

E-vita abdominal stent graft is suitable for challenging anatomies

The E-vita abdominal stent graft appears to be safe and effective in an initial midterm clinical experience with 30 abdominal aortic aneurysm patients, a study showed. Burkhart Zipfel, from the Department of Cardiothoracic and Vascular Surgery, Deutsches Herzzentrum Berlin, Germany, presented an update on the experience with the new graft at the VEITHSymposium, in New York, November 2009.

"This device appears especially suitable to challenging aneurysm anatomy, such as severely angulated necks or tortuous and dilated iliac arteries," Zipfel told delegates.

Zipfel said that the advantages of the E-vita abdominal graft (JOTEC GmbH) are that it has a unique delivery catheter, is easy to deploy with precision, its use is feasible for all variations of standard EVAR, it is excellent for hostile neck anatomies, and the E-vita abdominal is a good device for educational EVAR.

The E-vita abdominal graft has been on the market since the beginning of 2008. The device has a modular design with a bifurcated mainbody, contralateral leg, aortic extension cuff and iliac extension. "One of the special features is that you can choose between two main body lengths,

70mm and 50mm, to adapt to the anatomy," Zipfel said.

The first experience with the device was published by Zipfel et al in the *Journal of Endovascular Therapy* 2009;16:577-589. From January to August 2008, 38 patients presented with abdominal aortic aneurysms; six were treated with Zenith iliac side branch devices, seven with open repair, and six with other endovascular devices owing to logistical problems at the start of the study. The remaining 19 consecutive EVAR eligible patients (all men, mean age 70 years, range 58-87) were included in the study.

Results

The results showed that all stent-grafts were implanted at the intended position; no conversions to open surgery were necessary and no type I endoleak was noted. Fifteen bifurcated and four straight stent-grafts were implanted; the majority of the vascular accesses (29/35, 83%) were percutaneous. There was no 30-day mortality. In the mean 10-month follow-up (range 4-17), no stent fractures, migrations, or secondary endoleaks were noted. Aneurysm diameter was reduced in 8 (42%) and remained unchanged in 11 (58%) patients. One patient required open surgery at one

year for thrombotic occlusion of the stent-graft. Two octogenarian patients died during follow-up.

At the VEITHSymposium, Zipfel told delegates that 30 patients have been treated to date. The mean aneurysm diameter was 57mm (40-75mm). One third of the patients had hostile aortic neck. Implantation success was 97%. There was one conversion to open procedure because of a surgeon's failure to cannulate the contralateral limb. "Thirty-day mortality was zero. It is remarkable that at the end of the procedure there was quite a lot of type II endoleaks, which had occluded in 50% of the cases already in the CT-scans before discharge.

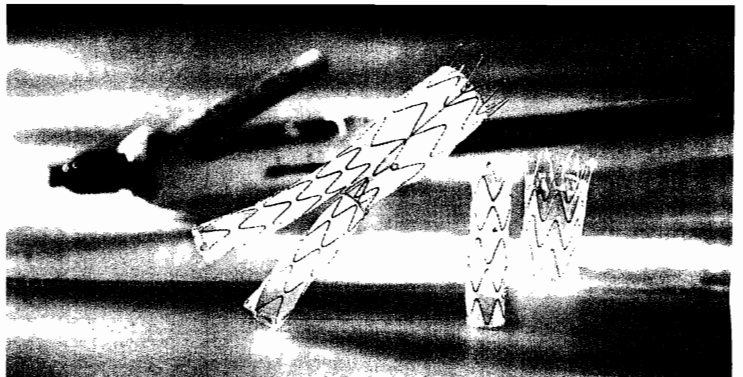
Mean follow-up was nine months (one to 17 months). There was reduction in the aneurysm size in eight (27%) patients, and the remaining 22 (73%) were unchanged. There was one device occlusion.

One of the limitations of the graft, Zipfel said, is that it is not recommended for necks shorter than 15mm, as for all non-fenestrated devices.

"There is also the risk of leg kinking in calcified iliac arteries, similar to in all interrupted z-stent designs," Zipfel said, adding that the new version of the device is more flexible.



Burkhart Zipfel



JOTEC's E-vita

INSTEAD fails to show survival benefit after TEVAR for type B dissection patients

Elective thoracic endovascular aortic repair failed to improve two-year survival and adverse event rates despite favourable aortic remodeling in the first randomised study on elective stent graft placement in survivors of uncomplicated type B aortic dissection. Further investigation will be needed to understand the appropriate role of stents in the treatment of type B dissections, the authors of the INSTEAD (Investigation of stent grafts in aortic dissection) trial said.

Results of INSTEAD, a study comparing thoracic endovascular repair with a stent graft with optimum medical management, were published in

Circulation in December 2009. Christoph A Nienaber, University of Rostock, Germany, is the principal investigator. In their conclusion, the authors wrote that the trial was underpowered to evaluate its primary mortality endpoint.

Thoracic endovascular aortic repair represents a novel concept for type B aortic dissection. Although life-saving in acute emergencies, outcomes and survival of endovascular repair in stable dissection are unknown.

One hundred forty patients in stable clinical condition at least two weeks after index dissection were randomly subjected to elective stent-graft placement in addition to optimal medical therapy (n=72) or to optimal medical therapy alone (n=68) with surveillance (arterial pressure according to World Health Organization guidelines <120/80 mm Hg).

The primary endpoint was all-cause death at two years, whereas aorta-related death, progression (with need for conversion or additional endovascular or open surgery), and aortic remodeling were secondary endpoints.

There was no difference in all-cause deaths, with a two-year cumulative survival rate of 95.6±2.5% with optimal medical

therapy versus 88.9±3.7% with thoracic endovascular aortic repair (p=0.15); the trial, however, turned out to be underpowered.

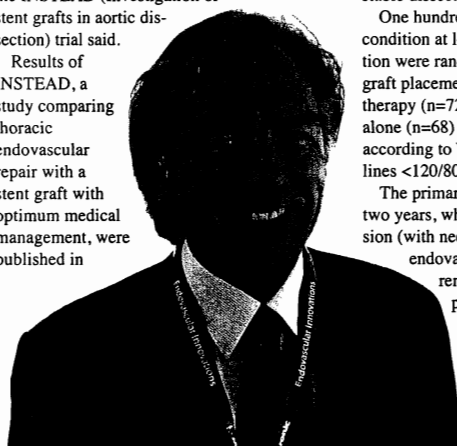
With only 11 fatalities (four medical therapy alone; seven thoracic endovascular repair), the study did not have the statistical power to detect a difference in overall mortality. Twenty-eight deaths would have been necessary to achieve the required statistical power. In the protocol, the researchers projected a 20% mortality rate with medical therapy, expecting that to be reduced to 3% to 5% with endovascular repair.

The aorta-related death rate was not different (p=0.44), and the risk for the combined endpoint of aorta-related death (rupture) and progression (including conversion or additional endovascular or open surgery) was similar (p=0.65). Three neurological adverse events occurred in the endovascular repair group (one paraplegia, one

stroke, and one transient paraparesis), versus one case of paraparesis with medical treatment.

Finally, aortic remodeling, with measures of true-lumen recovery and thoracic false-lumen thrombosis, which were equivalent for both groups at baseline, occurred in 91.3% of patients with endovascular repair versus 19.4% of those who received medical treatment (p<0.001), which suggests ongoing aortic remodeling.

At two years, true lumen diameter at the level C segment was greater in thoracic endovascular repair patients (32.3±6.4mm vs. 22.7±10.9mm, p<0.001), and false lumen diameter at the same segment was smaller in endovascular repair patients (12.5±16.7mm vs. 26.8±9.4 mm, p<0.001). Complete false-lumen thrombosis was far more frequent in endovascular repair patients (91.3% vs. 19.4%, p<0.001).



Outcomes at two years

	Medical therapy alone (n=68)	TEVAR (n=72)	P value
Survival	95.6 ± 2.5%	88.9 ± 3.7%	0.15
Freedom from aorta-related mortality	97 ± 2%	94.4 ± 2.7%	0.44
Freedom from progressive aortic disease	72.5 ± 5.5%	77.2 ± 5%	0.65

EVAR is a good option even for younger patients, says Makaroun

Endovascular repair of abdominal aortic aneurysms (EVAR) is a good option, even for patients who have a long life expectancy, according to Michel Makaroun, professor of surgery at the University of Pittsburgh, USA. He was speaking at the Vascular Society's annual meeting in Liverpool, UK, on 20 November 2009.

When considering whether to treat abdominal aortic aneurysms either by endovascular aneurysm repair or by open surgery a number of factors need to be taken into account, including the anatomy of the aneurysm, the age and life expectancy of the patient and both the patient's and the surgeon's preferences, Makaroun told delegates.

He began by presenting the case of an 86-year-old man with significant coronary artery disease and a large 6cm abdominal aortic aneurysm. "Very few would argue that this is not a good candidate for endovascular aneurysm repair instead of open repair," Makaroun said. In a second case of a younger patient, however, who is a competitive bicycle racer aged 62 years, in excellent health, with a large aneurysm suitable for endovascular aneurysm repair, the decision between open surgery or endovascular repair becomes more difficult, Makaroun said.

The downside of performing endovascular aneurysm repair on a patient who has a long life expectancy is that there are some possible late complications such as endoleaks, migration, and material fatigue, that require prolonged surveillance and re-interventions.

There are many single and multicentre clinical trials that can be referred to when making the decision between open surgery or endovascular repair, Makaroun said. There have been three randomised trials so far comparing the two methods (the EVAR, DREAM and OVER trials) and, as Makaroun told delegates, "All three have provided unequivocal proof that endovascular aneurysm repair has superior early results that may provide an advantage, at least in the first year."

The EVAR trial in the UK showed that the mortality rate at 30 days is significantly reduced (1.6% for endovascular aneurysm repair versus 6.0% for open repair in a per protocol analysis). Thirty-day mortality results from the Dutch DREAM trial were similar, Makaroun showed (1.2% for endovascular aneurysm repair versus 4.6% for open repair), as were the results of the OVER trial (0.2% for endovascular aneurysm repair versus 2.3% for open repair).

Several regulatory trials from the United States have also shown essentially the same results: a significant reduction in morbidity, Makaroun stated. In follow-up most have shown an advantage for endovascular repair in terms of freedom from major adverse events after five years.

The picture in the United States

A review from the New York State database of hospitals performing endovascular aneurysm repair showed that endovascular aneurysm repair is easily adopted and provides a significant advantage in terms of early mortality. Large reviews from the Medicare database, National Inpatient Sample (NIS) and the National Surgical Quality Improvement Program (NSQIP) all point to a rapid replacement of open procedures by endovascular aneurysm repair with a resultant improvement in overall results of aneurysm care in the United States. The mortality of aneurysm repair in the United States was cut in half after being stable for two decades. Although there are some acknowledged problems with administrative databases, Makaroun argued that they provide an important insight into hospital practice.

Speaking of his own experience, Makaroun said that in 2002 he performed more endovascu-

lar repair than open repair, becoming the picture for all surgeons across the United States. "And this is happening across all age groups," he said, "endovascular aneurysm repairs now outnumber surgical repairs, even in the 50 to 64 age groups."

Regarding the patient's preference, a UK study showed overwhelmingly that most patients would choose endovascular aneurysm repair (84%) over open surgery when given all the facts about the two procedures.

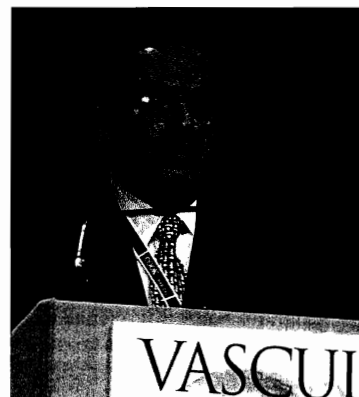
On complications following open surgery, Makaroun presented a summary of a paper from the Cleveland Clinic, where a 17% 30-day complication rate was recorded. Complications of surgery include embolisation to the small bowel and colon, small bowel obstruction, false aneurysms, aorto-enteric fistulas, incisional hernias and even endoleaks. Open repair, Makaroun emphasised, is not a "repair it and

forget it" procedure, it has its own long-term complications too.

Acceptable late results

Returning to the original young patient, who underwent endovascular aneurysm repair in 1999, he had a type 2 endoleak with a stable aneurysm size. He was able to compete in 38 races in 2002. Three years later, at the age of 69, the aneurysm was enlarging and his lumbar and inferior mesenteric artery were ligated without complications, and he returned to racing.

In summary, Makaroun told delegates that endovascular aneurysm repair has excellent early results, and acceptable late results. Giving a picture of the situation in the United States, Makaroun said that endovascular aneurysm repair has largely replaced open surgery in suitable candidates. This has been associated with a



Michel Makaroun

decrease in total mortality from elective aneurysm repair.

In conclusion, Makaroun said, endovascular aneurysm repair should be considered a good option even for young patients at low risk.

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