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Zenith Alpha™ Thoracic Endovascular Graft

Quentin Pellenc, Arnaud Roussel, Jean Senemaud, Romain De Blic, Yves Castier

Chirurgie Vasculaire

Hôpital Bichât, Paris

HÔPITAUX UNIVERSITAIRES PARIS NORD VAL DE SEINE
Bichat - Claude Bernard

université PARIS DIDEROT PARIS 7

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Device Overview

Zenith Alpha™ Thoracic Endovascular Graft was designed to offer:

- The lowest profile sheath available
- Improved conformability
- An extensive range of sizes
- An intuitive introduction system
- A durable aortic repair

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Device Overview

Zenith Alpha™ Thoracic Endovascular Graft

- Indication: Aneurysm/ulcer/traumatic injury of descending thoracic aorta
- Two-piece modular system
- Proximal and distal anchoring barbs
- Nitinol stents
- Graft diameters: 18-46 mm
- 16-20 Fr (ID) introduction system

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Influence of gender on outcomes after thoracic endovascular aneurysm repair

George J. Arnaoutakis, MD,a Eric B. Schneider, PhD,b Dean J. Arnaoutakis, MD, MBA,a James H. Black III, MD,a Ying Wei Lum, MD,a Bruce A. Perler, MD, MBA,a Julie A. Freischlag, MD,a and Christopher J. Abularrage, MD,a *Baltimore, Md*

Conclusions: Thirty-day unadjusted mortality after TEVAR for nonruptured thoracic aortic aneurysms is increased in women compared with men, but this univariate finding did not persist after risk adjustment. Multivariable analysis showed need for iliac artery exposure, age, and emergency surgery were independently associated with higher mortality rates. These results suggest a need for decreased device delivery size and improvements in endovascular technology.

(J Vasc Surg 2014;59:45-51.)

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Notable Features: Access and Fit

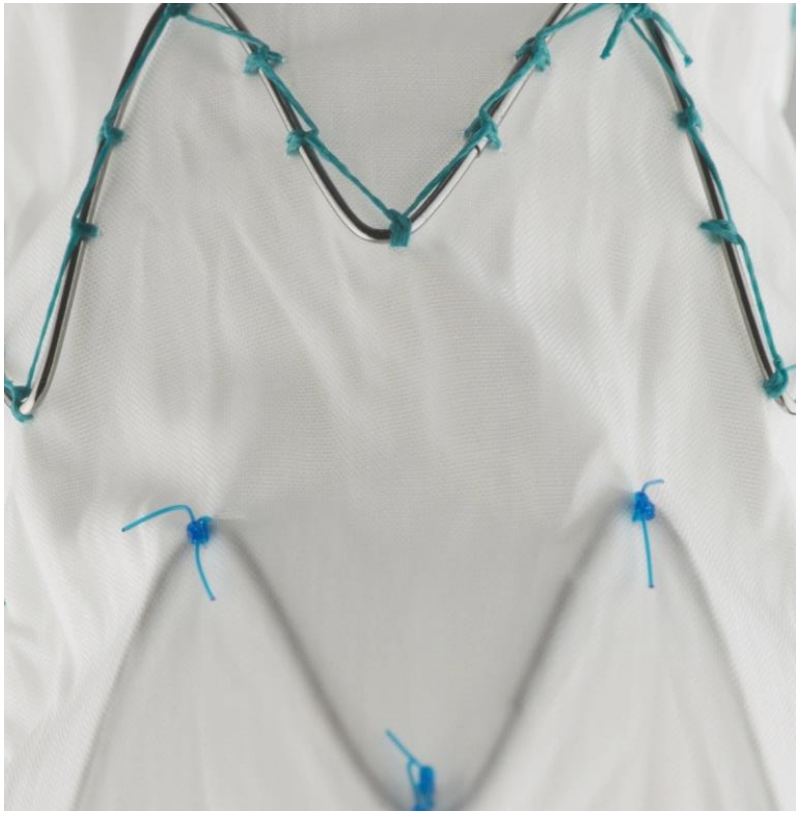
Designed to allow minimally invasive treatment of a broad range of patients

Low profile

- Nitinol stents
- Thin, tightly woven polyester

Percutaneous access

Extensive size range



Ilig, JVS, 2015

- Clinical trial (110 pts)
- Elective TT
- 1 year follow-up (108 pts)
- one year device success 93%
- Access site complications: 8%

- Results indicate expanded TEVAR applicability, including its use in women and patients with a smaller stature

One-year outcomes from the international multicenter study of the Zenith Alpha Thoracic Endovascular Graft for thoracic endovascular repair

Karl A. Illig, MD,[a] Takao Ohki, MD,[b] G. Chad Hughes, MD,[c] Masaaki Kato, MD,[d] Hideyuki Shimizu, MD,[e] Himanshu J. Patel, MD,[f] Ali Shahriari, MD,[g] and Shraddha Mehta, PhD,[h] on behalf of Zenith TX2 Low Profile study investigators, *Tampa, Fla; Tokyo and Osaka, Japan; Durham, NC; Ann Arbor, Mich; and Indianapolis and West Lafayette, Ind*

Objective: This study evaluated the safety and effectiveness of the Zenith Alpha Thoracic Endovascular Graft (Cook Medical, Bloomington, Ind) for the treatment of descending thoracic aortic aneurysms and large ulcers.
Methods: The Zenith Alpha Thoracic Endovascular Graft, with a 16F to 20F delivery system, was developed to address vascular access issues associated with larger-profile devices and to increase conformability in tortuous anatomy. This prospective, nonrandomized, multicenter study was conducted in Europe, Japan, and the United States. The main anatomical inclusion criteria included proximal neck seal zone of ≥20 mm, aortic arch radius of ≥30 mm, and a neck diameter of 18 to 42 mm. Patients were evaluated preprocedure, predischarge, and postdischarge 1, 6, and 12 months and yearly thereafter through 5 years.
Results: Between March 2010 and January 2013, 110 patients (58 men and 42 women; mean age, 72 ± 10 years) were enrolled in the study for the treatment of descending thoracic aortic aneurysms (n = 90) or ulcers (n = 20). Access was percutaneous in 36% (40 of 110) of patients. The study device was successfully implanted in all but two patients (both due to inability to gain access or advance to the target treatment site). There was no 30-day mortality. Five deaths occurred ≤1 year (only one was aneurysm-related by independent adjudication), resulting in a 95% freedom from all-cause mortality and a 99% freedom from thoracoabdominal aneurysm-related mortality. At one or more time points ≤1 year, type I endoleak (all distal) was observed in 4 patients, type III endoleak in 2, and aneurysm growth in 4. Five patients experienced stroke ≤1 year (2 procedure-related). No aortic rupture, paraplegia, paralysis, or permanent spinal cord injury was observed ≤1 year.
Conclusions: Early outcomes after Zenith Alpha implantation appear promising and suggest expanded thoracic endovascular aortic repair applicability in patients with smaller access vessels. Longer-term follow-up is ongoing. (J Vasc Surg 2015;■:1-10.)

From the Department of Surgery, Division of Vascular Surgery, University of South Florida, Tampa[a]; the Department of Surgery, Division of Vascular Surgery, Jikei University Hospital, Tokyo[b]; the Department of Surgery, Division of Vascular Surgery, Duke University Medical Center, Durham[c]; the Department of Surgery, Division of Vascular Surgery, Morinomiya Hospital, Osaka[d]; the Department of Surgery, Division of Vascular Surgery, Keio University Hospital, Tokyo[e]; the Department of Surgery, Division of Vascular Surgery, University of Michigan, Ann Arbor[f]; the Indiana Heart Institute, Indianapolis[g]; and the Cook Research Incorporated, West Lafayette.[h]

Author conflict of interest: This study was sponsored by Cook Medical. S.M. was an employee of Cook Research Incorporated, a Cook Group company. None of the other authors have any conflicts of interest. The authors had full access to the study data and took full responsibility of the integrity of study results. The authors were responsible for writing and editing of the manuscript, as well as the final decision to submit for publication.
Additional material for this article may be found online at www.jvascsurg.org.
Correspondence: Karl A. Illig, MD, Division of Vascular Surgery, University of South Florida Morsani College of Medicine, 2 Tampa General Cir, STC 7016, Tampa, FL 33606 (e-mail: kilig@health.usf.edu).
The editor and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to define review of any

Thoracic endovascular aortic repair (TEVAR) for aneurysms and penetrating ulcers has been performed regularly since the mid-1990s and has demonstrated benefits over open repair in reducing aneurysm-related mortality and severe morbidity.[1-6] An estimated 10,000 patients annually undergo thoracic aneurysm repair in the United States,[7] and commercially developed devices are now available from multiple manufacturers.

The Cook Zenith TX2 Endovascular Graft (Cook Medical, Bloomington, Ind) and its predecessors have been studied clinically since 2001. The Zenith TX2 device was made available in Australia in 2002, in Europe in 2004, and was approved for use in the United States in 2008. To date, ~30,000 such devices have been implanted worldwide. Short-term and long-term outcomes appear excellent.[5,6,8,9] Like most thoracic endografts, however, the introducer sheaths are relatively large, measuring 20F to 22F (7.7 mm to 8.5 mm in outer diameters) depending on the graft diameter used.

There is an unmet clinical need for smaller-profile

Conclusions: Early outcomes after Zenith Alpha implantation appear promising and suggest expanded thoracic endovascular aortic repair applicability in patients with smaller access vessels. Longer-term follow-up is ongoing. (J Vasc Surg 2015;■:1-10.)

Clinical Investigation

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Initial Clinical Experience With the Zenith Alpha Stent-Graft

Giovanni F. Torsello, MD[1,2,3], Martin Austermann, MD[2], Hugo K. Van Aken, MD, PhD[3], Giovanni B. Torsello, MD[2], and Giuseppe Panuccio, MD[2]

Abstract

Purpose: To assess safety and short-term efficacy of endovascular repair of the thoracic aorta with the new Zenith Alpha stent-graft. **Methods:** Between August 2010 and May 2014, 33 patients (21 men; mean age 73.2±9.0 years) were treated Zenith Alpha stent-graft (group ZA). Outcomes of this group were compared with those of 34 patients (25 men; mean age 70.3±8.5 years) treated contemporaneously with the Zenith TX-2 for the same pathologies (group TX). The primary outcome measure was technical success. Data on iliac tortuosity, minimum access vessel diameter, and previous unsuccessful treatment with other endografts was also recorded. **Results:** Technical success was 93.9% in group ZA and 91.2% in group TX (p=0.67). There was no case of surgical death or conversion to open repair in either group. Two (6%) type I endoleaks occurred in group ZA and 3 (9%) in group TX (p=0.67). Three patients died within 30 days in group ZA vs. none in group TX (p=0.07). Mean minimum access vessel diameter was significantly smaller (5.07 vs. 6.65 mm, p=0.002) and iliac tortuosity indices significantly higher in group ZA (1.34 vs. 1.25, p=0.02). Access vessel complications occurred in 1 (3%) patient in group ZA and 4 (12%) patients in group TX (p=0.17). Significantly more patients in group ZA (6, 18%) were unsuccessfully treated previously with other endografts vs. none in group TX (p=0.01). **Conclusion:** The new Zenith Alpha appears to be equally as safe and efficacious as the Zenith TX-2 while being used in patients with demanding access vessel morphology.

Keywords

thoracic endovascular aortic repair, thoracic aneurysm, thoracic endograft, low-profile device, vascular access, iliac artery, tortuosity, access vessel diameter, morphology

Introduction

Therapy of thoracic aortic disease has always been among the most complex treatments since the introduction of open aortic repair. Today, thoracic endovascular aortic repair (TEVAR) is a well-established option in the treatment of several aortic pathologies. In the past few years, TEVAR has assumed a larger role in treatment after studies demonstrated mortality and morbidity benefits of the endovascular approach over open reconstruction.[1] Clinical benefits, such as reduced blood loss, less need for intensive care treatment, and shortened time to ambulation, as well as a marked reduction in perioperative complications (eg, paraplegia or renal insufficiency),[1] have supported the use of TEVAR as the first-line treatment in selected patients.

Morphological characteristics involving the access vessels, landing zone, lesion position relative to the aortic branc
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with a marked decrease in profile and optimized flexibility.[3] The aim of this study was to compare the performance of this device with a predicate stent-graft of similar type in the treatment of thoracic aortic aneurysm (TAA) and other aortic pathologies, especially with regard to its applicability in patients with difficult access vessels.

Methods

Device Description

The Zenith Alpha TAA Endovascular Graft (William Cook Europe, Bjaeverskov, Denmark) has been described in

[1]Westphalian Center for Radiology, Münster, Germany
[2]St. Franziskus Hospital and University Clinic of Münster, Germany
[3]Department of Anesthesiology, Intensive Care and Pain Therapy,

Torsello, JET, 2015

-Single center study (33 pts) compared with TX2 (34 pts)

-Technical success: 94%

-Fewer access related complications (3% vs 12%) while being used in patients with more demanding access vessel morphology

in 1 (3%) patient in group ZA and 4 (12%) patients in group TX (p=0.17). Significantly more patients in group ZA (6, 18%) were unsuccessfully treated previously with other endografts vs. none in group TX (p=0.01). **Conclusion:** The new Zenith Alpha appears to be equally as safe and efficacious as the Zenith TX-2 while being used in patients with demanding access vessel morphology.

Melissano, JVS, 2015

Initial clinical experience with a new low-profile thoracic endograft

Germano Melissano, MD, Yamume Tshomba, MD, Enrico Rinaldi, MD, and Roberto Chiesa, MD,
Milan, Italy

Background: The Zenith Alpha thoracic endograft (William Cook Europe, ApS, Bjaverskov, Denmark) is a new low-profile thoracic endograft that has recently become commercially available in Europe. The reduced profile offers potential benefits and extended applicability, especially in patients with small or diseased iliofemoral vessels. The aim of this study was to evaluate the safety and efficacy of thoracic endovascular aortic repair performed with the new Zenith Alpha thoracic endograft.

Methods: From November 2013 to the present, Zenith Alpha thoracic stent grafts have been employed to treat 42 patients (31 men; median age, 71 years; range, 54-83 years) suffering from descending thoracic aortic disease: 34 degenerative aneurysms, 4 aortic ulcers, 2 false aneurysms following prior thoracic open repair, and 2 traumatic blunt injuries. The mean proximal neck length was 25 mm (range, 17-40 mm), with a mean access vessel diameter of 6.7 mm (range, 6-11 mm). In 11 cases, aortoiliac occlusive disease (TransAtlantic Inter-Society Consensus type B and C lesions) was present. The proximal landing was in zone 1 in 2 cases, in zone 2 in 25 cases, in zone 3 in 11 cases, and in zone 4 in 4 cases.

Results: Fifty-one endografts (45 proximal components and 6 distal components) were deployed in 42 patients. The endografts were deployed safely and effectively from one surgical femoral access site in all cases. In patients with associated aortoiliac disease, no adjunctive procedures for device insertion, except for predilation with balloon angioplasty in two cases, were required. No major complications related to the devices were observed in any of the patients during the postoperative course, and there was no perioperative mortality, paraparesis, or paraplegia. At 30 days, morbid events included one case of major stroke, two cases of transient acute renal failure, and one case of postimplantation syndrome. No access-related complications were recorded. Computed tomography performed within 6 months was obtained in 39 patients and confirmed 100% clinical success without device-related complications. No type I endoleaks or bird's beak effects were documented.

Conclusions: Our early experience shows that deployment of the new Zenith Alpha endograft from a surgical femoral access is safe and effective in treating thoracic aortic aneurysms, aortic ulcers, and traumatic blunt injuries, even in patients with small or diseased access vessels. Endograft conformance to the aorta and exclusion of the aneurysm were satisfactory. Long-term durability remains to be evaluated. (J Vasc Surg 2015;■:1-7.)

Thoracic endografts with proven clinical performance both in controlled studies and in daily clinical practice are offered by several manufacturers.[1-12] The market release of new devices often follows a staged calendar in different areas of the globe, and because of varied local regulations, not all devices that are commercially available in Europe are also available in the United States, Japan, or other countries.

Whereas all endografts are based on a blend of metal stents (nitinol or stainless steel) and fabric (Dacron or expanded polytetrafluoroethylene), they do differ in size, shape, radial force, conformability, and ease and precision of deployment. A difference in the clinical efficacy and durability in specific pathologic situations for the different devices has never been clearly shown in the literature; however, vascular specialists develop their own preferences on the basis of their experience and the particular characteristics of the individual patient. Therefore, it is extremely important to know the characteristics of each available product in detail to optimize planning and graft selection.[1,2]

Whereas hydrophilic introducer sheaths have reduced trauma to the iliofemoral access vessels in many cases, the inadequate size of the access vessels relative to the device, especially in tortuous and sclerocalcific arteries, may represent a contraindication to the procedure. In some cases, an iliac or aortic conduit may be needed to advance the graft, increasing the risk of hemorrhage and hemodynamic instability and possibly leading to increased mortality and morbidity, including spinal cord ischemia.

The new Zenith Alpha thoracic endograft (William

From the Division of Vascular Surgery, San Raffaele Scientific Institute, Vita-Salute San Raffaele University.

Author conflict of interest: G.M. is a principal investigator and co-principal investigator for several trials of thoracic and abdominal aortic stent graft by Cook Medical and a proctor and participant as a lecturer at symposia hosted by Cook Medical.

Reprint requests: Germano Melissano, MD, Vascular Surgery, San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Via Olgettina 60, 20132 Milan, Italy (e-mail: g.melissano@hsr.it).

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- Single center study (42 pts)
- Technical success in all cases
- 6 patients would not have been candidates for TEVAR using other devices

- 6 months follow up (31 pts)
- No device-related complications
- No type I endoleaks.

Conclusions: Our early experience shows that deployment of the new Zenith Alpha endograft from a surgical femoral access is safe and effective in treating thoracic aortic aneurysms, aortic ulcers, and traumatic blunt injuries, even in patients with small or diseased access vessels. Endograft conformance to the aorta and exclusion of the aneurysm were satisfactory. Long-term durability remains to be evaluated. (J Vasc Surg 2015;■:1-7.)

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Starnes, JVS, 2015

ARTICLE IN PRESS

From the Society for Vascular Surgery

Endovascular repair for blunt thoracic aortic injury using the Zenith Alpha low-profile device

Benjamin W. Starnes, MD,[a] Amit J. Dwivedi, MD,[b] Joseph S. Giglia, MD,[c] Karen Woo, MD,[d] and Chyon Yeh, PhD,[c] on behalf of the TRANSFIX Study Investigators, *Seattle, Wash; Louisville, Ky; Cincinnati, Ohio; Los Angeles, Calif; and West Lafayette, Ind*

Objective: The objective of this study was to report 30-day results from a prospective, nonrandomized, multicenter trial that evaluated the safety and effectiveness of the Zenith Alpha thoracic endovascular graft (Cook Medical, Bloomington, Ind) for treatment of blunt thoracic aortic injuries (BTAIs).

Methods: Eligible patients with BTAIs (grade II to grade IV) in the descending thoracic aorta were treated with the Zenith Alpha device, which is available in smaller graft diameters (starting at 18 mm) and lower profile delivery systems (starting at 16 F) than currently available thoracic endografts. The device (nitinol stents and polyester graft material) accommodates a tighter aortic curvature (radius of 20 mm) than the predicate Zenith TX2 Pro-Form. Follow-up clinical and imaging evaluations were performed at 30 days, at 6 and 12 months, and annually thereafter through 5 years. The primary end point was 30-day mortality.

Results: Between January 2013 and May 2014, 50 patients (44 men; mean age, 43 ± 19 years; range, 18-89 years) were treated with the Zenith Alpha device at 17 U.S. sites. The mean Injury Severity Score was 31 ± 14 (range, 3-66). Technical success was achieved in 100% of patients, with 0% intraoperative mortality. Device access was entirely percutaneous in 22 patients (44%). Smaller size grafts (18-24 mm) were used in 15 patients (30%). The mean procedure time was 85 ± 44 minutes (range, 34-278 minutes), and mean blood loss was 103 ± 145 mL (range, 0-1000 mL). The 30-day mortality rate was 2%; one patient died 24 days after the procedure of respiratory failure related to associated injuries and not to the device or procedure as adjudicated by an independent Clinical Events Committee (CEC). One patient experienced a stroke 7 days after the procedure (cause undetermined by the CEC), and one patient underwent reintervention for a site-reported proximal type I endoleak (core laboratory reported unknown endoleak type) at 30 days after the procedure. There have been no conversions to open surgical repair, paraplegia, or aortic rupture within 30 days.

Conclusions: Short-term results indicate that the Zenith Alpha thoracic endovascular graft appears safe and effective for the treatment of BTAIs. This low-profile device enables complete percutaneous repair in a large percentage of patients and can achieve high rates of technical success and very low rates of aortic injury-related mortality within 30 days. (J Vasc Surg 2015;■:1-9.)

During the past two decades, endovascular treatment has emerged as the standard of care for blunt thoracic aortic injury (BTAI) repair, demonstrating lower mortality and paraplegia rates than open repair.[1,2] The 2011 Society for Vascular Surgery Clinical Practice Guidelines[3] recommend endovascular repair of grade II to grade IV injuries and conservative nonoperative management for grade I minimal aortic injury. BTAI is most commonly the result of deceleration injuries, such as motor vehicle collisions or falls from extreme heights. As a result, patients presenting with BTAI on average are much younger than the typical patient undergoing thoracic aortic endograft repair for aneurysmal disease. As such, patients with BTAI often have smaller iliac access vessels, smaller thoracic aortas, and narrower aortic arch curvatures, which present challenges for thoracic endovascular aortic repair using currently available thoracic aortic endografts.

For this reason, in 2008, the American Association for the Surgery of Trauma (AAST) called for a "major and urgent need for improvement of the available endovascular devices" for the treatment of BTAI.[4] The Zenith Alpha thoracic endovascular graft (Cook Medical, Bloomington, Ind; referred to as Zenith Alpha in this manuscript) was designed to meet these needs with smaller introducer sheaths, smaller diameter devices, and a nitinol-based stent frame with thinner, more tightly woven Dacron graft material. The device also conforms better to narrow aortic arches. The purpose of this study

From the Division of Vascular Surgery, Department of Surgery, University of Washington, Seattle[a]; the Division of Vascular Surgery and Endovascular Therapeutics, Department of Surgery, University of Louisville, Louisville[b]; the Division of Vascular Surgery, Department of Surgery, University of Cincinnati, Cincinnati[c]; the Division of Vascular Surgery, Department of Surgery, University of Southern California Medical Center, Los Angeles[d]; and Cook Research Incorporated, West Lafayette.[e]

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Clinical Trial registration: NCT01688050.

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Additional material for this article may be found online at www.jvascsurg.org.

Correspondence: Benjamin Ware Starnes, MD, University of Washington, Box 359908, 325 Ninth Ave, Seattle, WA 98104 (e-mail: starnes@uw.edu).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

- TRANSFIX Study
  Blunt Thoracic Aortic Injury (50 pts)
- Technical success: 98%
- Percutaneous 44%
- 30-days: 1 death (not aortic related) (2%), 1 stroke (2%), 1 renal failure requiring dialysis (2%), and 1 case of wound complication
- 30-day imaging: Injury no longer visible in 76% (32/42) of patients

Conclusions: Short-term results indicate that the Zenith Alpha thoracic endovascular graft appears safe and effective for the treatment of BTAIs. This low-profile device enables complete percutaneous repair in a large percentage of patients and can achieve high rates of technical success and very low rates of aortic injury-related mortality within 30 days. (J Vasc Surg 2015;■:1-9.)

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Hôpital Bichat's Experience

- Avril 2015 – Dec 2016: 21 months
- 108 TEVAR procedures
- 47 Zenith alpha stentgrafts

35 Patients / 37 procedures

1,3 stentgraft per patient

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Patients

- Male: 22 / 35 (63%)
- Age: 61y +/- 14
- Emergency: 16 / 37 (43%)
- Marfan syndrome: 6 / 35 (17%)
- Access diameter < 6mm: 6 / 35 (17%)

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pathologies

	n	%
Chronic Dissection	15	43%
- Type A	6	
- Type B	9	
Aneurysm	7	20%
Penetrating Ulcer/ False A	6	17%
Traumatic aortic rupture	6	17%
A-O Fistula	1	3%

IFU + : 18 / 35 (52%)

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Stentgrafts

	n	%
Stentgrafts	47	100%
- Standard	41	87%
- Custome Made Device	6	13%
Components:		
proximal	45	96%
distal	2	4%

1,3 stentgraft per patient

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Stentgrafts

Average Diameter	**34 +/- 6 mm**
Average Length	**156 +/- 35 mm**

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Per-operative

- Performed in OR
- Femoral access: 34/ 35 (97%), 1 trans-apical approach
- Percutaneous approach: 21/35 (60%)
- CSF drain: 13 / 35 (37%)

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Per-operative

- Debranching: 6/35 (17%), all intentional
  - Zone 2: 3
  - Zone 1: 1
  - Zone 0: 0
  - Thoraco-abdominal: 2

- 1 intentional celiac Trunk Coverage (rTA)

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Case

- Male, 49 y
- Severe Ankylosing Spondylitis
- Immunosuppresive therapy
- Thoracic Aortitis with pseudo-aneurysms
- Previous TEVAR 2 years ago
- Recent chest pain

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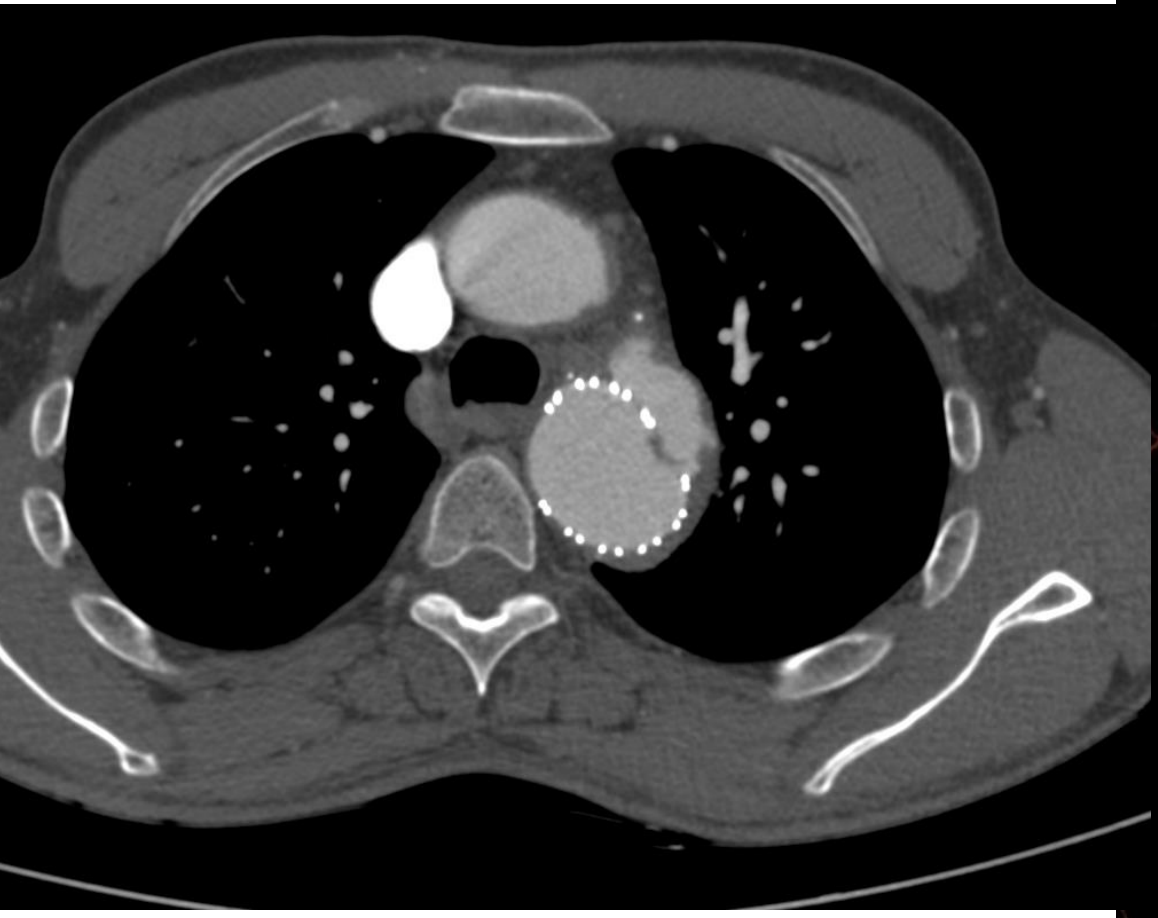

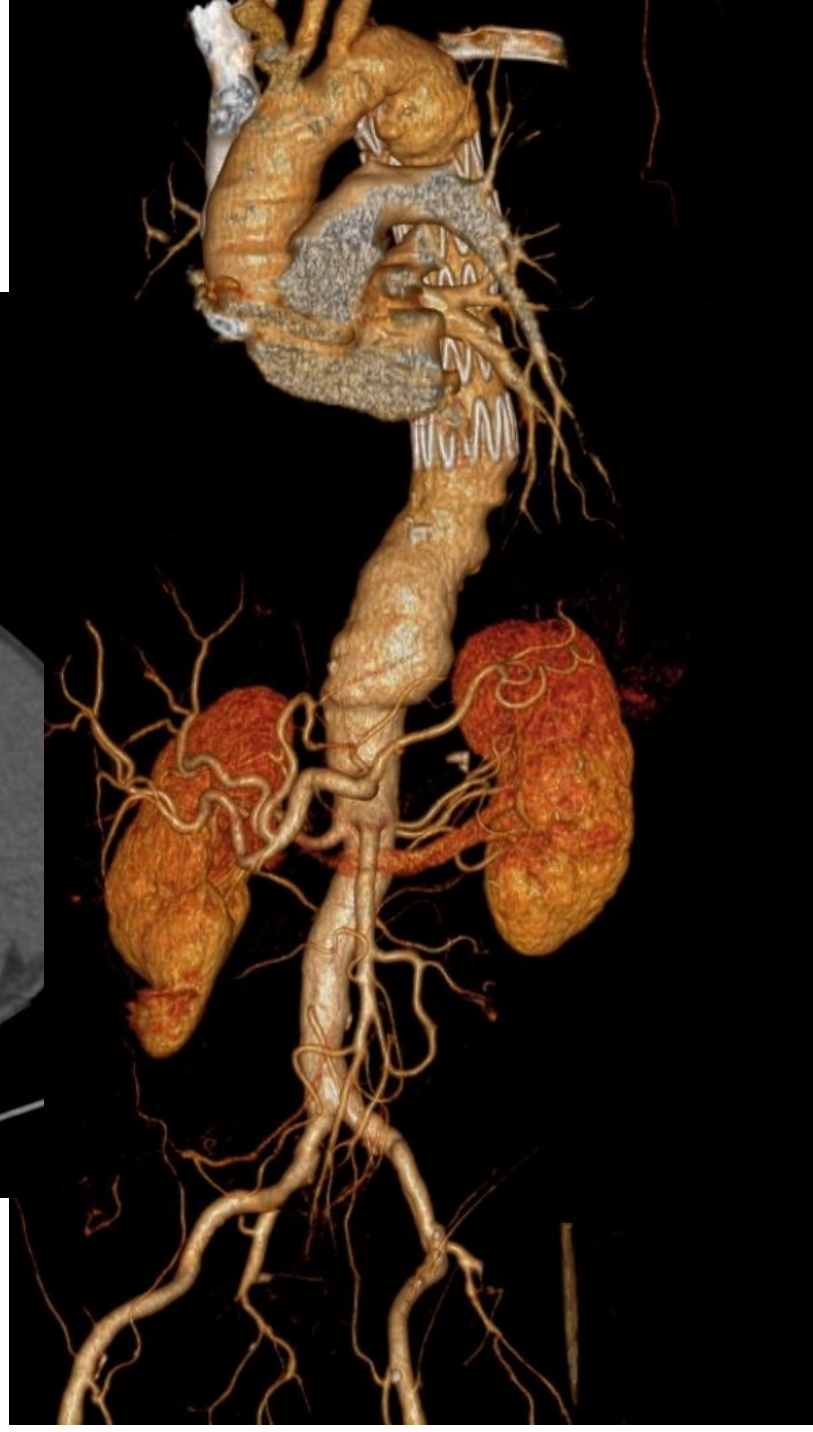

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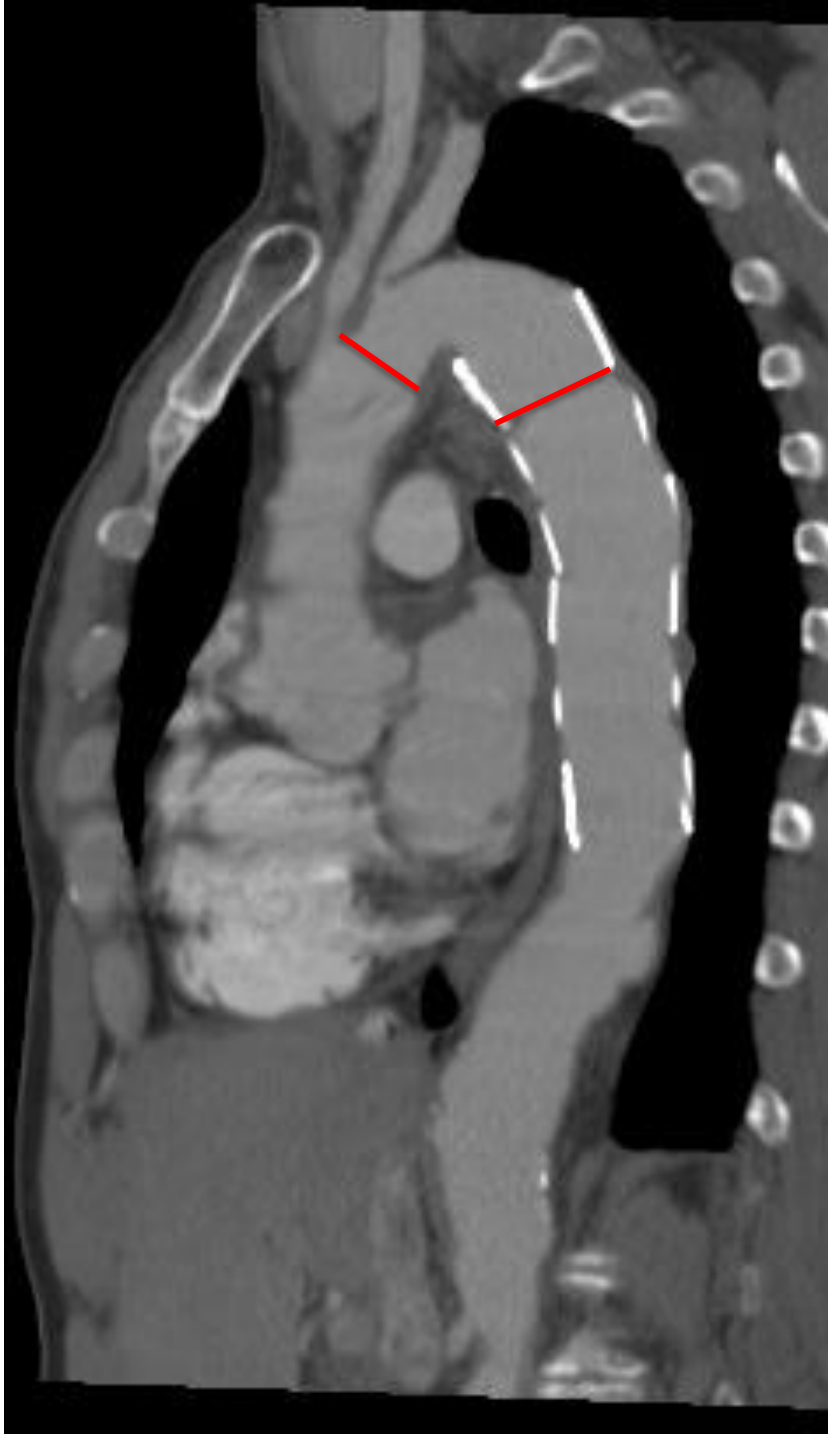
- Type 3 aortic arch
  Bovine arch

- Diameters:

- Arch: 30mm
- Previous stentgraft: 36 mm



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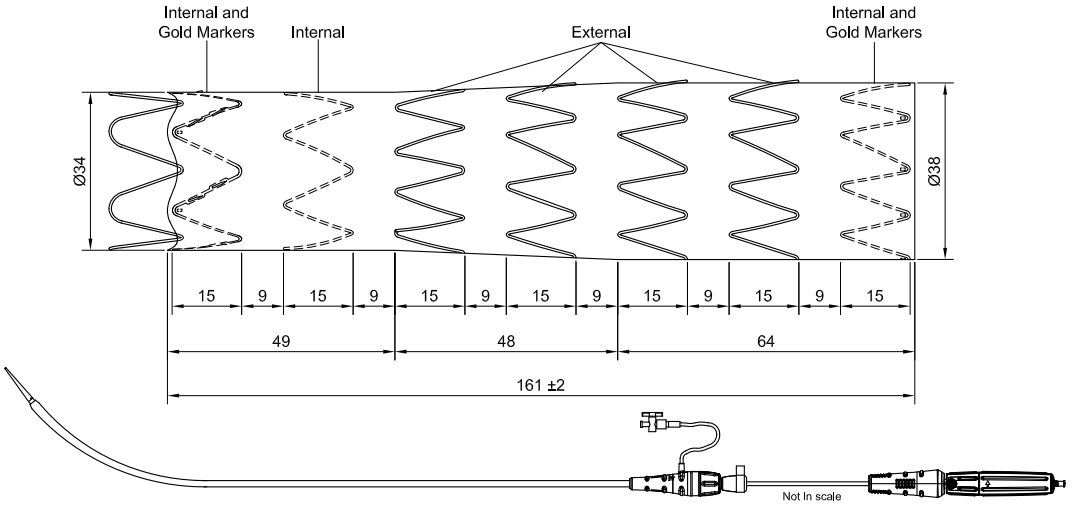
perop

- LSA transposition
- CMD, progressive 34 -38 mm x 161 mm
- Percutaneous approach

COOK MEDICAL **Approval of drawing**
WILLIAM COOK EUROPE
Confidential Information

CMD-Code: **CMD-ZTA-PT-F-6440-130815**
○ ASCENDING-CMD-DEVICE ◉ THORACIC-LP-CMD-DEVICE ○ THORACIC-FRANCE-CMD-DEVICE
○ THORACIC-CMD-DEVICE ○ ARCH-CMD-DEVICE

Introducer System Hydrophilic coated 18.0Fr. and length 85cm.
ID = 6.0mm
OD = 7.1mm
Patient name:
Approved by:
Dr. name._____ Date:_____



All measures are in mm. Tolerance u.o.s. ±1mm.
Drawing no.: **10224364** Scale: **1:1** Date: **13Aug2015/TBS** Approved:

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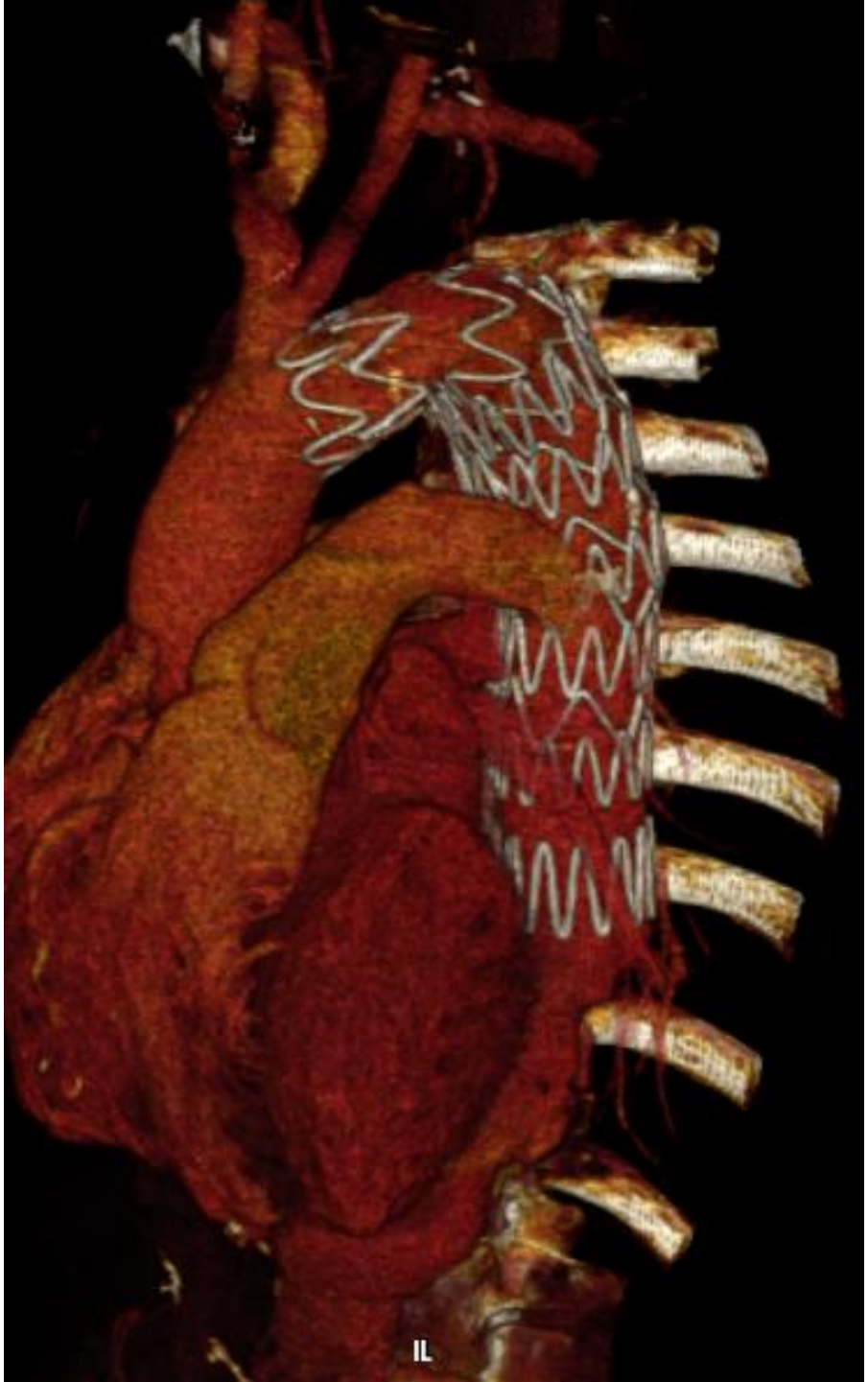
9 months CTA



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Per-operative

- NO ILIAC ANGIOPLASTY
- NO ACCESS Conduit
- Access related complications : 0

- NO PROXIMAL MALPOSITION
- Device related Complications: 0

Technical success: 92%

100% (IFU +)

(3 type 1 endoleaks)

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Post operative

- **Mortality at 30 days**: 4/35 (12%)
  - 1 Blunt injurie
  - 2 Ruptured TA, 1 rTAA
- **Stroke**: 0
- **Spinal cord ischemia**: 2/35 (6%)
  - 1 total (rTA)
  - 1 partial (symptomatic Chronic type B)
- **Access related complication**: 0

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Post operative

- Type 1 endoleak (8,5%): n=3

All 3 procedures not conformed to IFU

- Type 1a endoleak: 1
  - ascending aorta stent grafting for false aneurysm

- Type 1b endoleak: 2
  - 1 aneurysm (distal Neck 7mm)
  - 1 chronic Dissection

All successfully Treated with coils embolization

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Follow up

- Mean follow up: 7,5 months +/- 5
- Endoleak:
  - type 1: 0
  - type 2: 1
- Bird-beak comformation: 1 (ascending aorta implantation…)

  No bird beak in IFU indications

  Good applicability 97% of all cases
- Device related complication: 1 / 35 (3%)
  - Retrograd type A Dissection: 1 (patient with chronic type B dissection)
- Access related complication: 0

Device success at end of FU: 89% (all)

100% (IFU +)

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Conclusion

- Deployement of thoracic Zenith alpha stentgraft appears:
  - Safe
  - Effective
- In patient with aneurysm, aortic ulcer or traumatic aortic rupture
- Even with chronic dissection
- Good conformability prevents proximal type 1 endoleak and bird-beak configuration in IFU conformed indications
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- Low profile leads to no access related complication and allows percutaneous approach
- Suggests expanded TEVAR applicability