis between the ascending aorta and the head and neck vessels using a vascular graft. This then allows the transluminal

insertion of an endoluminal stent graft into the aortic arch and descending aorta either as a hybrid or second stage procedure.

## 2 Reasons for developing guidance on E-vita open plus for the treatment of complex aneurysms and dissections of the thoracic aorta

The Committee concluded that the E-vita open plus may benefit patients with aneurysms and dissections involving the ascending aorta, arch and descending aorta.

The Committee was presented with trial data that supported the use of the E-vita open plus in appropriate patients.

The Committee was advised that the patient population who would be considered for a one-stage procedure, with the E-vita open plus, is relatively small. However, the Committee considered that the difference in mortality between a one-staged surgical procedure (approximately 10%) and a two-staged surgical procedure (approximately 20%), could result in significant patient and system benefits. It also noted that there is an additional mortality rate of approximately 4% associated with the recovery period between the first and second stages.

The Committee noted that the E-vita open plus has superseded the E-vita open, but considered that the majority of the available data for the E-vita open would be relevant to an evaluation. The Committee was advised that the incidence of junctional endoleak may be reduced in patients treated with the newer technology.

The Committee was advised that approximately 20-30% of patients decline to undergo the planned second stage procedure because of negative experiences associated with the initial procedure.

The Committee noted that the costs of stents currently used in the thoracic aorta are comparable to the E-vita open plus and concluded that a cost analysis of the E-vita open plus compared with current surgical treatment options would be helpful.

The Committee noted that a proportion of patients suitable for treatment with the E-vita open plus have Marfan's syndrome which affects approximately 1 in 5000 of the population.

# 3 Statement of the decision problem

| | **Draft scope issued by NICE** |
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| Population | Patients with aneurysms or dissections of the thoracic aorta involving the ascending aorta, arch and descending aorta (Stanford Type A). |
| Intervention | E-vita open plus. |
| Comparator(s) | The comparators for this evaluation are the current management options which are either:<br>• Two stage open surgical repair with vascular graft placement, or<br>• Two stage repair with open surgical graft placement in the ascending aorta and arch, and endovascular stent graft placement in the descending aorta, or<br>• Open surgical 'debranching' of the head and neck vessels with endoluminal stent graft placement in the aortic arch and descending aorta<br>(see also 'Cost analysis' below) |
| Outcomes | The outcome measures to consider include:<br>• Technical procedure(s) completion and success<br>• Mortality<br>• Major complications, for example stroke, paraplegia, renal failure, myocardial infarction and others that may delay discharge<br>• Length of Intensive Care Unit stay<br>• Total length of stay<br>• Freedom from further interventions<br>• Long-term survival rates<br>• Incidence of junctional endoleak<br>• Device-related adverse events |
| Cost analysis | Comparator(s): Two stage surgical 'elephant trunk' with either open surgical second stage or endovascular second stage, and surgical debranching of the head and neck vessels with endoluminal stent graft placement in the aortic arch and descending aorta.<br>Costs will be considered from an NHS and personal social services perspective.<br>The time horizon for the cost analysis will be sufficiently long to |

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| | reflect any differences in costs and consequences between the technologies being compared.<br>Consideration should be given to:<br>• The implications of the use of multiple stents<br>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed. |
| Subgroups to be considered | Patients with:<br>• Acute Type A dissection<br>• Chronic Type A dissection<br>• Degenerative aneurysm |
| Special considerations, including issues related to equality | People with connective tissue disorders, in particular people with Marfan's syndrome and Ehlers-Danlos syndrome, are at an increased risk of developing an aortic aneurysm or dissection and may present at a younger age. |

# 4 Related NICE guidance

**Published**

- Endovascular stent-graft placement in thoracic aortic aneurysms and dissections. NICE interventional procedure guidance 127 (2005). Available from www.nice.org.uk/guidance/IPG127

**Under development**

NICE is developing the following guidance (details available from www.nice.org.uk):

There is no related guidance for this technology.

# 5 External organisations

## *5.1 Professional organisations*

### 5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Society for Cardiothoracic Surgery in Great Britain and Ireland
- British Society of Interventional Radiology

- British Society for Endovascular Therapy
- British Cardiovascular Intervention Society
- The Vascular Society

### 5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Society for Cardiothoracic Surgery in Great Britain and Ireland.
- British Society of Interventional Radiology
- British Society for Endovascular Therapy
- British Cardiovascular Intervention Society
- The Vascular Society

## *5.2 Patient organisations*

At the selection stage, NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Arrhythmia Alliance
- Action Heart
- British Cardiac Patients Association
- British Heart Foundation
- Cardiac Risk in the Young
- Cardiomyopathy Association
- Coronary Artery Disease Association (CORDA)
- Heartcare Partnership UK
- Marfan Association UK
- National Heart Forum (UK)
- Royal College of Surgeons Patient Liaison Group
- SADS UK
- The Somerville Foundation