

Rethinking Open Repairs of Abdominal Aortic Aneurysms: New Stent Can Improve Patient Care and Cost Efficiency

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Rethinking Open Repairs of Abdominal Aortic Aneurysms: New Stent Can Improve Patient Care and Cost Efficiency

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PROJECT OVERVIEW

Annually, 200,000 people are diagnosed with an abdominal aortic aneurysm (AAA) in the United States. The abdominal aorta is the largest artery in the abdominal cavity and can be prone to dilating into a balloon-shaped aneurysm as the wall of the blood vessel weakens from aging. Typically, individuals with AAA's present no symptoms, and severe abdominal pain is only reported if the aneurysm has ruptured¹. AAA's are often discovered when CT scans are taken of a patient's abdomen when seeking medical attention for another condition. Once diagnosed, patients are offered repair by vascular surgeons when the AAA is > 5 cm in size to prevent possible rupturing that could rapidly result in death.

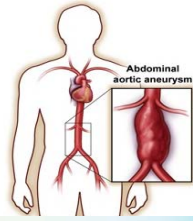


Figure 1: Location of an abdominal aortic aneurysm¹

First line treatment involves a minimally invasive procedure called endovascular aneurysm repair (EVAR) in which a catheter is inserted through the patient's femoral artery and is guided to the aneurysm site via X-ray imaging. A stent graft is expanded from the catheter to seal the artery walls, allowing blood flow to be restored through the stent graft and away from the aneurysm. Adequate infrarenal neck landing zone of 15-20 mm, is mandatory for proper deployment of the endograft². Alternatively, in patients with inadequate infrarenal neck, a much more invasive operation via an open abdominal approach must be performed with a complex surgical repair of the AAA with a graft, directly.

Ideally, all AAA's should be treated in a minimally invasive manner like that of the EVAR; however, the location of the aneurysm, paired with the patient's anatomy may not warrant an EVAR, leaving the open repair as the only surgical option. With an overwhelming population of AAA patients being elderly, this harsh open operation leads to high post-operational morbidity and mortality and a long hospital length of stay (LOS) of which yields high hospital costs. A new device called the Zenith® Fenestrated AAA Endovascular Graft aims to treat AAA patients with inadequate infrarenal landing zone in a minimally invasive manner, similar to that of the EVAR³. Unfortunately, its use is currently limited to university centers and so the research question we sought to answer was:

How many patients can be spared the complex open repair procedure with this technology if its usage was widely accessible?

ZENITH® FENESTREATED AAA ENDOVASCULAR GRAFT

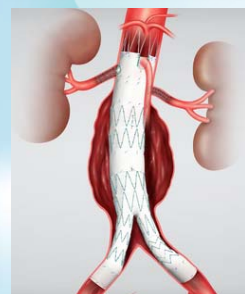


Figure 2 (left): The new Zenith® Fenestrated Graft is recommended as an endovascular approach to repair AAA's in patients with inadequate infrarenal neck landing zones for traditional EVAR³. It is still minimally invasive like that of the normal EVAR procedure, yet offers more flexibility in its requirements for use.

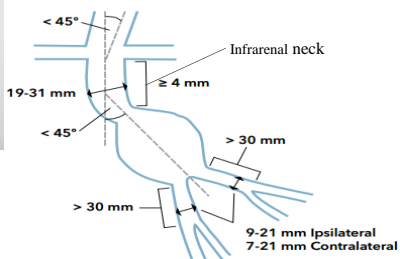


Figure 3 (right): The patient must have specific vascular anatomical measurements to indicate usage of this graft³.

METHODS

General Overview:



This project was a retrospective review of a prospectively maintained database of a single vascular surgeon's abdominal aortic aneurysm cases over a 4 year period from 2012 to 2015.

Medical records for all AAA patients during this time frame were analyzed and the following information recorded for each:

- Date of operation
- Type of operational procedure (EVAR vs open repair)
 - Specific indication for all open repairs over EVAR
- Hospital length of stay (LOS)

AAA patients were then separated based on their treatment operation into an EVAR control group or the open repair experimental group of interest. Abdominal CT scans of all the open repair patients were analyzed and these individuals had their vascular anatomy measured directly on their CT scan. These measurements were compared to that of Figure 3 and those individuals who fit all the instructions for use (IFU) were deemed to be fenestrated EVAR (FEVAR) candidates. Lastly, the average LOS was calculated for the two groups to quantitatively indicate how the potential FEVAR candidates could have received a much shorter hospital visit due to the minimally invasive EVAR nature of this procedure.

RESULTS

From 2012-2015, 114 aortic cases were performed by one vascular surgeon. In total there were 88 endovascular repairs, 18 open repairs, 8 ruptures of which were excluded from analysis, and 1 post-operative death that was not AAA related.

Figure 4: Data separated by year

	2015	2014	2013	2012	Total
Endovascular Repairs	30	28	21	9	88
Open Repairs	6	5	2	5	18
Zenith® Fenestrated Graft Repair Candidates	4	2	0	3	9
Ruptured Abdominal Aortic Aneurysm Patients	1	3	2	2	8

- Mean hospital LOS for EVAR was: 4.26 days; Range: 2 - 33 days
- Mean hospital LOS for Open repair was: 14.92 days; Range: 5 - 44 days
- # of open repair patients that were FEVAR candidates: 9 / 18 (50%)

CONCLUSIONS

- After creating a mini database of all the AAA patients treated by one vascular surgeon over a four year time period, separated based on their form of treatment, our data showed:
 - Of the 18 patients who underwent open repairs, 9 could have benefited from the use of the minimally invasive Zenith® Fenestrated Graft instead.
 - While 9 of 18 patients showing clear indications that they could have been spared a complex open repair from this FEVAR procedure is promising data, it unfortunately is not a large enough of a sample size to extrapolate that 50% of all AAA patients, in general, treated via an open repair could have benefited from this device.
- Aortic reconstruction for aneurysmal disease remains an important component of contemporary vascular practice with this surgeon's data showing 16% open repairs. These open repairs are fairly dangerous in our current "EVAR era", as one misplacement of a clamp can result in patient mortality and the complexity of the procedure itself yields extensive hospital LOS:
 - The mean LOS was 14.92 days for the open repair experimental group, compared to just 4.26 days of the endovascular repair control group. It is clear that the FEVAR procedure would result in greatly reduced LOS as well as costs associated with being in the hospital for so long.
- A multicenter prospective study of the usage of this Fenestrated graft has already proven this stent's safeness and effectiveness⁴:
 - No aneurysm ruptures after a mean follow-up of 37 ± 17 months.
 - Mean LOS was 3.3 ± 2.1 days.
- Overall, our research aimed to show that wider accessibility of this fenestrated graft technology could positively impact a large number of patients by expanding the minimally invasive options for complex aortic neck anatomy, while simultaneously resulting in a significant decrease in hospital costs, LOS, and post-operational morbidity and mortality.

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