The impact of stent graft evolution on the results of endovascular abdominal aortic aneurysm repair

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Objective: **There have been four eras in the development of endovascular aneurysm repair (EVAR): physician-made grafts, early industry devices, intermediary commercial endografts, and modern stent grafts. This study analyzes differences in outcomes between these four groups and the impact of device evolution and increased physician experience.**

Methods: **From 1992 to 2012, 1380 patients underwent elective EVAR. Fourteen different devices were used during this time. The four generations were defined as follows: era 1, all physician-made devices; era 2, June 1994 to June 2003; era 3, June 2003 to January 2008; and era 4, January 2008 to July 2012. Grafts used in each era were the following: era 1, physician made; era 2, early industry, such as EVT, Talent, AneuRx, Excluder, Quantum LP, Vanguard, Ancure, and Teramed; era 3, Talent, Endologix, Excluder, AAAdvantage, Zenith, and Aptus; and era 4, Zenith, Endurant, and Excluder.**

Results: **Mean age was 75.2 years, and 84.5% were men. Adjunctive procedures decreased from era 1 to era 2 ($P < .001$) but rose again in eras 3 and 4 ($P < .001$). Procedure times ($P < .001$), blood loss ($P < .001$), and length of stay ($P < .001$) have decreased in eras 2, 3, and 4 compared with era 1. Major perioperative complications (era 1, 23%; era 2, 5.9%; era 3, 4.9%; and era 4, 4.7%; $P < .001$), abdominal aortic aneurysm-related perioperative mortality (era 1, 4.3%; era 2, 0.2%; era 3, 0.06%; and era 4, 0.5%; $P < .001$), and all-cause perioperative mortality (era 1, 7.7%; era 2, 1.9%; era 3, 1.5%; and era 4, 0.47%; $P < .001$) have also decreased in eras 2, 3, and 4 compared with era 1. Type I and type III endoleaks ($P < .001$) and the need for reintervention ($P < .001$) have decreased. Freedom from aneurysm-related mortality has significantly improved.**

Conclusions: **EVAR has evolved during the last 20 years, resulting in an improvement in efficiency, outcomes, and procedural success. The most significant advance is seen in the transition from era 1 to the later eras. (J Vasc Surg 2014;59:1518-27.)**

More than two decades have passed since Parodi et al[1] described the first endovascular repair of an abdominal aortic aneurysm (AAA). Nearly 2 years later, Marin et al,[2,3] instructed by Dr Parodi, performed the first endovascular repair of an AAA in the United States. First iteration endografts for AAAs were used on a compassionate basis.[3] These patients were not candidates for an open AAA repair because of severe surgical risk. Since that time, endovascular aneurysm repair (EVAR) has become the preferred approach and at present is the most common procedure performed to correct AAA.[4,5]

When it was first implemented, EVAR was used selectively. As the technology and physician experience advanced, EVAR was used to treat more standard-risk patients. Physician-made devices continued to be used in this standard-risk cohort until 2003. We hypothesized that device development and operator experience have resulted in an overall improvement in EVAR outcomes. To demonstrate improved outcomes over time, four generations of EVAR were compared. Specifically, the results of treatment with physician-made devices and three subsequent cohorts of industry-made endografts were compared. The purpose of these comparisons was to determine the impact of device evolution and increased experience on outcomes.

METHODS

Study population. Between November 1992 and May 2012, 1853 aortic endografts were implanted. Of these procedures, 1380 patients underwent elective endovascular repair of infrarenal AAA. For a homogeneous patient population to be created for comparison, only patients undergoing an elective EVAR were included in this analysis. Patients from two institutions were included: the Montefiore Hospital, New York, and the Mount Sinai Hospital, New York.

Of the original 1853 stent grafts, 473 patients were excluded. These exclusions consisted of endografts placed for pseudoaneurysms, para-anastomotic aneurysms, aortoenteric or aortoduodenal fistulas, and penetrating ulcers. In addition, patients undergoing endovascular repair of isolated thoracic or iliac aneurysms, patients with aortic

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ruptures, and those patients referred from an outside institution for a secondary EVAR for endoleaks were excluded. The physician-made device cohort excluded physician-modified, industry-manufactured devices. Twenty-five patients were excluded because of lost or incomplete records.

Fourteen stent grafts were employed to treat the 1380 patients included in this study. These devices included 117 physician-made endografts and 1263 industry-manufactured stent grafts (Table I). The study protocol was approved by the Institutional Review Board.

Data collection. Demographics, preoperative characteristics, and intraoperative procedure details were collected from a prospectively maintained database that has been sustained since the first successful performance of EVAR in North America. This database was supplemented with a retrospective review of medical records. Survival was determined with medical records and the Social Security Death Index.

Medical high risk was assessed by the Glasgow Aneurysm Score (GAS), which was calculated with the methods described by Baas et al.[6] Patients were considered high risk when the GAS exceeded 76.5. Scores higher than 76.5 have been shown to increase the 30-day mortality rate for EVAR to 1.9% and for open AAA repair to 7.8%.[6] The overall numbers of comorbid conditions were calculated. Preoperative diagnostic angiography or computed tomography angiography was performed to confirm eligibility for endovascular repair. Preoperative adjunctive procedures (eg, embolization, management of concomitant occlusive disease) were also performed on an as-needed basis.

The recorded intraoperative parameters included operative time, anesthesia time, estimated blood loss, number of additional endovascular extensions, length of hospital stay, minor and major complications, and mortality. The use of additional extensions was defined as use of an extra cuff or limb in addition to the standard device configuration. Complications, endoleak rates and types, aneurysm growth, reinterventions, aneurysm-related death, and overall mortality were documented during the immediate postoperative period (0-30 days after the procedure) and for the entire duration of follow-up. Perioperative complications were defined as postoperative complications occurring within 30 days of EVAR. Complications were classified as major or minor according to the severity and extent of treatment required (Table II). These complications are consistent with the Society for Vascular Surgery reporting standards.[7]

To evaluate the impact of physician experience and device evolution on procedural outcomes after EVAR, cases were divided into four groups according to the type of stent graft used and the time intervals during which those devices were used (Table I). Era 1 (n = 117) was defined as all physician-made devices. Era 2 (n = 525) included early industry devices, used between June 1994 and June 2003. Era 3 (n = 526) comprised commercial endografts implanted between June 2003 and January 2008 as well as certain intermediary devices used after 2008 (Aptus and Endologix). Era 4 (n = 212) was defined as the most recent stent grafts and consisted of the remaining devices used between January 2008 and July 2012. The Medtronic AneuRx stent graft was used until October 2010, and the Medtronic Talent endograft was used until March 2011. These devices were later superseded by the Medtronic Endurant. Therefore, the Talent and AneuRx were not included in the fourth era but confined to eras 2 and 3. The Cook Zenith and Gore Excluder were multigenerational and were used in several eras. Specifically, the Excluder was used in eras 2, 3, and 4; the Zenith was used in eras 3 and 4.

Table I. Summary of Devices by Era

Device and manufacturer	*No.*	*Dates used*
Era 1: Physician made		
Juan Parodi	9	11/92-01/95
Michael Marin	108	06/94-06/03
Era 2: Early industry		
Endovascular Technologies (EVT)	5	06/94-05/96
Boston Scientific (Vanguard)	18	08/97-03/00
Guidant (Ancure)	9	05/00-03/01
Teramed (Ariba)	6	07/00-08/00
Cordis (Quantum LP)	31	04/02-04/03
Early Gore (Excluder)	20	05/98-06/03
Early Medtronic (Talent)[a]	402	04/98-03/11
Early AneuRx (AAAdvantage)	34	11/99-06/03
Era 3: Intermediary industry		
Aptus Endovascular (Aptus)[a]	3	12/07-02/08
Powerlink (Endologix)[a]	3	12/06-05/12
Intermediary Gore (Excluder)	175	06/03-01/08
Late Medtronic (Talent)[a]	241	04/98-03/11
Late AneuRx (AAAdvantage)[a]	86	06/03-10/10
Early Cook (Zenith)	18	12/03-01/08
Era 4: Modern industry		
Late Cook (Zenith)	9	01/08-02/12
Medtronic (Endurant)	69	09/08-07/12
Late Gore (Excluder)	134	01/08-07/12

Eras were defined generally to categorize the various endografts as best as possible by the time periods: era 1, all physician-made devices; era 2, June 1994 to June 2003; era 3, June 2003 to January 2008; era 4, January 2008 to July 2012.

EVT (Endovascular Technologies, Menlo Park, Calif); Vanguard (Boston Scientific, Natick, Mass); Ancure (Guidant, Indianapolis, Ind); Ariba (Teramed, Maple Grove, Minn); Quantum LP (Cordis, Waterloo, Belgium); Excluder (Gore, Flagstaff, Ariz); Talent (Medtronic, Minneapolis, Minn); AAAdvantage (AneuRx; Medtronic, Santa Rosa, Calif); Aptus (Aptus Endovascular, Sunnyvale, Calif); Endologix (Powerlink, Irvine, Calif); Zenith (Cook, Bloomington, Ind); and Endurant (Medtronic, Minneapolis, Minn).

[a]These devices were used outside of the date range defined by the eras because of case-by-case circumstances.

Follow-up. Follow-up was conducted per standard-of-care practices. Patients were evaluated at 30 days, at 6 months, and annually thereafter. Follow-up for patients enrolled in device trials was conducted in accordance with investigational device exemption and postmarket protocols. Patients unable to return to Mount Sinai but who agreed to follow-up with a study investigator remotely (ie, by mailing of imaging to the hospital) were included in this analysis. Patients were considered lost to follow-up in the