

## Aortic neck enlargement after endovascular aneurysm repair using balloon-expandable versus self-expanding endografts

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*Objective:* This study evaluated changes in aortic neck diameter after endovascular aneurysm repair (EVAR) using a balloon-expandable stent (BES) endograft compared with a commercially available self-expanding stent (SES) endograft. We hypothesized that forces applied to the aortic neck by SES endografts may induce aortic neck enlargement over time and that such enlargement may not occur in aneurysm patients treated with a device that does not use a proximal SES. *Methods:* This was a retrospective quantitative computed tomography (CT) image analysis of patients treated with the Nellix (Endologix, Irvine, Calif) BES (n = 49) or the Endurant II (Medtronic, Minneapolis, Minn) SES (n = 56) endograft from 2008 to 2010. Patients with preimplant, postimplant, and at least 1-year serial CT scans underwent quantitative morphometric assessment by two independent vascular radiologists blinded to the outcome results. Changes in the infrarenal neck over time were compared with the suprarenal aorta for each patient.

*Results:* Follow-up extended to 4.8 years for the BES and to 4.6 years for the SES, with no significant difference in median follow-up time (34 months for BESs and 24 months for SESs; P = .06). There were no differences in preimplant neck diameter (25.2 ± 0.9 mm vs 25.7 ± 1.1 mm; P = .54) or length (27.7 ± 3.7 mm vs 23.6 ± 3.7 mm; P = .12) between BESs and SESs at baseline. After implantation, neck diameter increased by 1.1 ± 0.5 mm in BES patients and 2.6 ± 0.5 mm in SES patients (P = .07) compared with the preoperative diameter. At 3 years, neck diameter increased by 0.5 ± 0.9 mm in BES patients and by 3.8 ± 1.0 mm in SES patients (P = .0002) compared with the first postoperative CT scan. The annual postimplant rate of increase in the infrarenal neck diameter was fivefold greater in SES patients (1.1 ± 0.1 mm/y) than in BES patients (0.22 ± 0.04 mm/y; P < .0001). There were no significant differences in the diameter of the suprarenal aorta at baseline or at 3 years and no differences in the annual rate of change in suprarenal aortic diameter between BES and SES endografts.

*Conclusions:* EVAR using SES endografts resulted in progressive infrarenal aortic neck enlargement, whereas EVAR using BES endografts resulted in no neck enlargement over time. These data suggest that infrarenal neck enlargement after EVAR with SES endografts is likely related to the force exerted by SES elements rather than disease progression in the infrarenal neck. (J Vasc Surg 2015;62:541-9.)

Endovascular aneurysm repair (EVAR) has largely replaced open surgery for elective repair of infrarenal aortic aneurysms with suitable anatomy. However, long-term

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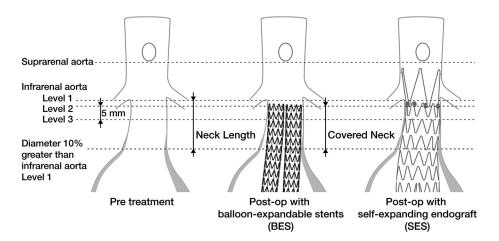
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durability of EVAR remains an ongoing concern due to late complications of aneurysm enlargement, device migration, new-onset type I endoleaks, the need for secondary procedures, and aneurysm rupture.<sup>1-4</sup> All currently available endograft devices in the United States use selfexpanding stent (SES) structures that exert radial force against the infrarenal aortic neck to provide fixation and seal. Most current-generation devices also incorporate suprarenal stent elements with penetrating hooks to enhance fixation.

Because the long-term durability of EVAR is dependent on continuous proximal and distal fixation and seal, varying degrees of oversizing are used to ensure continued seal and to guard against the potential of neck enlargement, which could destabilize proximal fixation and seal. Indeed, enlargement of the infrarenal aortic neck has been noted in 20% to 33% of patients at 2 years,<sup>5-8</sup> in 35% to 36% of patients at 3 years,<sup>9-11</sup> and in 59% of patients at 4 years<sup>12</sup> after implantation of a variety of devices. Longterm follow-up extending to 10 years has shown neck



**Fig 1.** Location of aortic diameter measurements on preimplant and postimplantation computed tomography (CT) scans in patients treated with balloon-expandable stent (*BES*) and self-expandable stent (*SES*) endografts. The suprarenal aortic diameter was measured just below the superior mesenteric artery. The infrarenal aortic neck diameter was measured at just below the lowermost renal artery (level 1), at the proximal end of the endograft (level 2), and 5 mm below the proximal end of the endograft (level 3). The infrarenal neck length and covered neck length were derived as shown.

enlargement up to the size of the implanted endograft in 100% of patients.<sup>13</sup> Neck enlargement has been related to the degree of stent graft oversizing at the time of implantation<sup>7,14,15</sup> and has been implicated in device migration and the development of new-onset type I endoleaks.<sup>5,11,12,16,17</sup> Although absence of aortic neck dilatation has been reported in patients treated with balloon-expandable stent (BES) grafts,<sup>18,19</sup> systematic reviews have found no clear association between neck dilation and SES grafts<sup>15</sup> and have concluded that aortic neck dilation is most probably an expression of ongoing aneurysm wall degeneration of the infrarenal aortic segment.<sup>20</sup>

The Nellix device (Endologix, Irvine, Calif), a novel endograft that uses BESs rather than SESs, along with polymer-filled endobags, to achieve fixation and seal of the aneurysm sac, has experienced favorable early clinical results.<sup>21-23</sup> The Nellix does not rely on proximal and distal radial force for fixation of the endograft, and the effect of this device on proximal neck enlargement and device migration are unknown. The purpose of this study was to evaluate changes in aortic neck diameter after endovascular infrarenal abdominal aortic aneurysm repair using the Nellix BES device compared with a concurrent experience using the latest-generation of the Endurant (Medtronic, Minneapolis, Minn), a commercially available SES device.

## METHODS

**Study population.** The study population included patients with asymptomatic infrarenal abdominal aortic aneurysms who underwent elective treatment from May 2008 to January 2010 at one of three clinical sites using the Nellix BES endograft (Riga, Latvia and Auckland, New Zealand) or the Endurant II SES aortic stent graft system (Nieuwegein, The Netherlands). BES patients were treated under Institutional Review Board-approved investigational device protocols, and the SES cohort comprised consecutive patients treated with the Endurant II SES device during the same period. All patients in both groups gave institutionally approved informed consent. Patients who had preimplant and postimplant computed tomography (CT) scans and follow-up contrast CT imaging studies at  $\geq 1$  year were included in the study.

Quantitative morphometric analysis. Preimplant and postimplant CT scans ( $\leq$ 30 days of device implantation) and annual follow-up CT scans were evaluated independently by two experienced vascular radiologists, who were blinded to outcome results, using Osirix MD 2.8.5 software (Pixmeo SARL, Bernex, Switzerland). CT scans were performed using 16-slice or 64-slice scanners with an axial slice thickness of <1.5 mm. All analyses were based on three-dimensional aortic reconstructions with measurements taken perpendicular to the vessel centerline.

Aortic diameters were measured adventitia-to-adventitia in the suprarenal aorta, just below the superior mesenteric artery, and in the infrarenal aortic neck at three levels: (1) just below the level of the lowermost renal artery, (2) at the proximal end of the stent structure, and (3) 5 mm below the level of the proximal end of the stent, as shown in Fig 1. At level 3, the BES was surrounded by endobag fabric, which is apposed to the aortic wall and may or may not contain polymer fill. The exact location of the infrarenal aortic neck level 2 and level 3 measurements on pretreatment scans was determined using the centerline distances from level 1 to level 2 and from level 1 to level 3 on the first post-treatment CT scan in each patient. Aortic aneurysm diameter was recorded at its maximum diameter perpendicular to the vessel centerline. Infrarenal aortic neck length was defined as the centerline distance between the level of the lowermost renal artery (level 1) and the

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