

**National Institute for Health and Care Excellence**  
**Medical Technologies Evaluation Programme**

**EP 106 – E-vita open plus for treating complex aneurysms and dissections of the thoracic aorta**

**Consultation comments**

**MTAC date: 18 October 2013**

There were 3 consultation comments from 2 consultees (1 sponsor and 1 other [Department of Health]). The comments are reproduced in full.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	2, JOTEC GmbH	<b>2.4, The technology</b>	Please amend detail or describe in more detail: Once the stent graft is in place, the delivery system is removed. The invaginated aortic arch portion is retracted 5-10 mm proximally and the anastomosis is created between the E-vita open graft prosthesis and the aortic wall. Afterwards, the complete proximal vascular graft component is drawn out.	Thank you for your comment. The Committee decided to change section 2.4 to provide further clarification that the invaginated vascular graft portion of the E-vita open plus is drawn out a short distance before the device is attached to the aorta.
2	2, JOTEC GmbH	<b>3.4</b>	Table 1: Amended by recently published data (Jakob et Tsagakis 2013: Ann. Cardiothoracic Surg 2,296-299, International E-vita open registry.) Included patients (n=416), Emergency surgery Previous proximal repair Presenting condition needing treatment Acute aortic dissection 138 (33,2%) 81% - Chronic aortic dissection 142 (34,1%) - 67% Thoracic aortic aneurysm 136 (32,7%) - - Table 2: Adverse events for the E-vita open plus as reported in Jakob et Tsagakis (2013) Acute dissection – 138 patients In-hospital mortality (beyond 30 days mortality)16%: Freedom from sec. aortic surgery or endovascular intervention after 5 years 96% and 90%, respectively Stroke 7% Paraplegia or paraparesis 4% Survival rate after 5 years 79% Chronic dissection 142 patients In-hospital mortality (beyond 30 days	Thank you for your comment. The External Assessment Centre reviewed the study, which was published after the sponsor and the External Assessment Centre had completed their literature searches. The External Assessment Centre produced a supplementary report, which was presented to the Committee and is included as an appendix to this table. The Committee decided to change

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			mortalita)14%: Freedom from sec. aortic surgery Å or endovascular intervention after 5 years 94% and 72%, respectively Stroke 5% Spinal cord injury 9% Survival rate after 5 years 86% Complex thoracic aortic aneurysmal disease - 136 patients 13%, 82% and 86%, respectively, 7%, 7%, 78%	section 3.6 to include reference to the study findings. A new Committee consideration (section 3.14) was added to describe the Committee's view on the evidence presented in this study.
3	1, DH	<b>General</b>	Thank you for the opportunity to comment on the scope and equality impact assessment for the above medical technology.  I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."*

## Appendix 1

### **Comparison of E-vita Open Plus Evidence from the International E-vita Open Registry published in papers in 2011 and 2013**

**Short report prepared by KITEC EAC 26 September 2013**

In its assessment report on E-vita Open Plus, the EAC used Jakob et al (2011) as the main source of clinical evidence for the key outcomes, and to populate the economic model. During the draft guidance consultation, new evidence on E-vita Open Plus was identified (Jakob and Tsagakis [2013]). The EAC reviewed the results of the newer paper to determine whether there were any substantive differences from the evidence provided in the earlier paper.

The Jakob et al (2011) paper reported results from the E-vita Open registry for the period January 2005 to December 2010 for 274 patients, and Jakob and Tsagakis (2013) has reported results for a longer period: January 2005 to October 2012, including 416 patients (see table 1). Although the number of patients was higher in the more recent Jakob and Tsagakis (2013) paper, the EAC found that this paper reported results mainly on the same three subgroups: acute aortic dissection (AAD), chronic aortic dissection (CAD), and aneurysm (TAA). The outcomes included in this additional paper which are of relevance for the EAC assessment, include in-hospital mortality, stroke and paraplegia. Key outcomes such as 30 day mortality, bleeding and renal failure that were reported in the 2011 paper, were not reported in the Jakob and Tsagakis (2013) paper. In that respect, the EAC considers that Jakob et al (2011) is more comprehensive, although the EAC notes that neither paper provides confidence intervals for estimates.

The Jakob and Tsagakis (2013) paper does not include the number of patients for each outcome (only percentages were listed) but does report results for the subgroups. While these subgroups were included in the original scope for the assessment issued by NICE, there was insufficient evidence for the comparators in subgroups and so these subgroups could not be incorporated into the modelling. Hence the subgroup data provided in the 2013 paper cannot be used by the EAC. Of relevance were the outcomes for all patients combined, therefore, the EAC combined the subgroup estimates to arrive at an overall estimate for the three reported outcomes (see table 2).

The comparison of the outcome data in the two papers revealed no important differences in the overall estimates for in-hospital mortality, stroke and paraplegia and therefore the EAC sees no necessity to change the assumptions in the cost model. Moreover, outcomes such as in-hospital mortality and the probability of paraplegia have already been subjected to sensitivity analysis and these did not change the cost saving conclusions of E-vita open plus, in either the short- or the long-term.

In summary, the EAC has reviewed the newly published paper and consider that it provides no new information relevant to the cost model. Hence the EAC considers that the original modelling, based on the 2011 outcomes, remains valid and appropriate.

**Table 1: Summary characteristics (corresponding table in EAC report is table 3a)**

References	Study size and period.	Overall age and gender.
Jakob et al (2011)	274 patients. Jan 2005 to Dec 2010.	Mean (SD) age 60(12). 74% males.
Jakob & Tsagakis (2013)	416 patients. Jan 2005 to Oct 2012.	AAD: Median age 61. CAD: Median age 60. TAA: Median age 69. No gender data.

Acute Aortic Dissection (AAD), Chronic Aortic Dissection (CAD), Aneurysm (TAA)

**Table 2: Comparison of outcome data (corresponding table in EAC report is table 3b)**

N (%)	Jakob et al (2011)				Jakob and Tsagakis (2013)*			
	AAD (N=88)	CAD (N=102)	TAA (N=84)	Total (N=274)	AAD (N=138)	CAD (N=142)	TAA (N=136)	Total (N=416)
<b>In-hospital Mortality</b>	16(18%)	13(13%)	12(14%)	41(15%)	22(16%)	20(14%)	18(13%)	60(14%)
<b>30 Day Mortality</b>	11(13%)	10(9.8%)	12(14%)	33(12%)	Not reported	Not reported	Not reported	Not reported
<b>Bleeding</b>	16(18%)	13(13%)	9(11%)	38(14%)	Not reported	Not reported	Not reported	Not reported
<b>Stroke</b>	5(5.7%)	3(2.9%)	8(9.5%)	16(5.8%)	10(7.2%)	7(4.9%)	10(7.4%)	27(6.5%)
<b>Paraplegia</b>	5(5.7%)	8(7.8%)	9(11%)	22(8.0%)	6(4.3%)	13(9.2%)	10(7.4%)	29(7.0%)
<b>Renal Failure</b>	1(1.1%)	4(3.9%)	5(6.0%)	10(3.6%)	Not reported	Not reported	Not reported	Not reported
<b>5 Year Survival Rate</b>	Not reported	Not reported	Not reported	74%	79%	86%	78%	Not reported

Acute Aortic Dissection (AAD), Chronic Aortic Dissection (CAD), Aneurysm (TAA)

\* Number of patients for outcomes were estimated from the reported percentages.

## References:

Jakob H, et al. (2011). The International E-vita open Registry: Data sets of 274 patients. J Cardiovasc Surg 52(5): 717-723.

Jakob H, Tsagakis K. (2013). International E-vita open registry. Ann Cardiothorac Surg 2(3): 296-299.