ELSEVIER

Composite Stent-Grafts Are Not Associated With Increased Endoleak or Reintervention Rates After Endovascular Abdominal Aneurysm Repair

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Background: Although present-generation endografts have expanded the indications for endovascular abdominal aneurysm repair, arterial anatomy frequently dictates the use of a combination of commercially available endografts and components for successful aneurysm repair. This study sought to determine whether there was an increase in endoleak or secondary intervention rates in individuals treated with composite endografts compared with noncomposite, or standard, endografts.

Methods: From 1999 to 2009, 421 endovascular abdominal aneurysm repairs were performed at a single institution. A total of 384 patients met criteria for inclusion, with at least one follow-up imaging study. Patients were then identified as having had a composite endograft, defined as any combination of two or more different commercially available endograft or stent components, versus a standard endograft. Primary outcomes measured were freedom from endoleak and secondary intervention.

Results: During the study period, 60 composite endograftings and 324 standard endograftings were performed. The groups were well matched for demographics, including age, gender, comorbidities, emergent need for procedure, and 30-day mortality (1.64% vs. 1.54%, nonsignificant). Median follow-up was 16.3 months (range, 19 days to 8.5 years) and 10.2 months (range, 4 days to 8.7 years) for composite and standard endografts, respectively. There was no significant difference between the groups in either endoleak or secondary intervention rates. Median time to endoleak detection was 2.0 months (range, 2 days to 3.9 years) for composite endografts and 2.8 months (range, 2 days to 6.9 years) for standard endografts. Median time to secondary intervention was 7.0 months (range, 4 days to 6.9 years) for composite endografts and 6.7 months (range, 1 day to 6.7 years) for standard endografts.

Conclusions: Composite endografts, namely, the combination of different commercially available endografts or stents used for the treatment of aortic aneurysms, are not associated with increased mortality, endoleak, or secondary intervention rates compared with noncomposite endografts.

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INTRODUCTION

There have been many advances in endograft technology since Parodi et al. performed the first endovascular abdominal aortic aneurysm repair (EVAR) in 1991.[1] During the intervening years, a number of EVAR devices have been developed by the industry and subsequently approved for commercial use in the United States by the Food and Drug Administration (FDA). These devices include Ancure (Guidant, Menlo Park, CA) in 1999, AneuRx (Medtronic, Sunnyvale, CA) in 1999, Excluder (W.L. Gore & Associates, Flagstaff, AZ) in 2002, Zenith (Cook Inc., Bloomington, IN) in 2003, Powerlink (Endologix, Irvine, CA) in 2004, Talent (Medtronic, Sunnyvale, CA) in 2008, and Endurant (Medtronic, Sunnyvale, CA, postdates study period) in 2010. Each of these devices differs subtly in construction, materials, and delivery system, making each appropriate for particular ranges of aortic dimensions and anatomy. However, not all potential EVAR candidates fall within the anatomic parameters of a single graft, as indicated in their indications for use (IFU), and it has become common practice to modify commercially available grafts by adding additional mixed endograft or stent components to more appropriately approximate patient anatomy (Fig. 1). This combination of graft components has not been fully tested by the FDA and is outside instructions for use from manufacturers. Often, these combinations are performed when needed for successful endovascular repair of complicated abdominal aortic aneurysm. These modifications can either be planned, as in the case of EVAR in the context of a large iliac aneurysm, or unplanned, as in the correction of intraoperative endoleak through the addition of components during the case. As a result of these practices, there is a sizable population of patients who have received endografts that were not used according to the product's IFU as the FDA intended, but instead combined with other endograft or stent components. In the literature, there have been reports of type 3 modular endoleaks resulting from the addition of additional graft or stent components to Ancure endografts.[2] There are also concerns about bioincompatability of adjacent discordant materials, especially when exposed to the long-term wear and tear of continuous blood pressure. Despite these concerns, patients with challenging arterial anatomy and aortic aneurysms continue to frequently require repair with multimodular composite endografts. Because of the proposed risk of endoleak with the use of composite endograft components, we sought to determine whether this population of patients would have higher rates of endoleak or secondary intervention.

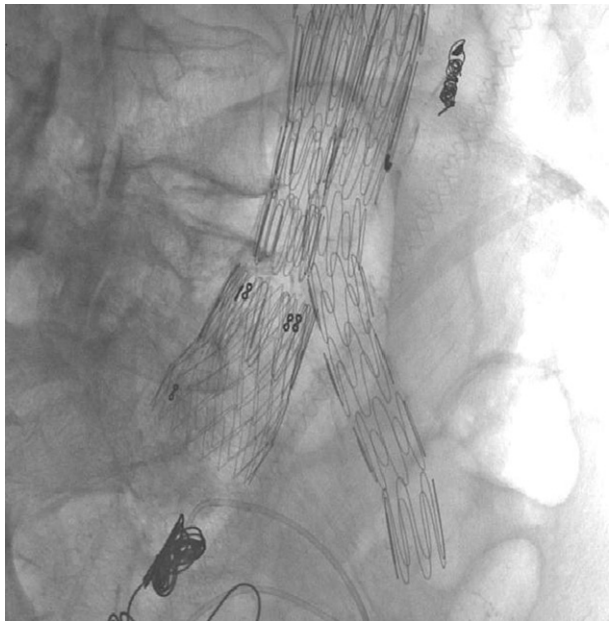

Fig. 1. Immediate composite endograft: Cook Zenith Endograft with AneuRx iliac cuff.

METHODS

From December 1999 to July 2009, 421 patients underwent EVAR at the University of Michigan Health System for infrarenal aortic aneurysms. A total of 384 patients met criteria for inclusion in this study, which was defined as having undergone at least one follow-up computed tomographic angiography or magnetic resonance angiography scan at this institution. Although the duration of follow-up was variable and heterogeneous, it was considered acceptable for this ''real-world'' retrospective observational study. Patients were then identified as having had a composite graft, defined as the combination of two or more commercially available endograft or stent components, versus a standard endograft. Primary standard endografts and covered stent-graft components used included Cook Zenith ($n = 169$), Cook Renu aortouni-iliac ($n = 5$), Gore Excluder ($n = 34$), Medtronic Talent ($n = 10$), Endologix Powerlink ($n = 4$), Lombard Aorfix ($n = 2$), Medtronic AneuRx ($n = 73$), Guidant Ancure ($n = 35$), and Wallgraft ($n = 1$). Additional components included Palmaz stents, Protégé stents, Cook Zilver stents, Boston Scientific Express stents, Cordis Genesis stents, Symphony stents, and Gore Viabahn stent-grafts.

In the analysis of risk of endoleak and secondary intervention, patients whose endovascular repair