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Endograft Sizing for Abdominal Aortic Aneurysms

Alex Sher and Rami O. Tadros

Additional information is available at the end of the chapter

Abstract

While a tight seal and fixation of aortic stent-grafts to the vessel wall are vital for positive outcomes in treating abdominal aortic aneurysms (AAAs), optimal aortic stent-graft sizing for endovascular aneurysm repair (EVAR) remains debatable. We performed a holistic review of the data surrounding the sizing of endografts using instructions for use (IFU) guidelines, as well as experimental, computational, and clinical studies. Most clinical studies that have investigated the role of sizing and outcomes are limited by the strict selection criteria, or the inability to account for the multitude of confounders associated with sizing. Currently, oversizing of endografts between 10 and 20% remains safe and favored, but sizing outside the IFU guidelines frequently occurs. Oversizing up to 25% appears to be associated with decreased rates of proximal endoleak and aneurysm sac enlargement, while excessive oversizing (>30%) has been linked to graft infolding, collapse, and aortic dilatation. It is unclear, however, whether there is an association between oversizing associated with neck dilatation and graft migration. During sizing, surgeons should take an individual approach and consider several factors including device type, calcification and/or thrombus of apposition site, hemodynamics, and aortoiliac morphology.

Keywords: endovascular aneurysm repair, sizing, endograft, instructions for use, abdominal aortic aneurysm

1. Introduction

Aortic aneurysms, a ballooning of a weakened portion of the aorta, are most frequently seen in the abdominal aorta. When indicated, an abdominal aortic aneurysm (AAA) can be treated with open surgical or endovascular repair. With a higher perioperative morbidity and mortality of open surgery [1–6], endovascular aneurysm repair (EVAR) of the abdominal aorta has grown in popularity as a safe, effective, and minimally invasive alternative

for certain patients. The goal of EVAR is to achieve adequate fixation and to seal the stent graft to the vessel wall, thus redirecting blood flow away from the pathologic section of the aorta n/a. Failure to do so can result in several noteworthy complications, including device migration or kinking, dilatation, and most commonly perigraft endoleak. In fact, some have reported endoleak complications in up to 20–25% of patients following the EVAR [7, 8]. Ultimately, these complications can lead to occlusion of adjacent branches, aneurysm sac growth, or even rupture.

Exploration of the use of nonporous endoprosthesis for the treatment of AAA dates back to 1976, when Parodi et al. [9] began to transform Dacron prosthetics into intraluminal devices. Several others went on to test the intraluminal grafts in animals with an array of sizing protocols [10–13]. However, it is difficult to interpret sizing practices from these early studies since most involved balloon-expandable stents and not the self-expandable stents that are frequently used today. Since the approval of self-expandable aortic stent-grafts in humans with AAAs over a decade ago, sizing has become a crucial component of the successful EVAR. Early feasibility studies recommended sizing the device larger than the vessel (i.e., oversizing) without strong scientific backing. After years of use, evidence for oversizing has been validated [14, 15]. Oversizing helps in securing the device in place and achieving adequate fixation and seal by increasing the frictional force between the vessel and device. Additionally, oversizing addresses the unevenness of each vessel and allows the vessel to take the circular shape of the device [16]. Ultimately, the device must generate a large enough radial force to resist displacement from the vessel wall, but not so large that the endograft starts to fold or cause adverse vessel remodeling.

Although most surgeons agree about the importance of sizing, several factors make it a difficult task. For one, angulated vessels may introduce variability in the degree of oversizing delivered around the vessel wall. Others include the presence of thrombus or calcification at the attachment sites, length and shape of apposition sites, graft features, and stability of vessels. Further complicating, sizing is the reality that the pulsatility of vessels and hemodynamics of each patient is variable. Nevertheless, the instructions for use (IFU) guidelines of most devices recommend sizing the endovascular graft 10–20% larger than the vessel diameter. However, these sizing recommendations lack comparable safety and effectiveness studies for aortic grafts sized outside that range. Moreover, graft oversizing in patients frequently varies from the manufacturer's IFU, with reported oversizing ranging from less than 5% to greater than 40% [17]. With this variability, and because the complication rate post EVAR remains significant, the optimal degree of oversizing continues to be a topic of interest for many surgeons.

2. Aim of the chapter

The aim of this chapter is to provide physicians with a useful resource when sizing stent-grafts for EVAR of the abdominal aorta. This chapter provides the instructions for use guidelines published by each graft manufacturer and objectively reviews the relationship between the endograft sizing and outcomes using experimental, computational, and clinical studies.

3. Early development and sizing

The difficulty of sizing prosthesis can be seen as early as the implantation of sutureless intra-luminal grafts during open surgery. With the goal of better fixation, Matsumae et al. [18] proposed the addition of elastic rings and saw no dislodgment or migration in nine canines with a ratio of 0.92–0.70 (31.4%) of ring to aorta diameter. In 1983, Nitinol wires were inserted in animals using a transluminal approach with only the stent dimensions reported [19, 20]. Since wires were not a feasible solution to exclude the aneurysm sac, several attempts were made testing intraluminal grafts in animals [9–13]. Balko et al. [10] used 10 mm intraluminal poly-urethane prosthesis with a compressible Nitinol wire frame in a 9 mm self-made aneurysm in sheep. Laborde et al. [13] used 10 mm modified tubular Dacron grafts affixed to balloon-expandable stents and applied it to 10 mm mongrel vessels and found inconsistent results; yet, they recommended expanding the stent to a diameter 10–15% larger than the aorta. In 1991, Parodi et al. [9] achieved a "watertight seal" in humans using a balloon-expandable stent, but unfortunately, the sizing of each patient was not reported. Soon after, several studies investigated the anatomy of patients with AAA in order to identify the range of endograft sizes necessary for treatment [21, 22]. Thus, the importance of accurately sizing endografts was clear early on. Manufacturers of these early grafts recommended that stent-grafts should be oversized a few millimeters. It is not clear, however, what scientific observations were used to make these recommendations. Even in 1999, an experimental study reported that they supported the "theoretical" advantage of oversizing prosthesis [15]. Nevertheless, these early feasibility studies highlight how oversizing has been an important part of EVAR since the early development.

4. Endograft devices and instructions for use

Since the first device implanted in patients in 1991, several modifications have been made with efforts to address access, fixation, and sealing. Devices can be classified as either balloon- or self-expandable. The most commonly used devices today are self-expandable and they have the advantage of providing more anatomically correct support. The manufacturers of approved endografts suggest measuring either from intima to intima (inner wall) or adventitia to adventitia (outer wall). Thus, when deciding how much to oversize, the apposition site diameter measurements should be device-specific. The following consists of a brief timeline of the currently available self-expandable devices.

In 1999, the Food and Drug Administration (FDA) first approved the use of two self-expandable endografts, the AneuRx (Medtronic Vascular, Santa Rosa, CA, USA) and Ancure (Guidant Corporation, Indianapolis, IN, USA). Yet, by 2001, Guidant suspended the production and announced the recall of all Ancure devices. In 2002 and 2003, respectively, the Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA) and Zenith (Cook Inc., Bloomington, IN, USA) devices gained approval. More recently, the Powerlink (Endologix, Irvine, CA, USA), Talent (Medtronic, Inc., Minneapolis, MN, USA), and Endurant (Medtronic, Inc., Minneapolis, MN, USA) devices were all approved. The characteristics of each device currently available along

with their recommended sizing protocols are given below (**Table 1**). The associated exclusion criteria, study designs, and outcomes from their clinical trials are also summarized (**Table 2**). Of note, the anatomical requirements for inclusion in these studies are often strict and do not represent the scope of patients currently being treated with EVAR. Thus, the anatomical characteristics of each study should be considered when evaluating the degree of oversizing used. Finally, by proving safety and effectiveness, many of these studies helped in guiding the recommendations for the endograft sizing today. What they did not show, however, was the effect of different levels of sizing on outcomes. In general, the instructions for use recommendations suggest using an individual approach and oversizing stent-grafts 10–20% in the abdominal aorta with a wider accepted range of up to 25% in the iliac arteries.

Device	Design	Active fixation	Suprarenal or infrarenal	Available sizes	Sizing recommendation
AneuRx (Medtronic, Inc.)	Modular, bifurcated, Nitinol stent, polyster fabric	No	Infrarenal	Main body: 20–28 mm, iliac limb: 12–24 mm	Approximately 2 mm larger than the aortic diameter and 1 mm larger iliac diameter (10–20% oversizing)—see IFU
Excluder (W.L. Gore & Associates, Inc.)	Modular, bifurcated, Nitinol stent, ePTFE fabric	Yes (anchors)	Infrarenal	Main body: 23–31 mm, iliac limb: 10–20 mm	At least 2 mm larger than the aortic inner diameter (10–21% oversizing) and 1 mm larger than the iliac inner diameter (7–25% oversizing)—see IFU
Zenith (Cook Medical, Inc.)	Modular, bifurcated, stainless steel Z-stents, polyster Dacron fabric	Yes (barbs)	Suprarenal	Main body: 22–36 mm, iliac limb: 8–24 mm	Varying based on outer diameter aortic: (14–24%) iliac: (0–20%)—see IFU
Powerlink (Endologix)	Modular, bifurcated unibody, cobalt chromium stent, ePTFE	No	Infrarenal	Main body: 25–28 mm, iliac limb: 16 mm, extension limb: 16–25 mm	Varying based on diameter—see IFU
Talent (Medtronic, Inc.)	Modular, bifurcated, nitinol stent, polyster fabric	No	Suprarenal	Main body: 22–36 mm, iliac limb: 8–24 mm	Varying based on diameter aortic: (14–24%) iliac: (0–20%)—see IFU
Endurant (Medtronic, Inc.)	Modular, bifurcated or aorta-uniiliac, Nitinol M-shaped stent, high filament polyster fabric	Yes (pins)	Suprarenal	Main body: 23–36 mm, iliac limb: 10–28 mm	Aorta: 10–20% larger than vessel inner diameter iliac: 10–25% larger than vessel inner diameter—see IFU

ePTFE, expanded polytetrafluoroethylene.

Table 1. Characteristics of commercially available self-expandable aortic stent-grafts.

Device	FDA approval	Clinical study sizing	Study design	N	Follow-up	Patients excluded	Anatomical characteristics	Outcomes
AneuRx	1999	Not specified (recommended 10–20% oversizing)	Nonrandomized, prospective, multicenter clinical study	416	6 months, 1 year	• Aneurysmal neck or proximal neck length <10 mm • Infrarenal neck diameter <18 mm or >26 mm • Neck angulation >60° • Iliac diameter >16 mm • Iliac landing zone length <15 mm • Vessel morphology not suitable for endovascular repair	• Median neck diameter 20–29 mm • Median aneurysm diameter 50–59 mm	**Migration** Predischarge—baseline 6 months—1.7% 1 year—1.6% **Endoleak (any)** Predischarge—43.8% 6 months—24% 1 year—17.4%
Excluder/low permeability excluder*	2002/2004	Not specified (recommended 10–21% oversizing aorta and 7–25% iliacs)	Nonrandomized prospective, multicenter clinical studies	563/139*	1 month, 6 months, 1 year, 2 years, 3 years, 4 years, 5 years	• Infrarenal proximal neck lengh <15 mm • Infrarenal aneurysmal aortic neck or diameter > 29 mm • Proximal neck angulation >60° • Presence of significant thrombus at implantation sites • Iliac and femoral arteries not suitable for EVAR • Vessel morphology not suitable for endovascular repair	• Median aneurysm diameter 50–59 mm	**Migration** month—0%; 6 months—0.4%; 1 year—0.7%; >2 years—0% **Endoleak (any; type 1)** 1 month—27.3%, 2.6% 6 months—25.5%, 2.6% 1 year—22.5%, 0.4% 2 years—21.9%, 0.9% 3 years—22.1%, 1.2% 4 years—20.5%, 1.0% 5 years—16.4%, 0.8%

Device	FDA approval	Clinical study sizing	Study design	N	Follow-up	Patients excluded	Anatomical characteristics	Outcomes
Zenith	2003	Not specified (recommended 14–24% oversizing aorta and 0–20% iliacs)	Nonrandomized, prospective, multicenter clinical studies	352 (200 standard, 100 high risk, 52 roll-in)	1 month, 6 months, 1 year	• Infrarenal proximal neck length <15 mm • Infrarenal neck outer diameter <18 mm or >32 mm • Suprarenal angulation >45° or infrarenal angulation >60° • Iliac diameter <7.5 mm or >20 mm • Iliac length <10 mm • Vessel morphology not suitable for endovascular repair	• Median aneurysm diameter 50–59 mm	**Migration (>5 mm and without sequel)** 1 year—2.5%, 2.8%, 0% (standard, high risk, roll in) **Endoleak (any)** 1 year—7.4%, 8.8%, 3.4% (standard, high risk, roll in)
Powerlink	2004	10–20% relative to the neck diameter	Nonrandomized, prospective, multicenter clinical studies	192	1 month, 6 months, 1 year	• Infrarenal proximal neck length <15 mm • Infrarenal neck diameter <18 mm or >26 mm • Neck angulation >60° • Iliac artery diameter <7 mm • Iliac landing zone length <15 mm • Vessel morphology not suitable for endovascular repair	• Aneurysm diameter 51 ± 6.6 mm • Proximal seal zone length 29.3 ± 11.3 mm • Right iliac diameter 12.3 ± 2.3 mm • Left iliac diameter 12.1 ± 1.8 mm	**Migration (>5 mm without sequel)** 1 year—4.4% **Endoleak (any; new type I)** 1 month—22.7%, 0.8% 6 months—12.9%, 0% 1 year—14.1%, 0% 2 year—4.9%

	approval	**sizing**					**characteristics**	
Talent	2008	Not specified (recommended 14–24% oversizing aorta and 0–20% iliacs)	Nonrandomized, prospective, multicenter clinical studies	166	1 month, 6 months, 1 year	• Infrarenal proximal neck length of <10 mm • Infrarenal proximal neck diameter <18 mm or >32 mm • Neck angulation >60° • Iliac artery diameter of <8 mm or >22 mm • Iliac artery length of <15 mm • Vessel morphology not suitable for endovascular repair	• Aneurysm diameter 51 ± 6.6 mm • Proximal seal zone length 29.3 ± 11.3 mm • Right iliac diameter 12.3 ± 2.3 mm • Left iliac distal diameter 12.1 ± 1.8 mm	**Migration** 1 year—0.8% **Endoleak (any; type I)** 1 month—19.3%, 9.3% 1 year—9.2%, 2.5%
Endurant/ endurant II**	2010/2012	Approximately 20% greater than inner diameter	Nonrandomized, prospective, multicenter clinical studies	150	1 month, 6 months, 1 year	• Infrarenal proximal neck length <10 mm or significant calcification or thrombus • Proximal neck diameter <19 mm or >32 mm • >45° suprarenal or >60° infrarenal neck angles • Iliac fixation site diameter <8 mm or >25 mm • Aneurysmal iliac arteries or lengths <15 mm • Vessel morphology not suitable for endovascular repair	• Aneurysm diameter 55.9 ± 8.7 mm • Proximal neck length 31.0 ± 14.3 mm • Proximal neck diameter 23.5 ± 3.0 mm • Suprarenal angle 16.0 ± 10.3° • Infrarenal angle 35.2 ± 13.7° • Right iliac diameter 14.2 ± 42 mm • Left iliac diameter 13.9 ± 3.1 mm	**Migration** 1 year 0% **Endoleak (any; type I)** 1 month—16.1%, 0% 6 months—11.6%, 0% 12 months—9.8%, 0%

Modifations to the original Gore Excluder were made and tested because of aneurysm enlargement rates.

New delivery system with extended hydrophilic coating, two new limb lengths, new radiopacity on contralateral gate.

Table 2. Instructions for use—clinical studies.

5. Clinical outcomes and oversizing

The goal of EVAR is a long-term exclusion of the aneurysm, without any complications such as graft migration or endoleak. Obtaining a tight seal and adequate fixation are important in lowering intrasac pressure and limiting further disease progression. In 2009, a systematic review evaluated the relationship between oversizing and outcomes and reported that 10–20% oversizing is relatively safe and remains as the preferred sizing choice of surgeons [17].

5.1. Biomechanics and vessel remodeling

Understanding the effects of EVAR on both the vessel wall and device itself is important for making improvements in endovascular surgery. Several authors have attempted to investigate these consequences with specific consideration to the effects of oversizing. When a stent is apposed to an artery, the force created from the vessel wall opposes a stent's outward radial force. After deployment, equilibrium is achieved between the vessel and stent-graft where the radial force is proportional to the final diameter of the incorporated device [23]. Thus, radial force is significantly correlated with the degree of oversizing. If the force delivered to the vessel exceeds the equilibrium, it is plausible that the inward folding (i.e., infolding) or collapse of the graft can occur. In turn, infolding of the graft at its border can result in new interfaces between the blood flow and the graft, thus resulting in an increased risk of migration. In fact, excessive oversizing, in particular greater than 30%, has been linked to infolding of the device [24, 25]. In further analysis, Lin et al. [26] showed significantly less likelihood of folding when oversized below 23.5%. Interestingly, when stents collapse they do so asymmetrically. This has been shown in vitro where certain areas of the stent have more rigidity and thus takes on more force [23].

Another potential consequence of the radial force delivered to the vessel wall is the ability of the vessel to remodel. If the radial force is large enough, the vessel can dilate in order to accommodate for the stent graft. Several authors have reported these changes in the aneurysm neck after the EVAR [16, 27–33]. In the results of four U.S. phase II trials, neck dilatation of 3 mm or more was reported in 13–20% of patients 2 years post EVAR [30]. In a study with longer follow-up (4 years) but with smaller sample size, all patients showed at least 2 mm of neck dilatation [33]. These results follow a previous description that the self-expandable stent-grafts dilate the aortic neck until the nominal diameter of the stent graft is reached [34]. This initial adaptation has been reported for almost all the self-expandable endograft-treated aortic necks as an adjustment to the devices present and is associated with the percentage of oversizing [31]. However, it is unclear, if oversizing is associated with dilatation beyond this initial adaptation. Importantly, expansion of the aortic neck to the size of the graft is infrequently associated with adverse complications [33]. However, neck dilatation exceeding the degree of oversizing can put patients at an increased risk of developing endoleak or graft migration [35].

The mechanism, in which, a dilatation larger than the percentage of oversizing can result in migration, is thought to be through a reduction in frictional force. Thus, many authors have shown that oversizing is positively correlated with neck dilatation [25, 28, 31, 33, 36–38].

Conners et al. [25] reported that oversizing greater than 20% was strongly associated with an accelerated late neck expansion. However, the effect of oversizing on dilatation is not black and white. In fact, several authors have failed to find any significant correlation when compared to the postoperative diameter [27, 31, 39, 40]. For example, Cao et al. [27] failed to find an association between >15% oversizing and neck enlargement. This suggests that oversizing is not the only factor involved in the continued expansion of the aortic neck. Different endografts, stent types, and intramural or hemodynamic conditions could also play a role. It is also expected that a patient's genetics is likely to influence susceptibility to enlargement. Although unproven, the intrinsic characteristics of the host aorta could also potentially encourage remodeling. If so, markers, such as elastin and collagen may be useful preoperatively in predicting dilatation.

5.2. Graft migration

Caudal migration of the endovascular graft is one cause of the unsuccessful EVAR. In fact, migration following the EVAR has been reported in many studies with rates ranging from 0% to 45%, varying with different patient populations, follow-up times, and stent-grafts used [25, 41–43]. Migration can occur for a number of reasons, but can be best understood in the context of the biomechanical forces. If the drag force generated by the blood flow overcomes the fixation force between the endograft and aortic wall, the graft will dislodge or migrate. The main factors causing this imbalance are continued aortic neck dilatation, pulsatile blood flow acting on the seal zone, and mechanical or biological features complicating the attachment. Continuous exposure of displacement forces in the direction perpendicular to the endograft may cause eccentric graft compression and result in migration [44]. In turn, graft migration can lead to other complications, such as, endoleak, occlusion, or rupture. In addition, displacement of the stent graft from its apposition site may result in the need for secondary intervention. Since graft oversizing has been linked to aortic dilatation and because it plays an important part in achieving adequate fixation, correctly oversizing the device can potentially limit migration.

Several studies have investigated the association between oversizing and device migration [25, 27, 31, 33, 40, 45–49]. It should be noted that the definition of migration may vary from study to study and the amount of migration can ultimately be associated with worse outcomes. For example, migration of a few millimeters, when compared to complete migration into the aneurysm sac, will have significantly different consequences. Oversizing can help limit migration by increasing the contact pressure between the vessel wall and device [50]. One experimental study found that when oversized an average of 27.7%, 336 g was needed to cause migration, as opposed to only 305 g needed to displace grafts oversized an average of 14.4% [15]. In terms of specific ranges, oversizing >20% seems to require a greater pullout force than when sized under 20% [15]. This result can help explain the trend toward greater oversizing in patients experiencing migration when oversized a mean of 23.5% vs. 18.2% [25]. In a larger study of 1082 patients, oversizing 10–30% had the lowest percentage of migration [46]. Not oversizing enough, e.g., 10% will require lower magnitudes necessary to cause migration compared to devices oversized 20% [51]. Interestingly, migration has been suggested to occur after two displacement forces, one to start the movement and the second, substantially greater, force to cause significant caudal movement [51].

As a potential solution for migration, several devices are now made with active fixation (barbs, anchors, and pins). Barbs and hooks increase the force needed to dislodge a graft [52]. Yet, migration of these grafts can still occur. Thus, when considering the connection of oversizing and device migration, the device type may play a crucial role. Increasing data has indicated that the biomechanical forces vary between devices with regard to active fixation. Kratzberg et al. [48] has shown that as the number of barbs penetrating the aortic wall increases, so does the pullout force. However, the displacement force is not significantly affected by oversizing until above 30%, at which less force is then needed to dislodge the graft [48, 51]. Importantly, grafts oversized >30% can experience significant circumferential deformation/folding at its perimeter that negatively affects the attachment [48]. This has been suggested as a major reason for the lower pullout force for grafts oversized >30% compared to those sized 4–10%, 11–20%, and 21–30% [48]. Sternbergh et al. [40] had similar findings, where they found a 14 time increase in device migration of 5 mm or more for zenith (active fixation) stent-grafts oversized above 30%. Thus, excessive oversizing of aortic stent-grafts with active fixation may come with adverse outcomes. Congruently, Vad et al. have proposed sizing these stents up to 15% [50].

5.3. Endoleak

Although the pathogenesis of aneurysm enlargement is not completely understood, it is generally accepted that the persistent blood flow into the aneurysm sac can lead to further expansion and potentially rupture. Thus, incomplete exclusion and resulting perigraft flow, termed as endoleak, is a significant complication of EVAR. In particular, type I (incomplete seal) and III (mechanical failure of the graft) endoleaks are associated with worse outcomes, with type 1A (proximal) leak posing the greatest risk of rupture [14]. Endoleak is amongst the most common failures reported with rates ranging from approximately 5 to 40% [14, 53–55]. Furthermore, some authors estimate that endoleaks account for over 60% of EVAR reinterventions [56]. Importantly, type I leaks have been attributed to inadequate sizing of endografts [14]. Thus, the impact of oversizing and its role in limiting endoleaks has received considerable attention.

One mechanism in which oversizing has been suggested to cause endoleak is through infolding of the endograft. As mentioned earlier, higher degrees of oversizing have been linked to greater folds [24]. This is significant because the presence of endoleak was subsequently correlated to the size of the biggest fold [24]. Another cause of endoleak is due to the expansion of the aorta often seen from excessive oversizing. Aortic dilatation can create gaps between the endograft and vessel wall, thus allowing the blood to flow into the aneurysm. A third mechanism for endoleaks is from undersizing the aortic stent graft. Undersized grafts exert a weaker radial force on the vessel wall and thus can be influenced by smaller displacement forces from the pulsatile blood flow. In turn, a decrease in radial force can lead to the development of proximal endoleaks [57]. This is likely to occur through the spaces that exist between the stent graft and vessel wall. In particular, separation during the decreasing phase of hydrostatic pressure has been described [57]. This suggests a delayed deformation as the pressure on the attachment site decreases and the aorta relaxes.

Many studies have investigated endoleaks, but few have looked at the relationship between leak and oversizing. One such study of 2146 patients undergoing EVAR with multiple device types, showed a decreased risk of proximal endoleak starting at 10% oversizing with narrow confidence intervals up to 25% [14]. In another study, oversizing >20% was associated with fewer endoleaks (all) and less aneurysm sac enlargement, with the lowest rate of endoleaks occurring between 20 and 25% [58]. A mechanics study had similar findings suggesting that oversizing 20% helps prevent the occurrence of type I endoleaks [57].

Still, several studies failed to find any significance between oversizing and endoleaks, including one that investigated those oversized >30% [40, 54, 59, 60]. Several of these studies were difficult to interpret, due to varying population characteristics and methodology. One reason for this is that oversizing can be complicated by several factors, one being the conditions at the attachment sites. Atherosclerotic plaque, thrombus, and calcifications can interfere with the device-wall interface. Intuitively, the presence of plaque between the graft and the vessel lowers the frictional coefficient, and thus the force too. Amblard et al. suggested that the plaque configuration at the attachment site can be used to predict type I endoleaks [57]. Apposition site morphology has also been thought to contribute to the risk of endoleak. Conical necks, in particular, can pose increased risk because oversizing in the proximal and distal portions of these necks are uneven. This often results in one end being undersized. Thus, greater oversizing may be appropriate if the characteristics are difficult, such as, a reverse tapered neck [61].

6. Histology of the attachment sites and oversizing

Several adaptations occur to the arterial wall after EVAR. Few studies have looked at the effects of oversizing in the abdominal aorta, but the changes seen in the thoracic aorta can still provide valuable information. When a stent graft is implanted, a foreign body reaction can result. One adaptation is a considerable loss of elasticity, especially at the area of compression, regardless of the percentage of oversizing [62]. The same study showed that the max strength sustained and the stress supported by fragments of the aortic wall suffered a linear and progressive loss with increased oversizing [62]. This change can be contributed to a reorganization and change in quantity of collagen and elastic fibers distributed around the apposition sites. In particular, collagen increases in the aortic wall irrespective of the degree of oversizing [62] On the other hand, the amount of muscle fibers decrease in the inner third of the wall with more oversizing [62]. Importantly, oversizing >40% showed evidence of disruption of the fiber content and formation of an aneurysm within the aortic wall [63]. These results should be taken with caution, as the biology of the vessel at the infrarenal level may differ.

7. Imaging/preoperative measurements

Accurate sizing of aortic stent-grafts depends on precise preoperative measurements of the aorta and iliac arteries. In the past, measurements were done using computerized tomography angiography (CTA) axial images, but more recently three-dimensional (3D) reconstructions

with center lumen line (CLL) analysis have taken over [64, 65]. The use of CLL has improved the measurement of preoperative diameters and lengths with superior outcomes, and less intra- and interobserver variability [64, 66]. Yet, accurate and reproducible measurement remains a challenge. Arteries are frequently not perfect circles and thus measurement can vary based on the axis. In response, some have proposed alternative methods that are yet to be validated, such as using circumference [67]. Thus, while using CLL, it is important to follow the manufacturer's IFU measurement instructions. This has become even more evident, as an increasing number of patients undergoing EVAR today have complex apposition site features complicating their measurement.

The use of dynamic CTA can also provide some valuable insight for preoperative planning. Using dynamic CTA, several authors have found that the aortic and iliac arteries diameter, circumference, angles, and lengths change during the cardiac cycle [68–70]. Specifically, an asymmetrical distension is seen with smaller dimensions occurring during diastole. Interestingly, preoperative aneurysm neck pulsatility remains similar even years after EVAR, but the baseline pulsatility is higher for those who experience graft migration [71]. Furthermore, distension due to dynamic changes in the iliac arteries has been suggested to be a cause of distal endoleak [68]. These two observations show how the pulsatility of a patient's vessels can contribute to the over or undersizing of stent-grafts and ultimately lead to poor outcomes. In fact, in one study, endografts were inadequately sized for approximately 25% of patients [72]. Since pulsatility can vary from patient to patient, measurement of those with complex vessel dynamics should be given appropriate attention. Additionally, the fact that vessels expand asymmetrically further supports the use of oversizing as a way to limit gaps between the graft and vessel wall. To account for these dynamic changes during the cardiac cycle, oversizing as much as 20% has been recommended [17, 68].

8. Recent sizing, our experience, conclusions

Advancements in endovascular technique, imaging technology, and device design have led to an expanded use of EVAR in the treatment of AAAs.

Aortic stent-grafts create a new channel for the blood flow and thus shield the diseased aortic wall from continued pressure. A number of factors influence the sealing and fixation of self-expandable stent-grafts. Some include: (1) vessel shape/diameter, (2) seal zone length, (3) angulation/tortuosity, (4) calcification/thrombus, (5) device design (active fixation, material), and (6) vessel hemodynamics. Thus, the anatomy and conditions at or around the apposition sites are important to consider when sizing.

Some recent studies have provided the degree of oversizing of their cohorts and reported outcomes. The ENGAGE study of 1262 patients (approximately one-fifth outside IFU) oversized 20% with respect to the inner vessel diameter reported with no stent migration at 1 year and with satisfactory outcomes [42]. Pitton et al. showed strong results after 10-year follow-up with 20–25% oversizing of proximal diameters and 10–15% oversizing distally [73]. Similarly, in a recent study, 351 patients (mean outer-to-outer wall oversizing 17.7 ± 10.7%) from 2003 to 2014 showed that >20% oversizing was associated with decreased

rates of endoleaks (all) compared with 10–20% oversizing, with the lowest rates in patients oversized 20–25% [58]. Interestingly, larger infrarenal neck diameters were associated with less oversizing. This is suggestive that larger vessels are at risk of being undersized. Although the rate of limb occlusion after EVAR is relatively low, it is worth mentioning that greater than 15% oversizing at the iliac artery was identified as an independent risk factor for limb occlusion [74].

Almost all the recommendations for the degree of oversizing made by manufacturers are based on the patients with ideal conditions, such as, straight aortic necks and nontortuous iliac arteries. This can be problematic when endografts are delivered to complicated apposition sites. For consistency in preoperative measurement, surgeons should follow the protocols outlined by each device manufacturer, as to which axis measurements should be taken from. With regards to oversizing, sizing up to 25% in the aortic neck appears to increase the radial force and lower the risk of proximal endoleak. Although inconclusive, additional oversizing above 25% may be associated with greater risk of aortic dilatation or graft infolding with the potential to cause migration. Ultimately, oversizing, using the current standard of 10–20% remains safe and effective. As more complicated EVAR patients present, practice may need to be adjusted on a patient-specific basis.

Author details

Alex Sher and Rami O. Tadros[*]

Address all correspondence to: rami.tadros@mountsinai.org

The Mount Sinai Medical Center, New York, NY, USA

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