

# CORREÇÃO ENDOVASCULAR DE ANEURISMAS: STATUS ATUAL NAS ESPECIFICAÇÕES E RESULTADOS DAS ENDOPRÓTESES

## ENDOASCULAR ANEURYSM REPAIR: CURRENT STATUS ON DEVICE SPECIFICATIONS AND OUTCOMES

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Recebido a 02 de março de 2018

Aceite a 07 de junho de 2018

### RESUMO

**Introdução:** Desde a sua introdução, em 1991, o tratamento endovascular (EVAR) tornou-se o método de eleição na correção dos aneurismas da aorta abdominal (AAA). Inúmeros dispositivos foram produzidos, desde então, abrangendo anatomias cada vez mais complexas. O objetivo desta revisão é proporcionar uma atualização nas endopróteses disponíveis e comparar os seus resultados.

**Materiais e Métodos:** Foi realizada uma pesquisa, nas bases de dados da MEDLINE, sobre características das endopróteses e respetivos resultados.

**Resultados:** Atualmente, existe uma grande variedade de endopróteses aprovada com propriedades anatómicas distintas. Existem seis próteses com aprovação CE e FDA: Zenith®, AFX®, C3 EXCLUDER®, Endurant® II, Ovation® e Aorfix™; e seis com a aprovação CE: Anaconda™, E-vita ABDOMINAL XT®, E-tegra®, Incraft®, TREOVANCE® e Altura™.

Existem, ainda, quatro próteses fenestradas e ramificadas disponíveis para o tratamento de aneurismas toracoabdominais: Zenith® Fenestrated, Fenestrated Anaconda™, Zenith® p-Branch® and Zenith® t-Branch®.

As endopróteses Endurant II e Treovance acomodam colos aórticos  $\geq 10$  mm; Aorfix e Anaconda são mais flexíveis no que respeita à angulação, permitindo que o ângulo aórtico se estenda até 90°. Por fim, as próteses Zenith, C3 Excluder, Ovation e Incraft podem ser usadas em locais de fixação distal com comprimento  $\geq 10$  mm.

**Conclusão:** As próteses de nova geração têm um melhor desempenho que as mais ancestrais, especialmente no que diz respeito a anatomias complicadas. Os resultados a médio prazo entre as próteses contemporâneas assemelham-se para a maioria das variáveis. Contudo, não existem estudos controlados randomizados comparativos entre as diferentes endopróteses, dificultando a obtenção de conclusões. São necessárias revisões de longo prazo para assumir, assertivamente, pressupostos acerca do desempenho das diferentes próteses.

### Palavras-chave

Aneurisma da aorta abdominal; Correção endovascular de aneurismas da aorta abdominal; endoprótese

### ABSTRACT

**Introduction:** Since its first introduction in 1991, endovascular aneurysm repair (EVAR) became the preferred modality for abdominal aortic aneurysms (AAA) repair. Several devices have been launched over the years addressing progressively more complex anatomies. The aim of this review is to provide an update on current endografts and compare their results.

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**Methods:** MEDLINE databases were searched for endografts features and respective outcomes.

**Results:** Currently, a significant variety of grafts is approved for clinical use, targeting different anatomic properties. There are presently six CE and FDA approved devices: Zenith®, AFX®, C3 EXCLUDER®, Endurant® II, Ovation® and Aorfix™; while six more have only the CE mark: Anaconda™, E-vita ABDOMINAL XT®, E-tegra®, Incraft®, TREOVANCE® and Altura™. Also, there are four fenestrated and branched endografts available for treating thoracoabdominal aneurysms: Zenith® Fenestrated, Fenestrated Anaconda™, Zenith® p-Branch® and Zenith® t-Branch®.

The Endurant II and Treovance stent grafts can accommodate neck lengths  $\geq 10$  mm; Aorfix and Anaconda are more liberal regarding neck angulation, extending of infrarenal neck angulation up to  $90^\circ$ . Finally, Zenith, C3 Excluder, Ovation and Incraft stent grafts can be used with distal fixation length  $\geq 10$  mm.

**Conclusion:** New-generation endografts perform better than the older ones, especially in challenging anatomies. Mid-term outcomes between contemporary stent-grafts seem to be similar for most of the outcomes. However, no randomized controlled trials exist comparing different contemporary stent grafts, making conclusions difficult to accomplish. Long-term follow-up reviews are required to assertively take assumptions about different stent grafts performance.

### Keywords

Abdominal aortic aneurysm, Endovascular Aneurysm Repair, Endograft

## INTRODUCTION

Endovascular aneurysm repair (EVAR) was first introduced in 1991 by Parodi et al.<sup>(1)</sup> and is currently the preferred method for AAA repair due to its minimal invasive profile.<sup>(2)(3)</sup> The landmark randomized clinical trials have emphasized the short-term survival benefits confirmed by large US registries on Medicare beneficiaries.<sup>(4)(6)</sup>

Still, anatomic restraints remain the Achilles Heel of its full applicability. EVAR results are affected by the different anatomic features and, therefore, they constitute a serious concern both for physicians and for stent graft manufacturers. Several Instructions for Use (IFU) have been designed based on anatomic characteristics, in order to maximize EVAR outcomes.<sup>(7)(8)</sup>

The need to exclude progressively more complex AAA, translated in stent graft technological evolution, with introduction of innovative devices widening the eligibility to EVAR.<sup>(2)</sup> Despite the wide range of endografts available, a detailed overview of stent graft particularities and comparison of results are scarcely described.

This review aims to present an update on the current endografts available for aortic abdominal and thoracoabdominal aneurysms repair.

## METHODS

Study design and literature search

A literature search on the MEDLINE databases was performed, to identify studies describing endografts properties and outcomes.

Studies were included if they met the next criteria: data on human implantations, published since 2010 and in English language.

### FDA and CE approved stent grafts

#### Zenith® (Cook Medical Technologies, Bloomington, IN, USA)

The Zenith graft was firstly introduced in 1993 and FDA approved in 2003. Since then, this device underwent several modifications, and is now able to accommodate aortic neck and iliac artery diameters up to 32 and 20 mm, respectively. It is a three-piece modular, bifurcated graft made of woven polyester sutured to a stainless-steel stent frame with proximal active fixation with barbs.<sup>(2)(9)(10)</sup>

The main body is designed to bifurcate right above the aortic bifurcation for added stability. It comes in diameters that vary from 22-36 mm. The main body can be delivered through introducer sheaths measuring from 20-24F. The iliac limb extensions come in a variety of working lengths (37-122 mm), which are introduced through sheaths ranging between 14F and 16F. The major advantage of Zenith is the fact that allows the treatment of a wide range of aortic and iliac arteries diameters.<sup>(10)</sup>

The Zenith stent graft is indicated for treatment of patients with infrarenal neck  $\leq 60^\circ$  and suprarenal neck  $\leq 45^\circ$ . Regarding neck length, Zenith is suitable for necks with  $\geq 15$ mm. This stent graft is indicated in iliac diameters 7.5-20 mm and can be applied when distal fixation length  $\geq 10$  mm.

#### AFX® (Endologix Inc., Irvine, CA, USA)

The AFX graft, available since 2011, is the only unibody endograft that is currently approved in the US. It is made



of a cobalt-chromium stainless steel endoskeleton which is sutured only at the proximal and distal ends of the inner surface of the *graft* material, a low porosity expanded polytetrafluoroethylene (ePTFE), allowing its flexibility.<sup>(11)</sup> It is the only *graft* with anatomical fixation to the aortic bifurcation, offering fixation into both proximal and distal landing zones, in contrast to almost all other *grafts* that present their main fixation point in the infrarenal neck. As the main body rests on the aortic bifurcation, this *graft* seems to be protected from migration.<sup>(11)(12)</sup>

This *graft* accommodates onto the irregularities of the aortic neck which allows its use for narrow bifurcations ( $\leq 15$ mm). Moreover, the AFX has a more durable ePTFE fabric than the Powerlink® system, its predecessor.<sup>(9)</sup>

The AFX main body is available in different diameters - 22, 25 and 28 mm - and lengths - from 40-120 mm (body) and 30-55 mm (limbs).<sup>(11)</sup>

The delivery system of this *stent graft* consists of a 17F hydrophilic introducer sheath with a hemostatic valve and a 9F contralateral percutaneous access and is approved for neck lengths  $\geq 15$  mm neck with an infrarenal angulation less than  $60^\circ$ . The AFX *stent graft* can be used in neck diameters from 18-32 mm. This *stent graft* can be used in patients with iliac diameters 10-23 mm and with distal fixation length  $\geq 15$  mm. However, its navigation and deployment can be challenging for physicians even those with moderate experience, because of its extreme flexibility.<sup>(2)(9)(13)</sup>

### **C3 EXCLUDER® (W.L. Gore & Associates, Inc., USA)**

The Excluder endograft was firstly launched in 1997 and it underwent several modifications, until it was replaced by the third generation device with C3 Delivery System.<sup>(14)(15)</sup> The C3 Excluder is a modular-bifurcated device with a PTFE-fabric and active infrarenal attachment with barbs. While there were no changes made to the device itself, the C3 system, FDA approved in 2011, provides the ability to reposition the *graft* prior to final release from the delivery catheter. This way, the device can be adjusted until the ideal location is reached.<sup>(2)(14)</sup>

This device is currently approved to treat infrarenal aortic neck diameters ranging from 19-32 mm with a minimum aortic neck length of 15 mm and a proximal aortic neck angulation  $\leq 60^\circ$ . Iliac diameters that are adequate for this endograft range 8-25 mm. Distal fixation length should be  $\geq 10$  mm. The C3 Excluder requires a separate introducer sheath with diameters of 18 or 20F for main body deployment.<sup>(3)</sup>

This endograft has been used for 20 years now, with proven safety, efficacy and long-term durability. The enhancements made to this device have led it to become the US market leader for EVAR.<sup>(16)</sup>

### **Endurant® II (Medtronic Vascular, Inc., Minneapolis, MN, USA)**

The Endurant II device, FDA approved in 2012, is the latest generation device that started with the Talent® *stent graft*. Before its introduction, about 1/3 of patients with AAA and about 50% of high-risk AAA patients were excluded from EVAR because of anatomic criteria.<sup>(17)</sup>

It is a modular-bifurcated, composed of nitinol *stents* and polyester *graft*, low-profile (23-36 mm main body sizes deployed through 18F access) device with a sheathless hydrophilic delivery system.<sup>(2)(13)</sup>

The Endurant II provides better resistance to migration in short and angulated proximal aortic necks because of its combination of M-shaped configuration of nitinol *stents* and enhanced suprarenal active fixation with anchoring pins.<sup>(2)</sup>

Precise deployment is achieved using the controlled release system which allows separate deployment of the barbed suprarenal fixation *stent* apart from the main body. Multiple lengths and diameters are available for the iliac limbs with the largest flared limb measuring 28 mm. This *stent graft* is approved for aortic necks at least 10 mm in length with angulation  $\leq 60^\circ$ .<sup>(13)</sup>

This endograft can be used in neck diameters 19-32 mm. In what concerns to iliac diameters, it's indicated when range 8-25 mm. Distal fixation length must be  $\geq 15$  mm.

### **Ovation® (Trivascular Inc, USA)**

The Ovation endograft, FDA approved in 2012, was developed to navigate small, tortuous, or diseased vessels as well as short aortic necks. This device has one of the lowest delivery profile currently approved, 14-15F outer diameter for the main body, and 13-15F for the iliac limbs, providing treatment for patients that present a wide range of iliac access.<sup>(9)(18)</sup>

This device is a bifurcated tri-modular device consisting of an aortic body comprised of ePTFE material, iliac limbs and iliac extensions as required.

IFU for Ovation *stent graft* include proximal neck angulation  $< 60^\circ$ , proximal aortic neck length  $< 7$  mm, aortic neck diameter 16-30 mm (at 13 mm below the lowest renal artery), distal iliac landing zone  $< 10$ mm, and/or aortic neck/iliac inner wall diameter inappropriately sized to the *stent graft*.<sup>(13)</sup>

### **Aorfix™ (Lombard Medical, Didcot, UK)**

The Lombard Aorfix *stent graft* is the more recently FDA approved device (2013) and it was designed to accommodate severe neck angulation.

The Aorfix is a modular device made of woven polyester and a continuous electropolished nitinol wire using a ring *stent* configuration that allows the *stent graft* to be flexed axially without collapsing or twisting. Its features allow

the accommodation of necks with angulation up to 90°, which lies outside the IFU for other devices.<sup>(9)(19)</sup>

The bifurcated endograft has body diameters ranging from 24-31 mm combined with iliac limbs that can vary from 10-20 mm in diameter. The body length ranges from 81- 142 mm. Aortic segments of bifurcated *grafts* with attached ipsilateral leg prostheses are commonly delivered through a 22F sheath, while the contralateral leg is delivered via a 14F sheath. The delivery system provides fine adjustment and precise positioning even inside tortuous anatomy.<sup>(19)</sup>

This endograft is indicated to treat aneurysms with neck lengths  $\geq 15$  mm, neck diameters ranging from 19 to 33 mm and neck angles  $\leq 90^\circ$ . Also, it should be applied when iliac diameters 9-19 mm and distal fixation length  $\geq 15$  mm.

#### CE approved stent grafts

Anaconda™ (Vascutek, Terumo, Inchinnan, Scotland, UK)

The Anaconda *stent graft* system, CE marked in 2005, is a tri-modular device with woven polyester fabric and nitinol skeleton. Since its first introduction, this device suffered alterations that allowed the decrease of migration risk.<sup>(20)</sup>

The main body comes in different proximal diameters that range from 21.5 to 34 mm. On the other hand, the iliac limbs proximal diameters vary from 10 to 23 mm.

The delivery system of the main body has an outer diameter of 20.4 or 22.5F and consists of a flexible thermoplastic fluoropolymer hydrophilic-coated sheath with a repositionable deployment system that enables relocation for optimal positioning; the delivery system for the iliac limbs has an outer diameter of 18.3F.<sup>(13)</sup>

The Anaconda *stent graft* is indicated to treat infrarenal neck angulations up to 90°, with proven results within challenging anatomy.<sup>(21)</sup>

Anaconda is indicated to treat patients with neck length  $\geq 15$  mm and neck diameters ranging 16-31 mm. Iliac diameters range between 8.5mm and 21mm, while appropriated distal fixation length is  $\geq 20$  mm.

#### E-vita ABDOMINAL XT® (Jotec, Hechingen, Germany)

The E-vita *stent graft* is a bi-modular device, first approved for the European market in 2008, composed of low porosity woven polyester fabric and nitinol *stents*, with suprarenal fixation.

The bifurcated main body is available in 150 and 170 mm ipsilateral lengths and in body lengths of 80 and 100 mm to the end of the 14 mm-diameter contralateral connection socket. Proximal diameters range from 24 to 34 mm and iliac diameters from 12 to 24 mm.

Delivery systems for main bodies and aortic extensions are available in 20 and 22F - for contralateral legs and iliac extensions even in sizes as from 16F. The "Squeeze-to-

-Release" mechanism allows for gradual or continuous release at minimum effort, providing most precise positioning and handling.

This device is designated to aortic neck length  $\geq 15$ mm, comprehending diameters range 19-29 mm. It is indicated for neck angles  $\leq 60^\circ$ . It allows treating patients with distal fixation length  $\geq 15$  mm and iliac diameters range 11-23 mm.

#### E-tegra® (Jotec, Hechingen, Germany)

The E-tegra endograft, CE approved in 2014, is a bi-modular device and consists of a main body and a contralateral leg. The system can be individually adapted once iliac and aortic extensions are available in the market. For selected cases the aorto-uni-iliac device will be indicated.

The main body of this *stent graft* is available 80 and 100 mm length, while the proximal diameter ranges from 23 to 36 mm. The contralateral leg is available with a proximal diameter of 15 mm, while iliac extension varies from 13 to 27 mm. It shares the same delivery system, "Squeeze-to-Release", with E-vita ABDOMINAL XT, which is available in 18 and 20F for the main body, aortic extensions and aorto-uni-iliac components and start at only 16F for contralateral legs and iliac extensions.

The main differences between this endograft and E-vita ABDOMINAL XT are the fact that E-tegra is more flexible, allowing neck diameters up to 32mm to be treated. Also, E-tegra is indicated in aortic neck angulation up to 75°.

#### Incraft® (Cordis, Fremont, CA, USA)

The Incraft *stent graft*, available since 2014, is a next-generation, ultra-low profile, bifurcated *graft* that was designed to overcome the limitation of smaller and more diseased access vessels.

It is a tri-modular device constructed of a seamless, low porosity, woven polyester *graft* maintained by a series of self-expanding nitinol *stents* throughout the whole *graft*.<sup>(2)</sup> The main body comes in 26 and 30 mm diameters, while iliac *graft* limbs are available in diameters that range from 13-20 mm.<sup>(22)</sup>

The most remarkable features of this *stent graft* are: low profile - with a delivery system for the main body with an outer diameter of 14F, which enables delivering through narrow iliac vessels - and extremely bendable delivery system; "in situ length adjustment" of the limb prostheses for optimal distal landing; suture knots on the outer surface of the limb prostheses comprise an interlocking mechanism between the components, that removes the risk of limb separation.<sup>(23)</sup>

The Incraft endograft is indicated in neck length  $\geq 15$  mm, neck diameters 17-31 mm, neck angulation  $\leq 60^\circ$ . Iliac diameter can range from 7-22 mm.



**TREOVANCE® (Bolton Medical, Inc., Barcelona, Spain)**

The Treovance *stent graft*, CE approved since 2015, it's a tri-modular system that consists of a main bifurcated body and two leg extensions. It is made of self-expanding nitinol *stents* sutured to woven polyester fabric. Unlike other endografts that have suprarenal or infrarenal fixation, multiple proximal fixation points are provided by suprarenal and infrarenal barbs extending from the suprarenal *stent*. The double level of proximal barbs contributes to minimize the risk of migration even in tortuous anatomies.<sup>(24)</sup>

The main body of this endograft comes in different diameters (20-36 mm) while each leg is always the same diameter (14 mm), regardless of the proximal diameter size.

The delivery system is low-profile, flexible and hydrophilic with detachable sheaths. Sheath sizes for the main body ranges from 18 (for main bodies up to 28 mm) to 19F (for larger diameters) and iliac limb system ranges from 13 to 14F.<sup>(13)</sup>

This device has quite specific IFU, allowing treatment of neck lengths  $\geq 10$  mm; neck diameters 17-32mm if neck length  $\geq 10$  mm, and 16-30 mm if neck length  $>15$ mm; iliac diameter 8-13, if iliac length  $\geq 10$  mm and 14-20 mm if iliac length  $\geq 15$  mm.

**Altura™ (Lombard Medical, Didcot, UK)**

The Altura *stent graft* is the most recent CE marked endograft (2015). It consists of a braided nitinol frame, a fabric woven polyester sleeve with a flexible modular system. Its fixation is suprarenal. The evolutionary step was to split the main infrarenal body into two sections, which has the potential to simplify EVAR.

The top and bottom *stents* are placed first, and if the *stent* overlap is too small, a simple universal bridging piece is placed to bridge the central portion.

One of the features that makes this device unique is that there's no need for contralateral limb cannulation, as both iliac limbs are simply inserted over the preexisting stiff wires. The delivery system has an ultra-low profile with an outer diameter of 14F.

This endograft is available in diameters that range between 24-30 mm, whereas the suprarenal *stent* diameter ranges from 29-36 mm. The leg has a 13 mm universal diameter. The iliac limbs diameters vary from 13-21 mm.

Altura *stent graft* is indicated if neck length  $\geq 15$  mm, neck diameters from 18-28 mm, neck angulation  $\leq 60^\circ$  and iliac diameter 8-18mm.

**Tabela 1** FDA and CE approved devices. Main characteristics.

Device	Graft material	Support	Design	Proximal fixation
Zenith (Cook Medical)	Woven polyester	Stainless steel	Tri-modular	Suprarenal
AFX (Endologix)	ePTFE	Cobalt-chromium stainless steel	Unibody	Infrarenal
C3 Excluder (Gore)	ePTFE	Nitinol	Bi-modular	Infrarenal
Endurant II (Medtronic)	Woven polyester	Nitinol	Bi-modular	Suprarenal
Ovation (Trivascular)	ePTFE	Nitinol	Tri-modular	Suprarenal
Aorfix (Lombard Medical)	Woven polyester	Nitinol	Bi-modular	Infrarenal
Anaconda (Vascutek)	Woven polyester	Nitinol	Tri-modular	Infrarenal
E-vita ABDOMINAL XT (Jotec)	Woven polyester	Nitinol	Bi-modular	Suprarenal
E-tegra (Jotec)	Woven polyester	Nitinol	Bi-modular	Suprarenal
Incraft (Cordis)	Woven polyester	Nitinol	Tri-modular	Suprarenal
Treovance (Bolton Medical)	Woven polyester	Nitinol	Tri-modular	Suprarenal and infrarenal
Altura (Lombard Medical)	Woven polyester	Nitinol	Bi-modular	Suprarenal

Tabela 2 Instructions for Use (IFU).

Device	Neck length (mm)	Neck diameter (mm)	Neck angulation (°)	Distal fixation length (mm)	Iliac diameter (mm)
Zenith (Cook Medical)	≥15	18-32	Infrarenal ≤60; suprarenal ≤ 45	≥10	7.5-20
AFX (Endologix)	≥15	18-32	≤60	≥15	10-23
C3 Excluder (Gore)	≥15	19-32	≤60	≥10	8-25
Endurant II (Medtronic)	≥10	19-32	≤ 60	≥15	8-25
Ovation (Trivascular)	-	16-30 at 13 mm IR*	≤60 if neck ≥10 mm ≤45 if neck <10mm	≥10	8-20
Aorfix (Lombard Medical)	≥15	19-33	≤ 90	≥15	9-19
Anaconda (Vascutek)	≥15	16-31	≤90	≥20	8.5-21
E-vita ABDOMINAL XT (Jotec)	≥15	19-29	≤60	≥15	11-23
E-tegra (Jotec)	≥15	19-32	≤75	≥15	8-25
Incraft (Cordis)	≥15	17-31	≤60	≥10	7-22
Treovance (Bolton Medical)	≥10	17-32 with neck length ≥10; 16-30 with neck length ≥15	IR ≤ 60 if neck length 10-14 mm; 60-75 if neck length >15 mm	≥10 with diameter 8-13 ≥15 with diameter 14-20	8-13 if iliac length ≥10; 14-20 if iliac length ≥15
Altura (Lombard Medical)	≥15	18-28	≤60	≥15	8-18

### Fenestrated and Branched Stent Grafts

Up to 40% of patients are unsuitable for traditional EVAR. In patients with a juxtarenal or thoracoabdominal aneurysm there is no proximal or distal zone for anchorage. To overcome these limitations, fenestrated and branched *stent grafts* were developed.<sup>(25)(28)</sup>

Fenestrated *grafts* were developed with holes in the device, which are positioned adjacent to the aortic branch artery orifices. Distinctively, branched *stent grafts* incorporate pre-attached limbs or cuffs targeted for visceral aortic branches.<sup>(29)</sup>

#### Zenith® Fenestrated AAA Endovascular Graft (Cook Medical Technologies, Bloomington, IN, USA)

The only fenestrated *stent graft* currently FDA approved is the Zenith fenestrated endovascular *stent graft*.<sup>(26)</sup>

This device is a modular system with three components: a proximal body *graft*, a distal bifurcated body *graft* and one iliac leg. These are made of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z® *stents* with braided polyester and monofilament polypropylene suture. Ancillary devices such as main body extensions, iliac leg extensions, converters and iliac plugs

may also be required. The delivery system uses a 20 or 22F H&L-B One-Shot Introduction System.

The Zenith Fenestrated is indicated to treat patients with abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair, including non-aneurysmal infrarenal aortic segment proximal to the aneurysm with a length ≥4mm and unsuitable for a non-fenestrated *graft*; a diameter ≥19mm and ≤31mm and angulation <45°. Ipsilateral iliac artery distal fixation must be >30mm in length and 9-21mm in diameter, while contralateral iliac artery distal fixation site >30mm in length and 7-21mm in diameter is required.

#### Fenestrated Anaconda™ (Vascutek, Terumo, Inchinnan, Scotland, UK)

The Fenestrated Anaconda *stent graft* is not FDA-approved; however it is commercially available in Europe. The system consists of an aortic endograft and two separate iliac limbs. The proximal end of the main body consists of two separate nitinol ring *stents* and four pairs of nitinol hooks that aid in sealing. The main body itself does not contain any *stents*, allowing for flexibility in fenestration placement. After deployment, the device can be fully repositioned. It



also offers a magnetically assisted limb cannulation system that can decrease contralateral cannulation time. This *stent graft* is custom made for each patient. <sup>(28)(30)(32)</sup>

#### **Zenith® p-Branch® Endovascular Graft (Cook Medical Technologies, Bloomington, IN, USA)**

The Zenith pivot branch (p-branch) endograft is a tubular, fenestrated device designed to work as a single implant when the distal landing site within a prior aortic repair is  $\leq 22$  mm or as the proximal component of a modular bifurcated system that may be combined with other Zenith devices. It is made of polyethylene terephthalate fabric with a proximal stainless steel uncovered barbed supraceliac *stent*, followed by a series of nitinol Z-*stents* that incorporate a scallop for the celiac artery, a fenestration for the superior mesenteric artery and two renal pivot fenestrations. The renal fenestrations are precannulated, making it easier to catheterize the target vessels. <sup>(33)(34)</sup> The delivery system consists of a 20 F system.

The Zenith p-branch is indicated to treat patients with a non-aneurysmal aortic segment proximal to the aneurysm with  $\geq 4$  mm of length, a 21-31mm diameter, an angle  $< 60^\circ$  relative to the centerline of the aneurysm and an angle  $< 45^\circ$  relative to the supraceliac aorta. Also, renal vessel origins as measured relative to the superior mesenteric artery compatible with the renal fenestration and celiac vessel origin compatible with the celiac scallop. <sup>(35)</sup>

#### **Zenith® t-Branch® Thoracoabdominal Endovascular Graft (Cook Medical Technologies, Bloomington, IN, USA)**

The Zenith t-Branch thoracoabdominal endovascular *graft* is designed to be used in combination with other Zenith thoracic endovascular *grafts*, Zenith distal endovascular *grafts* and iliac leg *grafts*.

It consists of a tubular *graft* with four branches and with a covered *stent* at the proximal end that contains barbs for additional fixation of the device. The purpose of the branches is to allow uninterrupted blood flow to visceral vessels of the aorta. This device is designed to be connected with the celiac, superior mesenteric and two renal arteries via self-expanding covered vascular bridging *stents*.

It is made of woven polyester sewn to self-expanding stainless steel Cook-Z® *stents* with braided polyester and monofilament polypropylene suture.

The delivery system uses a 22F H&L-B One-Shot Introduction System.

The Zenith t-Branch is indicated for the endovascular treatment of high-risk patients with thoracoabdominal aneurysms who are not amenable to open surgical repair. The patient must have a non-aneurysmal thoracic aorta

fixation segment proximal to the aneurysm with an angle  $< 90^\circ$ , with a length  $\geq 25$ mm and a diameter  $\geq 24$ mm and  $\leq 30$ mm.

Alternatively, this endograft can be attached to a preexisting endovascular *graft*.

Also, celiac and superior mesenteric arteries must be 6-10mm in diameter, renal arteries 4-8mm, the distance between each cuff and the corresponding arterial orifice  $< 50$ mm and the line between the cuff and the arterial orifice as projected onto the vessel wall deviates by no more than  $45^\circ$  from the long axis of the aorta.

## DISCUSSION

EVAR represents the most common modality for AAA repair. However, a significant *stent graft* evolution has occurred over the last years.

The first generation endografts were devices with very high complication rates, particularly *stent* migration and limb occlusion. <sup>(3)</sup>

Since then, the manufacturers made an effort to correct major *drawbacks*: *Stent* migration and limb occlusion rates have been drastically reduced, which allowed a great increase in their durability, leading to lower rates of morbidity. The most iconic examples are the evolution of Talent *stent graft* to Endurant and also the advancement made with the Excluder. <sup>(3)(36-40)</sup>

Based on available literature, endografts have overlapping results in what concerns major adverse events. (Table 3)

The Zenith endograft, in a mean *follow-up* period of 66.4-99.2 months, presented 2-2.1% of AAA-related death, 1.1-4.2% of aneurysm rupture, 14.9-25.9% of secondary intervention, 6.73-12.6% of type I *endoleaks*, 0.7-1.1% of *stent* migration ( $\geq 10$  mm) and 3.4-7.7% of limb occlusion. <sup>(39)(41)</sup> The AFX *stent graft*, in a mean *follow-up* period of 9-10 months, showed the following *outcomes*: null rates of AAA-related deaths, aneurysm rupture or limb occlusion; 5.6% of secondary intervention, 0-1.93% of type I *endoleak* and, finally, *stent* migration ( $\geq 10$  mm) range 0-0.97%. <sup>(11)(42)</sup>

The Excluder *stent graft*, in a mean *follow-up* period of 15.9-60 months, presented 0-4.4% of AAA-related deaths, 0-0.7% of aneurysm rupture, 6.5-22.5% of secondary interventions, 1-7.8% of type I *endoleaks*, 0-13.4% of *stent* migration ( $\geq 10$  mm) and 0.5-1.4% of limb occlusion. <sup>(40)(43-45)</sup>

The Endurant device, in a mean *follow-up* period of 12-60 months, it were reported 0-3% of AAA-related death, 0-1% of aneurysm rupture, 3.8-27% of secondary intervention, 0-7% of type I *endoleaks*, null rates of *stent* migration ( $\geq 10$  mm) in all four studies and 1.3-4% of limb occlusion. <sup>(46-49)</sup>

The Endurant device was also studied in challenging anatomies. Inclusion criteria were short proximal aortic necks ( $\leq 15$  mm) and/or small ( $< 8$  mm), calcified and severely angulated/tortuous (Iliac tortuosity index [ITI]  $\geq 1.4$ ) iliac access vessels. In a mean *follow-up* period of 15 months 2% aneurysm-related death was registered with 4% of patients presenting with had contained aneurysm ruptures. Reintervention was needed in 8% of patients. There was a 6% rate of type I *endoleak* as well as a 6% rate of type II *endoleak*. Graft limb occlusion was noticed in 4% of patients.<sup>(50)</sup>

Five-year data from the ENGAGE registry, which included *follow-up* imaging from approximately 500 of the 1262 initial patients, was presented at the 39th Charing Cross Symposium, in 2017. It was stated a 97.8% freedom from AAA-related death, 84.3% freedom from secondary procedures and 89.4% stable or decrease in AAA sac diameter.

The Ovation endograft, in a mean *follow-up* period of 12-20.4 months, presented 0-0.6% of AAA-related deaths, null aneurysm rupture and *stent* migration ( $\geq 10$  mm) rates, 3.8-6.2% of secondary intervention, 5.1-34% of *endoleaks*, all type II, and limb occlusion ranging 0.64-1.2%.<sup>(18)(51)</sup>

As it goes for the Aorfix endograft, in a mean *follow-up* period of 14-60 months, aneurysm-related deaths ranges from 0 to 4%, while presenting 0-1% of aneurysm rupture, 0-17% of reintervention, 0-5% of type I *endoleak*, 0-4% of *stent* migration ( $\geq 10$  mm) and, finally, 0-3.8% of limb occlusion.<sup>(52-54)</sup>

In a 40-month study, with the use of Anaconda *stent graft* it was obtained 0% of AAA-related death, 2.8% of aneurysm rupture, 16.7% of secondary intervention, 41.7% of *endoleak*, including 11.1% type I *endoleak*, 6% of *stent* migration and 14% of limb occlusion.<sup>(21)</sup>

In what concerns to the Incraft device, in a 24-month *follow-up* period, null rates of aneurysm-related death, aneurysm rupture and also *stent* migration were observed. There was a 5% reintervention rate, 38.8% *endoleak* rate, all type II, and 1.7% limb occlusion rate.<sup>(22)</sup>

For TREVANCE, in a mean *follow-up* period ranging from 30 days to 12 months, it was registered a 0% of AAA-related deaths, as well as aneurysm rupture, secondary intervention, *stent* migration and limb occlusion. There was a 10-11% type II *endoleak* rate.<sup>(24)(55)</sup>

For the most recent *stent graft*, Altura, there's only provisory results from the ELEVATE registry; At 1 year, clinical success was obtained in 97.3% of the 103 initial patients, type I *endoleak* rate was 1%, and there are no recorded cases of migration. There are now 30 Altura treated patients with 2-year *follow-up* and all of them are free from type I *endoleak*, as are the 12 patients with 3-year *follow-up*. At 3 years, no migrations are

reported. A 1000 patients multicenter registry, ALTITUDE study, started in 2017.<sup>(56)</sup>

Unfortunately, there is no recent data available neither for E-vita ABDOMINAL XT nor E-tegra.

In what concerns to fenestrated and branched devices, the obtained results in the different studies are also similar. (Table 4)

The Zenith Fenestrated endograft, in a mean *follow-up* period of 30-54 months, presented 0-1.5% of AAA-related death, 0-6.7% of aneurysm rupture, 13.3-22.4% of secondary intervention, 1.5-13.3% of type I *endoleaks*, 3% of *stent* migration ( $\geq 10$  mm) and 20.9% of limb occlusion.<sup>(57)(58)</sup>

The Fenestrated Anaconda *stent graft*, in a mean *follow-up* period of 11-12 months, presented 1-4% of AAA-related death, 0% of aneurysm rupture, 0-7.9% of secondary intervention and 10.9-12% of type I *endoleaks*.<sup>(32)(59)</sup>

The Zenith p-Branch endograft, in a mean *follow-up* period of 4.3-38 months, presented no AAA-related death nor aneurysm rupture; 12.5-34% of secondary intervention, 0-1.3% of type I *endoleaks*, 1.3% of *stent* migration ( $\geq 10$  mm) and 6.3-10.5% of limb occlusion.<sup>(35)(60)</sup>

The Zenith t-Branch thoracoabdominal endograft, in a mean *follow-up* period of 5-24 months, presented 0-9% of AAA-related death, 0% of type I *endoleaks*, and 0-2.4% of limb occlusion.<sup>(61)(62)</sup>

A major flaw in many of these endografts *outcomes* is the lack of long-term data.

While the older *stent grafts*, like Zenith, Excluder and Endurant have long-term ( $\geq 5$  years) results published, other *stent grafts* recently introduced, only have short to midterm data available. This makes the comparison between different endografts unreasonable. Despite this, the few available long-term *outcomes* withstand the effectiveness and safety of EVAR technique.

From the data presented in this review, it can be settled that new generation endografts perform better, particularly in challenging anatomies. The paradigmatic example is the Gore C3 Excluder. The C3 system results in reduced procedural time and, simultaneously, it allows a great number of patients to be eligible for EVAR. Despite there was no significant difference in what concerns to major adverse events neither in survival rates, compared to the previous generation, the C3 system demonstrated to be safer and more effective in high-risk patients.<sup>(14)</sup>

Furthermore, the comparative studies point out that more recent endoprosthesis are associated with less complications, re-intervention and mortality rates; and are more implanted in challenging anatomies. Verzini et al. reported a higher 7-year freedom from reintervention and late conversion events (83.6 vs. 74.2%, 96.1 vs 89.1%) for the



newer endografts.<sup>(63)</sup> In a single center study comparing the *outcomes* of Endurant with Talent, its predecessor, the rate of type I *endoleak* was higher for the Talent group (5.7 vs. 2.8%,  $p=0.614$ ). Type III *endoleaks* were reported only in this group (2.9%,  $p=0.493$ ) while type II *endoleaks* were significantly more frequent in patients treated with the old-generation endograft (28.6 vs. 8.3%,  $p=0.035$ ).<sup>(64)</sup> However, continuous surveillance is imperative whether old *grafts* or new generation *stents* are used.<sup>(2)(65)</sup> Reports from different *stent graft performance* reveal that EVAR represents a safe and efficient modality of treatment regardless of the type of endograft used, as long as compliance to IFU for each *stent graft* is respected.<sup>(66-69)</sup> It's of high importance to emphasize that no randomized

comparative trial between different *stent grafts* has been carried out. This epitomizes the difficulty in generalizing the selection of the appropriate device and, on the reverse side of the coin, the ephemerality of endografts.

## CONCLUSION

New-generation endografts appear to provide better results while broadening eligibility criteria. Long-term data *performance* seems to be similar for the different devices. This reinforces the need for a tailored selection of devices according to patient's anatomy. Still, further long-term studies are needed to assure differences in EVAR durability and efficacy between different devices.

Tabela 3 Major Studies Outcomes Summary.

Device	Follow-up (months)	AAA-related death (%)	Aneurysm rupture (%)	Reinterventions (%)	Endoleaks (%)	Type I endoleaks (%)	Migration (%)	Iliac limb occlusion (%)
Zenith <sup>(38,41)</sup>	66.4-99.2	2-2.1	1.1-4.2	14.9-25.9	25.6-32.9	6.73-12.6	0.7-1.1	3.4-7.7
AFX <sup>(11,42)</sup>	9-10	0	0	5.6	4.8-8.7	0-1.93	0-0.97	0
Excluder <sup>(40)(43-45)</sup>	15.9-60	0-4.4	0-0.7	6.5-22.5	4-31	1-7.8	0-13.4	0.5-1.4
Endurant <sup>(46-49)</sup>	12-60	0-3	0-1	3.8-27	6.8-35	0-7	0	1.3-4
Ovation <sup>(18)(51)</sup>	12-20.4	0-0.6	0	3.8-6.2	5.1-34	0	0	0.64-1.2
Aorfix <sup>(52-54)</sup>	14-60	0-4	0-1	0-17	3.8-9	0-5	0-4	0-3.8
Anaconda <sup>(21)</sup>	40	0	2.8	16.7	41.7	11.1	6	14
Incraft <sup>(22)</sup>	24	0	0	5	38.8	0	0	1.7
Treovance <sup>(24)(55)</sup>	1-12	0	0	2.9	10-11	0	0	0

Tabela 4 Major Studies for Fenestrated and Branched Devices Outcomes Summary

Device	Follow-up (months)	AAA-related death (%)	Aneurysm rupture (%)	Reinterventions (%)	Endoleaks (%)	Type I endoleaks (%)	Migration (%)	Iliac limb occlusion (%)
Zenith Fenestrated <sup>(57,58)</sup>	30-54	0-1.5	0-6.7	13.3-22.4	26.7-35.8	1.5-13.3	3	20.9
Fenestrated Anaconda <sup>(32,59)</sup>	11-12	1-4	0	0-7.9	29.7-40	10.9-12	-	-
Zenith p-Branch <sup>(35,60)</sup>	4.3-38	0	0	12.5-34	8	0-1.3	1.3	6.3-10.5
Zenith t-Branch <sup>(61,62)</sup>	5-24	0-9	-	-	33.3-43	0	-	0-2.4

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