

# Long-Term Results after Endovascular Aneurysm Repair (EVAR) with the Zenith Stent Graft

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**Citation:** Väärämäki S, Uurto I, Suominen V  
et al. Long-Term Results after Endovascular  
Aneurysm Repair (EVAR) with the Zenith  
Stent Graft. J Vasc Endovasc Therapy 2019,  
Vol.4 No.3:16

## Abstract

The device-specific long-term results of endovascular aneurysm repair (EVAR) is limited as most of the studies are large multicentre trials reporting the combined results of different devices. The main concern regarding endovascular approach for abdominal aortic aneurysm (AAA) has been the high complication and re-intervention rates after EVAR compared to open repair (OR). This concern has led to a recommendation of lifelong surveillance. However, almost 80% of EVAR patients undergo re-intervention-free surveillance. Therefore, the annual monitoring of all EVAR patients is, therefore, unnecessary.

The fatal AAA rupture after EVAR is rare, but an annual rupture risk of 0.49% remains despite the systematic follow-up. The most common cause of death after EVAR is the cardiac event. The overall survival among these patients is poor as multiple comorbidities diminish the life expectancy. Approximately only half of the EVAR-treated patients reach the 5-year follow-up. At the same time, every tenth patient lives up to 16 years and over thus highlighting the importance of durability of the stent grafts. The basic features of the Cook Zenith stent graft haven't changed much over the years. Available long-term data can, therefore, be used in decision making when considering AAA treatment with Zenith device and discussing the treatment options with the patient.

**Keywords:** EVAR; Zenith; Stent graft; Surveillance; Follow-up; Complication; Re-intervention; survival

**Received:** August 20, 2019; **Accepted:** August 30, 2019; **Published:** September 09, 2019

## Introduction

The number of endovascular aneurysm repairs (EVARs) has continuously increased since its introduction over twenty years ago [1-3]. Successful short-term results have been reported, but the systematic long-term results are still limited. This concerns especially device-specific results.

The EVAR Trial 1 was the first randomized controlled trial comparing EVAR to OR with long-term results now available [4]. The short-term data showed significantly lower mortality in EVAR group during the first six months, but beyond eight years mortality rates were conversely [4,5]. The difference in late mortality was predominantly caused by the late aneurysm ruptures in EVAR group [4]. Also, the rate of re-interventions was higher among EVAR patients compared to OR at all follow-up time points. The trial was started in 1999 and some of the stent grafts implanted at that time are no longer available thus making the utilization of the results into current practise difficult. The device specific short-term data showed fewer re-interventions and lowest all-cause mortality in patients treated

with the Zenith (Cook Inc, Bloomington, Ind.) stent graft, but the highest graft occlusion rate compared to other stent grafts [6].

The Zenith is the only stent graft still in use since its introduction in 1997 and approval by U.S Food and Drug Administration (FDA) in 2003. The structural design of the device has remained basically the same since its introduction over twenty years ago. To date, three long-term studies analysing over ten-year follow-up results of the Zenith stent graft have been published [4,7,8]. These studies show low aneurysm rupture, conversion and re-intervention rate up to sixteen-years, but also highlights the need for lifelong surveillance. The objective of this review is to summarise the long-term results of the Zenith stent graft.

## Long-Term Survival

Currently EVAR is the method of choice for treating abdominal aortic aneurysm (AAA), although it was originally developed to offer a less-invasive treatment option to OR for patients with multiple co-morbidities. Therefore, it is understandable that in papers reporting long-term results of Zenith stent graft approximately only half of the patients are still alive at five years

[7,9]. On the other hand, one quarter of the patients are still alive fourteen years after the initial EVAR procedure and every tenth survived up to sixteen years. As EVAR has almost replaced OR in AAA treatment we need to be able to offer the patients devices that are durable over a long period of time.

During the long-term follow-up approximately 22% of the patients under systematic surveillance require additional procedure for graft related complications [7]. The re-intervention-free survivals are high at 5, 10 and 16 years with the Zenith stent graft (80-88%, 73-76% and 73%) [7,9]. The most common complication is an endoleak type II, but eventually only one-third of them require treatment [7]. The recent guideline of European Society for Vascular Surgery (ESVS) for the treatment of AAA recommends even less frequently need for treatment [10]. The complications that were often seen in other early stent grafts, such as endoleak type III, stent fracture and migration, are uncommon with the Zenith stent graft even in the long-term surveillance [11,12]. Reported rates for migration and for stent fracture are 0.3-2% and 0.7%, respectively [4,7,8]. Two long-term studies of the Zenith stent graft report type III endoleak to be the most common form of late stent graft failure, however with low rates of 0.7-1.5% [8,9]. This finding emphasizes the meaning of durability of stent grafts as it implies an unstable stent graft structure or position.

Despite its many positive features, the Zenith stent graft has been criticized for the increased risk of limb occlusion. It has been suggested that the underlying reason for occlusion is the segmental long stents in skeleton [6,13,14]. In general, the reported occlusion rates vary between 0-8.8% in short- and mid-term studies [15,16]. The corresponding figures especially for the Zenith device are 2.7-5.6% with most of the occlusions occurring during the early years after EVAR [9,17,18]. The current long-term studies confirm this finding as in up to sixteen-year surveillance the occlusion was detected in 3.4-5% of the patients [7,9].

In our long-term study with the Zenith stent graft, despite the regular surveillance and active treatment of complications, the annual aneurysm rupture rate remains at 0.49% [7]. These ruptures (N=10) were mainly secondary due to late type I endoleak. Some of them could have been avoided by open conversion, but the patients were considered too sick for OR. Nine out of ten ruptures occurred among patients under regular surveillance. Interestingly, early type II endoleak was found to be a significant risk factor for late re-intervention and even aneurysm rupture despite the fact that almost half of them seal spontaneously and only minority of them resulted in sac enlargement in early surveillance. The finding is in line with the EVAR Trial 1 [4]. Most of the ruptures are seen in early years after EVAR, but one rupture as late as fourteen years after uncomplicated early survival occurred in our long-term study [7,8]. In spite of all the challenges with the endovascular technique, the aneurysm rupture-free survival after EVAR is high with the Zenith stent graft; 96-98% at ten years [7-9].

### Surveillance after EVAR

Many centres fail in regular EVAR surveillance and considerable number of patients are lost to follow-up [19,20]. These patients seem to have the worse survival outcomes [21]. In EVAR Trial 1 many patients were discharged from surveillance after several

years. The secondary aneurysm rupture rate was higher in EVAR group compared to OR, but owing to the insufficient surveillance, some patients may have lost the option of planned re-intervention preventing the rupture [9]. Despite the systematic surveillance, the aneurysm rupture is not totally avoidable, and the aneurysm rupture risk remains [7].

New complications keep appearing years after EVAR and the lifelong surveillance is mandatory to detect all potential re-intervention requiring complications. Most of the patients are re-intervention-free survivors (78%) and clearly not all patients need annual life-long surveillance after EVAR [7]. There are recommendations for surveillance after EVAR which significantly reduce the burden of follow-up visits [10]. EVAR Trail 1 showed that re-interventions occur in long-term surveillance also in patients who were free from re-interventions at two and five years. Therefore, we must avoid too early modified selected surveillance after EVAR [4].

Increased cancer mortality was detected among EVAR patients in EVAR Trial 1, but the long-term study of Zenith didn't confirm that finding as the cancer mortality in the study population and the age-matched general population were similar [4,7]. In modern computed tomography (CT) the radiation exposure is lower than early years and most of the surveillance is carried out by ultrasonography nowadays so the currently treated patients will probably never exceed the amount of radiation that their counterparts were exposed in early years of EVAR. Indeed, the focus should be instead in treatment providers repeated radiation exposure. The recent guidelines recommend ultrasonography (US) based surveillance reducing the cumulative radiation dose of the patient in long-term surveillance and many centres have shift the surveillance from CT to US years ago [10,22].

## Conclusion

The Zenith stent graft provides an effective treatment option for AAA patients. It shows high re-intervention- and aneurysm rupture-free survival in long-term follow-up. Despite the systematic surveillance aneurysm rupture is not totally avoidable. Most of the patients have uncomplicated surveillance and in future, we need studies to clarify, how to safely maximize the surveillance intervals but still find the life-threatening complications early enough. The endovascular treatment and imaging technology have improved during the last decades, but we need safe, systematic, easy and cost-effective surveillance after EVAR.

The summary of EVAR Trials states, that there is no survival difference between EVAR and OR in long-term and EVAR is more costly over a patient's lifetime. With currently used devices, modern imaging modalities and personalized surveillance the advantages of EVAR might, however, be achieved. The good long-term results with Zenith stent graft support the use of EVAR for AAA treatment also in the future.

## References

1. Suckow BD, Goodney PP, Columbo JA, Kang R, Stone DH, et

- al. (2018) National trends in open surgical, endovascular, and branched-fenestrated endovascular aortic aneurysm repair in Medicare patients. *J Vasc Surg* 67:1690-1697.
2. Jetty P, Husereau D (2012) Trends in the utilization of endovascular therapy for elective and ruptured abdominal aortic aneurysm procedures in Canada. *J Vasc Surg* 56:1518-526.
  3. Sachs T, Schermerhorn M, Pomposelli F, Cotterill P, O'Malley J, et al. (2011) Resident and fellow experiences after the introduction of endovascular aneurysm repair for abdominal aortic aneurysm. *J Vasc Surg* 54:881-888.
  4. Patel R, Sweeting MJ, Powell JT, Greenhalgh RM, EVAR trial investigators (2016) Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. *The Lancet* 388:2366-2374.
  5. Greenhalgh RM, EVAR (2004) Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. *The Lancet* 364:843-848.
  6. Brown LC, Greenhalgh RM, Kwong GP, Powell JT, Thompson SG, et al. (2007) Secondary interventions and mortality following endovascular aortic aneurysm repair: device-specific results from the UK EVAR trials. *Eur J Vasc Endovasc Surg* 34:281-290.
  7. Väärämäki S, Salenius JP, Pimenoff G, Uurto I, Suominen V (2019) Systematic Long-term Follow Up After Endovascular Abdominal Aortic Aneurysm Repair With the Zenith Stent Graft. *Eur J Vasc Endovasc Surg* 58:182-188.
  8. Ramirez JL, Schaller MS, Wu B, Reilly LM, Chuter TAM, et al. (2019) Late graft failure is rare after endovascular aneurysm repair using the Zenith stent graft in a cohort of high-risk patients. *J Vasc Surg*.
  9. Verzini F, Romano L, Parlani G, Isernia G, Simonte G, et al. (2017) Fourteen-year outcomes of abdominal aortic endovascular repair with the Zenith stent graft. *J Vasc Surg* 65:318-329.
  10. Wanhainen A, Verzini F, Van Herzele I, Allaire E, Bown M, et al. (2019) Editor's Choice - European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms. *Eur J Vasc Endovasc Surg* 57:8-93.
  11. Mestres G, Zarka ZA, García-Madrid C, Riambau V (2010) Early abdominal aortic endografts: a decade follow-up results. *Eur J Vasc Endovasc Surg* 40:722-728.
  12. Väärämäki S, Pimenoff G, Heikkinen M, Suominen V, Saarinen J, et al. (2007) Ten-year outcomes after endovascular aneurysm repair (EVAR) and magnitude of additional procedures. *Scand J Surg* 96:221-228.
  13. Baum RA, Shetty SK, Carpenter JP, Soulen MC, Velazquez OC, et al. (2000) Limb kinking in supported and unsupported abdominal aortic stent-grafts. *J Vasc Interv Radiol* 11:1165-1171.
  14. Maleux G, Koolen M, Heye S, Nevelsteen A (2008) Limb occlusion after endovascular repair of abdominal aortic aneurysms with supported endografts. *J Vasc Interv Radiol* 19:1409-1412.
  15. Mantas GK, Antonopoulos CN, Sfyroeras GS, Moulakakis KG, Kakisis JD, et al. (2015) Factors Predisposing to Endograft Limb Occlusion after Endovascular Aortic Repair. *Eur J Vasc Endovasc Surg* 49:39-44.
  16. Abbruzzese TA, Kwolek CJ, Brewster DC, Chung TK, Kang J, et al. (2008) Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis. *J Vasc Surg* 48:19-28.
  17. Väärämäki S, Suominen V, Pimenoff G, Saarinen J, Salenius J (2012) Long-term experience of endovascular aneurysm repair with Zenith prosthesis: diminishing graft-related complications over time. *Ann Vasc Surg* 26:845-851.
  18. Mertens J, Houthoofd S, Daenens K, Fourneau I, Maleux G, et al. (2011) Long-term results after endovascular abdominal aortic aneurysm repair using the Cook Zenith endograft. *J Vasc Surg* 54:48-57.
  19. Jones WB, Taylor SM, Kalbaugh CA, Joels CS, Blackhurst DW, et al. (2007) Lost to follow-up: a potential under-appreciated limitation of endovascular aneurysm repair. *J Vasc Surg* 46:434-440.
  20. Garg T, Baker LC, Mell MW (2015) Postoperative Surveillance and Long-term Outcomes After Endovascular Aneurysm Repair Among Medicare Beneficiaries. *JAMA Surg* 150:957-963.
  21. Hicks CW, Zarkowsky DS, Bostock IC, Stone DH, Black JH, et al. (2017) Endovascular aneurysm repair patients who are lost to follow-up have worse outcomes. *J Vasc Surg* 65:1625-1635.
  22. Patel R, Powell JT, Sweeting MJ, Epstein DM, Barrett J, et al. (2018) The UK Endovascular Aneurysm Repair (EVAR) randomised controlled trials: long-term follow-up and cost-effectiveness analysis.