(A) SIGNIFICANCE

Aortic aneurysms, a type of cardiovascular disease in which aortic blood vessels bulge and weaken, contribute significantly to premature death of smokers [1]. Aortic aneurysms grow fastest in smokers and aortic aneurysms in smokers are more likely to rupture [2]. The Global Burden of Diseases, Injuries, and Risk Factors Study found that an individual with aortic aneurysm in 2010 would lose a staggering 57.4 years of life [2]. Abdominal aortic aneurysms (AAA) are the 14th leading cause of death in the USA [3].

A subset of aortic aneurysms is the thoracoabdominal aortic aneurysm (TAAA). The incidence of TAAA in the US population is estimated as 10/100000 person-years [4]. In this condition, both the thoracic and abdominal segments of the aorta weaken and enlarge to a diameter of at least 50% greater than normal. TAAA's expand in size over time, with over 43% of TAAAs larger than 7 cm progressing to life-threatening conditions. These conditions include rupture, in which the vessel bursts and causes internal bleeding, and dissection, in which layers of the vessel separate [5,6]. To prevent death, it is necessary to identify and treat TAAA's before they rupture [7].

TAAA is closely linked to tobacco-related narrowing and hardening of the arteries (arteriosclerosis). When patients suffer from chronic obstructive pulmonary disease (COPD), another condition commonly linked to tobacco smoking in the US, their TAAA is 3.6 times more likely to rupture [8,9].

REPAIR OF AAAs and TAAAs

Surgical repair of abdominal aortic aneurysms has been performed in the US since 1955 [5]. Current surgical treatment includes two basic options: open aortic reconstruction or insertion of a stent graft (endograft) through endovascular aneurysm repair (EVAR). Beginning in 1999 endovascular repair of AAA received FDA approval and since that time has rapidly gained acceptance and accounts for over 70% of infrarenal AAA surgeries [10,11]. Open surgical repair is a highly invasive procedure associated with serious negative outcomes, such as renal failure, cardiac complications, spinal cord ischemia, and death [10,12]. EVAR has different potential modes of failure than open repair. In EVAR, the aneurysm is left intact while blood is rerouted through the stent graft. Any persistent flow to the aneurysm sac, known as endoleak, could lead to progressive aneurysm growth and potentially AAA rupture [10]. While long-range outcomes may be similar for open and EVAR methods, EVAR has been associated with faster hospital release [13] and a significant reduction in morbidity and mortality during the three years following AAA repair [7,14].

TAAAs are categorized using a system that currently includes five extent classifications, as shown in Figure 1 [5,15]. TAAAs of extents 1 through 5 can be treated using open or EVAR techniques. EVAR devices that treat TAAAs and allow reliable blood flow to thoracoabdominal arteries are available outside the USA, but in the USA are currently limited to sites with physician sponsored IDEs [16].

Some surgeons have pursued a combination open-endovascular or hybrid debranching approach, but this approach was shown to be high risk [17,18]. Other vascular specialists have adopted an all endovascular approach using a combination of parallel grafts referred to as snorkels, chimneys and periscopes (CHIMPS) [19,20]. This approach uses available endovascular grafts in an off-label manner to maintain visceral (superior mesenteric and celiac artery) and renal artery perfusion [21]. While there are a number of reports demonstrating the success of this approach, it has many critics that report

the high incidence of endoleaks (gutter leaks) and organ ischemia from thrombosis of the snorkel and chimney stents [[22]22].

Because open surgical repair of TAAA have a significant morbidity and mortality, an endovascular option for repair is actively being explored [[23]23]. While many device companies have developed products that are available outside of the USA, only Cook Medical has a thoracoabdominal branched endograft anywhere near trial in the USA. Current availability of this endograft is limited to just 3 or 4 sites in the USA with physician-sponsored IDEs [[24]24].

DEVICE OPTIONS

Today, off-the-shelf endovascular stent grafts (endografts) are commercially available in the USA for repair of aneurysms of the infrarenal aorta and the thoracic aorta, which are the most common locations for AAA. However, these devices do not adequately address the needs and/or anatomical conditions of TAAA patients [5]. FDA-approved EVAR devices in the USA are all designed for infrarenal insertion (below the kidney arteries); none are available yet for treatment of thoracoabdominal aneurysms (above renal arteries). However by using complex techniques (snorkels, chimneys, periscopes) surgeons are able to extend the applicability of EVAR to more patients. [[25]25]

The need exists in the US for a commercial stent graft device that can be introduced through the femoral artery and placed above the right and left renal, superior mesenteric, and inferior mesenteric arteries to treat TAAAs and allow for reliable blood flow to those arterial branches after deployment. A few physician sponsored IDEs using custom and physician modified endografts have been conducted to address this gap [[26272829][30]26,27,28,29,30]. Studies of those approaches are still underway to assess their viability.

Our approach offers a viable short-term solution that could also provide an alternative four-branch design to Cooks T-branch endograft, which is available overseas but has not been submitted for FDA approval in the US. Our approach of using a custom-made universal converter would allow the device to be compatible with other manufacturers' infrarenal stent graft series. Alternatively, our device be licensed by a manufacturer and used to extend the usefulness of their stent graft devices.

DESIGN CONSIDERATIONS

Prior attempts to create an endograft that meets the requirements of TAAA repair have featured a variety of designs. Chimneys and snorkel grafts are feasible techniques that don't require custom device modification, but they do have increased risk of junction leaks and endoleaks (gutter leaks) vs branched devices. Periscopes, which are backward chimneys, also incur leakage and inconsistent pressure [[31][33]31,32,33]. One recent study associated renal failure with snorkel and chimney designs, possibly linked to incompatible sizing of the devices [[34]34].

Numerous case reports have demonstrated techniques using combinations of off-the-shelf devices to create branched configurations successfully to create thoricabdominal branch devices [[35]35], although they are expensive and have not yet undergone long-term device testing. Branched endografts have been shown to provide superior results over time, with hemodynamics more similar to the native aorta, less risk of junction leaks, and better conformability to the aorta [[36]36].

We propose a branched endograft converter that couples with an off-the-shelf infrarenal endograft (EVAR) and can be implanted using preloaded guidewires and bridged to the visceral arteries with commercially available covered stent grafts (Gore Viabahn). Physician-modified endografts have been shown to be effective in repairing aortic aneurysms [[37]37] and when used in combination with guidewires they support good patient outcomes and easier surgical access during the insertion procedure [[3839]38,39]**.**

Our research project will design and test a universal multi-branch converter device that modifies three currently commercial available infrarenal endografts (such as Gore® Excluder®, Medtronic® Endurant®, and Cook® Zenith®), and can be introduced through the femoral artery and placed above the right and left renal, superior mesenteric and inferior mesenteric arteries using a preloaded guidewire technique.

As described in a patent application filed by University of South Florida on behalf of the primary investigator [[40]40], the converter device could provide up to four branches to allow treatment of TAAA branches using endovascular techniques (see Figure 2). It would work with a standard, commercially available infrarenal device with two limbs. Our 4-branched converter device will seal into the contralateral gate of a standard EVAR device, as noted by number 210 in Figure 3.

Research has shown that using physician modifications to existing devices provides valuable field input that can support future clinical direction [37,41[41]]. In addition, a researcher in Brazil successfully used a similar approach to our proposed project, in which a customized endograft was crafted by the surgeon under sterile conditions at the time of the surgery [39]. By creating a standard branch conversion device, we would eliminate the need for modification of the main body of the commercial infrarenal device and thus simplify the procedure.

TESTING CONSIDERATIONS

Once the converter device is created, pre-testing is necessary before the device can be used in humans. Because there is no suitable animal model, *in vivo* animal testing is not available for endografts that treat TAAA. Therefore, pre-testing of these devices typically requires use of simulated anatomical models in the laboratory before attempting clinical testing. For pre-tests, our proposed project will employ computer-aided design (CAD) modeling and three-dimensional (3D) printing to create models of actual TAAAs based on computed tomography (CT) imaging. 3D printing has become a viable and accepted approach to creating anatomical models [[42]42].

The device will be inserted into the 3D anatomical models using endovascular techniques and tested for durability, compliance, flexibility, and structural fatigue. Once our device has been validated in mechanical models, we will apply for a FDA physician-sponsored IDE. Once the IDE is obtained, human device implantation will proceed at Tampa General Hospital with TAAA patients at high risk for open surgery. To establish proof of concept in a clinical setting, a minimum of 10 TAAA patients will be needed to receive this device and get two years of clinical follow-up and aneurysm surveillance using CT angiography. If the patient population is available, the proposed project will treat up to 20 TAAA patients.

RESEARCH AIMS

To address the needs and constraints described above, our proposed research has the following aims.

Aim 1: Prototype a universal multi-branch converter that customizes off-the-shelf endovascular aneurysm repair (EVAR) infrarenal stent grafts for insertion in patients with TAAA.

Aim 2: Run simulated engineering tests on the prototype for factors such as flow, efficacy and compatibility with commercial EVAR devices and adjust the design as appropriate.

Aim 3: Under an FDA physician sponsored IDE, surgically insert the final, successful prototype from Aim 2 in patients who require a stent graft to treat TAAAs and gather data on the outcomes.

By achieving these aims, this research would advance medical knowledge and improve treatment of cardiovascular patients suffering from TAAA. A successful outcome could culminate in the commercialization of a novel medical device that is produced by a commercial firm in Florida (preferably) or elsewhere. The new device would simplify the process of device customization and enable more rapid surgical intervention that helps avoid life-threatening ruptures of TAAAs. Further, achieving these aims would reaffirm the value of the state's investment in state-of-the-art device engineering and simulation facilities at USF Health CAMLS. A successful outcome would likewise demonstrate that biomedical device development is a viable economic opportunity in Florida.

(B) INNOVATION

The proposed research effort supports a new clinical paradigm by supporting EVAR for this patient population that has been underserved. The proposed project would provide immediate endovascular treatment options for patients with TAAA and it could help industry develop a new platform for branched TAAA devices. This effort supports innovation, by refining and improving current surgical treatment as further explained below.

REDUCED RISK OF DEVICE FAILURE

Use of snorkel and chimneys increases the risk of endoleaks and limb occlusions, as explained earlier [25,31,33,34]. The proposed branched design approach minimizes the risk of gutter leaks and other failure modes, in part because it requires limited modification of the commercial endograft. By creating a standard branch conversion device, we would eliminate the need for excessive modification of the main body of the commercial infrarenal device and thus simplify the procedure. If successful, the proposed research could lead to a commercially available off-the-shelf (not custom) branched thoracoabdominal endograft.

WORKS WITH A WIDE RANGE OF DEVICES

Various researchers [39,35], have modified devices to combine with off-the-shelf endografts. Each of those devices will work with only one commercial infrarenal endograft. Our design, however, is intended to be more universal and work with multiple off-the-shelf infrarenal endografts.

The proposed research takes an innovative approach to solving a medical challenge by creating a companion "universal" device that works with and modifies readily available and off-the-shelf commercial device stent grafts. The specific approach is sufficiently novel that the primary investigator's institution has already submitted a provisional patent application for the universal multi-branch converter device.

EXPANDS PATIENT OPTIONS

Patients diagnosed with TAAA currently have these options:

1) Wait and watch if the aneurysm grows to a size where the risk of rupture outweighs the risks of surgical intervention.

2) Pursue pharmacological treatment, which has not been shown to significantly reduce aneurysm growth and subsequent morbidity and mortality from TAAA.

3) Pursue "open" surgical treatment with its concomitant risks.

4) Pursue endovascular aneurysm repair at a surgical site that has received a physician-sponsored IDE that allows the surgeon to modify a commercially available stent graft off-label or to use a stent graft currently under evaluation for FDA approval. For a custom commercial device available under IDE, the patient must wait approximately one month for the device to be prepared and available for surgical insertion.

Patients would benefit from participating in our IDE and others would benefit from any commercial device availability that results from this proof-of-concept research effort.

ENABLES FUTURE DESIGNS

Techniques for treating complex aortic disease are undergoing ongoing innovation. The first endograft was an out-of-the-box concept that set aside surgical dogma of abdominal incisions and suturing of polyester grafts to the aorta [[43]43]. The efficacy and durability of EVAR and Thoracic Endovascular Aortic Repair (TEVAR) have been proven in numerous studies from around the world [[44][45][46][47][48][49]44,45,46,47,48,49]. Short-term reduction of morbidity and mortality is the driving force behind the rapid and widespread adoption of this technology. Now the focus of innovation is to be able to treat more of the abdominal aorta with simpler approaches using a more universal technology, less customization, and more off the shelf and easier-to-use devices that adapt to more anatomy [[50][51]50,51].

This device is part of that ongoing evolution. Over the 16 years since FDA approval of the first EVAR device, we have seen the introduction of devices for a wide range of abdominal and thoracic aortic pathology. EVAR is the treatment of choice for AAA, and TEVAR is the treatment of choice for aortic transection, Type B dissection, and thoracic aortic aneurysms [[52][53]52,53].

New technology has been introduced to lower the delivery system profile of EVAR devices, reduce the minimal aortic neck requirements, and treat more angulated aortic necks [[54],[55]54,55]. Industry has

introduced a number of new devices aimed at addressing the shortcomings of the original EVAR and TEVAR devices, including treating critical branches of the thoracic and abdominal aorta [5657]56,57]. Prior to industry adopting new technologies, physicians have modified the procedures to include parallel grafts, chimneys and snorkels as well as directly modified the endografts to expand the patient population that can be treated with endovascular devices [585960]58,59,60].

While industry continues to work on developing new devices, the requirements of the regulatory bodies around the world significantly delay introduction of new technology into the healthcare market. Innovative physicians working with the FDA and acquiring PS-IDEs have been instrumental in developing strategies to expand the endovascular technology to high risk patients at risk of aortic aneurysm rupture [61[61]]. Our strategy to use existing EVAR devices with a universal branch convertor adds a new design and strategy that can potentially aid development of new endovascular stent grafts for the treatment of TAAAs. While our design will allow treatment of TAAAs using existing technology, ultimately we envision a TAAA specific device using a branched component similar to our design.

(C) APPROACH

We envision a two-phase approach to this research as follows:

- Phase 1: Preparation (Years 1, 2) *Correlates with Research Aims 1 and 2*
- Phase 2: IDE clinical testing (Years 2, 3, 4, 5) *Correlates with Research Aim 3*

Some project tasks will occur concurrently, as shown in the workflow diagrams for Phase 1 (Figure 4.) and Phase 2 (Figure 5).

Details of the methodology of each phase is described below, including milestones and potential obstacles. In addition, we discuss related clinical risks and how they will be mitigated.

PHASE 1: PREPARATION (YEARS 1, 2)

In Phase 1 we will undertake the tasks necessary to prepare for IDE application and testing in Phase 2. Tasks will include gathering full requirements, creating anatomical models, establishing the test bed in the simulation laboratory, and building device prototypes, as explained in the detailed list of Phase 1 activities that follows. This phase correlates with Research Aims 2 and 2.

A. Review literature
Complete a detailed literature review covering the device design, test technology, surgical procedure, and related technology. The team has already begun collecting articles (see citations) on the concept of graft modification with branches, and on simulation and device testing. This literature review will be performed by the entire team.

B. Identify anatomies
Obtain and evaluate computerized tomography (CT) scans of various thoracoabdominal aneurysm patients. These scans will be used to identify three anomalous TAAA anatomies with variations of branch angles for use in creating simulation models. The CT scans will be gathered by the Primary Investigator, Dr. Shames. The patient details and CT images will be de-identified for the proposed model construction.

C. Create anatomical models

Based on the identified anatomies, create three computer-assisted design (CAD) models that will allow 3D printing of anatomical models of those TAAAs. Integration of the 3-D models into a pump-driven flow model to allow simulation of the endovascular procedures. This step will be performed in the Innovation Center at CAMLS by mechanical engineer Mark Moyer, project engineer Mario Simoes, and PI Dr. Murray Shames.

See Table 1 for a breakdown of the simulation testing configurations and usage of the anatomical models.

D. Obtain necessary surgical equipment

Obtain samples of appropriate and commercially available infrarenal stent grafts from three different manufacturers for use in testing, including Gore® Excluder®, Medtronic® Endurant®, and Cook® Zenith®. Obtain two universal device platforms: 1) Gore Excluder limb and 2) Cook Zenith limb. Obtain samples of surgical guidewires, delivery sheaths, angioplasty balloons, balloon expandable stents and self expanding stents (Medtronic, Cook) and Viabahn stents (Gore Medical). This step will be performed by the Primary Investigator, Dr. Shames.

See Table 1 for a breakdown of the simulation testing configurations and usage of the commercial endografts and delivery platforms.

E. Design device prototypes

Prepare and perfect the design of the universal converter device for treatment of thoracoabdominal aortic aneurysm, following descriptions in the provisional patent, so that the device is compatible with all three commercial endografts obtained in Task D.

F. Produce device prototypes

The multi-branch universal converter device will be handmade by suturing four 6mm Gore PTFE (Gore, Flagstaff AZ) limbs to the distal end of the Gore excluder limb or the Cook Zenith limb as in Figure 2. Each branch will be sutured to the other branches (Figure 6) with 5-0 Gore suture and then the branch unit will be sutured directly to the limb also with 5-0 Gore suture (Figure 7).

G. Conduct basic tests of device prototype

- The branch device will be tested for permeability, fatigue, and conformability with the proposed bifurcated EVAR devices using mechanical testing performed by the engineering staff at CAMLS (Mario Simoes and Mark Armstrong). Special attention will be focused on the durability of the suture line and the interaction of the limb with the EVAR devices.
- Interaction testing between the Gore branches and the Gore Viabahn bridge stents will be conducted to determine the optimal oversizing required to ensure seal.
- Pullout force testing will be performed to ensure adequate interaction between the branches and the bridge stents.

H. Simulate surgical insertion of prototype

In this task, the PI prepares the prototypes and then deploys the device in the simulation flow model and test bed according to the test plan in Table 1. The simulated surgical procedures will be performed under digital subtraction fluoroscopy in the Hybrid room at CAMLS, using the following steps:

1. Build the 4-branch universal converter to fit the contralateral limb of an existing commercial endograft. The distal limb of Gore Excluder iliac limb or the Cook Zenith iliac limb will be partially deployed in sterile environment to expose the distal aspect of the stent graft. Four branches (6mm PTFE – Gore grafts 15mm to 30 mm, Gore Medical, Flagstaff, AZ) will be sewn to each other and then to the distal end of the graft using 5-0 Gore suture to create a secure attachment between each branch and the endovascular graft. Each branch will be precannulated with a 300cm SV-5 0.018 guidewire.
2. Alternating devices will be built on 2 platforms
    1. Gore Excluder 16X16X7.5 cm
    2. Cook Zenith Flex Limb 16X16X7.5 cm
3. The universal converter device will then be introduced into a delivery sheath (22 F 55cm Gore Dry-Seal sheath).
4. Using standard EVAR techniques, the bifurcated aortic endograft (EVAR), either Cook Zenith, Medtronic Endurant or Gore Excluder (C3) will be inserted into the thoracic aorta under fluoroscopic guidance from the contralateral femoral access site. The distal aspect of the contralateral limb will be placed anteriorly 3-4 cm cephalad to the celiac artery origin.
5. Through the contralateral femoral access the contralateral gate will be cannulated and the Glidewire exchanged for a stiff guidewire.
6. The branched limb will then be advanced into the contralateral gate over the stiff guidewire and deployed securely in the contralateral gate.
7. From the brachial approach the first 0.018 guidewire will be snared using an endovascular wire snare. After capturing the wire, a 7F 90cm Cook Flex Sheath will be advanced through the selected branch.
8. Using a selection of guidewires and catheters, the celiac artery will be cannulated. The appropriately sized (10% bigger than target artery) celiac artery bridge stent (Gore Viabahn) will be advanced over the SV-5 wire and deployed with 2-3cm into the celiac artery and complete overlap into the branch limb. The stent graft will then be balloon dilated with a matched size angioplasty balloon.
9. The subsequent branches (SMA and renals) will be sequentially snared, catheterized and stented using the same techniques (7-8).
10. Once all limbs are completed final imaging using contrast angiography will be performed to demonstrate graft limb patency and exclude endoleaks.

I. Test the inserted device

The following tests will be performed to establish patency of the simulated device and its insertion; successful device delivery will be assessed based on:

1. Delivery of the convertor device and deployment in the contralateral gate.
2. Successful wire capture and sheath delivery.
3. Branch cannulation and stent delivery.
4. Successful cannulation of each subsequent branch.
5. Angiography to confirm branch patency and successful stent deployment.
6. The device will be left in the flow model with continues flow for up to 7 days to evaluate for device fatigue.
7. CT Scan to evaluate the configuration of the endografts.

   a. CT scan will allow evaluation of device overlap.
   b. Appropriate interaction of components.
   c. Evidence of branch kinking.
8. After CT evaluation, the TAAA model will be explanted and evaluated directly by Dr. Shames or engineering team to inspect for technical issues.
   a. Suture line disruption
   b. Evidence of branch tearing

The following data for each trial will be collected, recorded, and stored in a secure file at CAMLS: 1) total time of the procedure, 2) fluoroscopy time, 3) contrast volume and 4) technical difficulties encountered. Trial data will be compared and evaluated at the completion of the design process. We will review outcomes and revise the prototype as needed to eliminate endoleaks, suture fracture, branch kinking, and component separation and to ensure satisfactory flow to all branches under pressure.

J. Use iterative design

Following the simulation tests, we will refine the device as needed and repeat steps F- I until the device is satisfactorily tested.

K. Submission to professional publication

Findings and experience from Phase 1 will be submitted for publication to a peer-reviewed endovascular publication and national vascular society meeting for presentation.

PHASE 2: IDE APPLICATION AND CLINICAL TESTING (YEARS 2, 3, 4, 5)

During the end of year 2, at the conclusion of Phase 1, the primary investigator will apply for the Physician Sponsored-Investigational Device Exemption (IDE) of the universal multi-branch converter device configuration that performed best during the Phase 1. Once the IDE is approved, patients will be recruited and the device will be surgically inserted into suitable candidates at the Aortic Center of Tampa General Hospital.

All patients will receive the universal multi-branch converter device configuration that performed best during the Phase 1 mechanical simulation testing and subsequently received IDE approval. The specific commercial EVAR device used will be selected based upon patient anatomy and graft size requirements at the time of patient enrollment into the IDE trial.

Phase 2 correlates with Research Aim 3. Details of the tasks involved with the IDE are provided in the remainder of this section.

L. Obtain IDE

We will apply to the FDA to obtain Physician Sponsored-Investigational Device Exemption (IDE) for the device that performed best during Phase 1 testing. The IDE application will be prepared and submitted by the Primary Investigator, Dr. Shames, with assistance from the research nurse, clinical coordinator, and/or vascular surgery resident staff. Note: Dr. Shames has already filed a provisional patent application with USF for the proposed device in July 2015 [40].

M. Recruit patients and obtain informed consent

Adults with TAAA will be asked by their cardiovascular specialist if they would be willing to speak with a member of the research team regarding this study; if they agree, the Principal Investigator and a research assistant will be immediately available to discuss the details of the study. If, after discussion with the PI, the patient would like to participate in this study, informed consent will be obtained. Informed consent forms will be signed by the patient or their designated surrogate, who will be supplied with a copy of the form (consent will only be necessary as part of the IDE) All information will be explained in a non-technical fashion, ample time will be available for the subjects and families to ask any questions, and they will also be asked if they have any specific questions or concerns about the study.

Patients will be informed of the risks associated with surgical procedure (see "Patient Risks and Mitigation" section) and loss of confidentiality of collected information. If a fluent Spanish-speaking research associate is not available, hospital interpreter services will be used to interpret all aspects of the consent. Hospital interpreter services will be engaged to translate for other non-English or non-Spanish speaking patients who indicate interest in participating.

Informed consent will be obtained, clearly describing the details of the IDE and the procedure. Demographic and medical data will be collected from all subjects. Demographic data will include age, gender, and race, which will be used for data analysis. Medical data will include the presence or absence of smoking, comorbidities, previous interventions and medical conditions. All patients will provide a comprehensive medical history, physical exam, blood sample (creatinine, comprehensive metabolic panel, CBC, PT/PTT and INR), and CT angiography of the thoracic and abdominal aorta.

CT imaging with 3-D reconstructions will be reviewed by the PI to accurately measure all visceral branches and determine stent size and graft configurations. Standard 15-20% oversizing will be used for the EVAR device. Additional TEVAR devices may be required to extend the graft into the more proximal thoracic aorta to secure an adequate proximal seal zone. We will use one stent graft manufacturer for each procedure to be determined by the PI at the time of CT review.

Eligibility Inclusion Criteria:

- Juxtarenal, suprarenal and thoracoabdominal aortic pathology as follows in hemodynamically stable patients:
    - Intact or contained ruptured aortic or aortoiliac aneurysms (atherosclerotic/degenerative or saccular) involving or in close approximation to the visceral segment of the aorta.
    - Diameter >5.5 cm if asymptomatic, or 5.0 cm with enlargement of >0.5cm in 6 months.
    - History of growth >0.5 cm per year
    - Any size if ruptured or symptomatic
    - Penetrating aortic ulcer (PAU)
    - >2.0cm in depth
- The patient must be deemed high-risk surgical candidate according to the following established criteria: ASA (American Society of Anesthesiologists) class IV.
- The patient must be high risk for open surgery (ASA IV, severe pulmonary disease, previous aortic surgery, previous left lung surgery, Chronic Kidney Disease).

Eligibility Exclusion Criteria:

- Less than 18 years of age.
- Life expectancy less than 12 months based on the surgeon's assessment.
- Pregnant or breastfeeding or planning on becoming pregnant within 60 months.
- Inability or refusal to give informed consent.
- Unwilling or unable to comply with the follow-up schedule.
- Less than 30 days beyond primary endpoint for other investigative drug or device study.
- Patients who have a condition that threatens to infect the stent graft or its branches.
- Patients or their legally authorized representatives who do not sign the informed consent.
- Patients with expected survival less than one year.
- Patients who have certain infections (e.g., Hepatitis B or C, and HIV) that can affect the study results.
- Known allergy to the device components (i.e. stainless steel, polyester, solder, gold, or nitinol).
- History of anaphylactic reaction to contrast material that cannot be adequately premedicated.
- Systemic or local infection that may increase the risk of endovascular graft infection.
- Baseline eGFR <30mL/min (calculated by the Modification of Diet in Renal Disease formula) and not on hemo- or peritoneal dialysis. If the patient is currently on dialysis, or is currently planning on initiating dialysis, then they may undergo repair.
- History of connective tissue disorders.
- Body habitus that would inhibit X-ray visualization of the aorta.
- Major surgical or interventional procedure unrelated to the treatment of the aneurysm planned ≤30 days of the endovascular repair.
- Unstable angina, defined as a progressive increase in symptoms, new onset at rest or nocturnal angina, or onset of prolonged angina.
- Irreversible coagulopathy.
- Anatomical Exclusion Criteria:
    - Aortic transection due to acute trauma.
    - Aortic dissection.
    - Infectious ("mycotic") etiology of the aortic disease.
    - Significant occlusive disease or tortuosity precluding delivery of the device components.
    - Proximal Landing zone <20mm in length. The proximal landing zone can be within zones 2 through 8, with least 20mm of proximal seal and fixation in aorta or Dacron.
    - Proximal neck, defined as the thoracic aorta distal to the native left carotid artery, measured outer wall to outer wall on a sectional image (CT) >41 mm in diameter or < 18 mm in diameter
    - Distal landing zone <20mm in length if the landing zone is in the aorta, or <20mm if the landing zone is in the iliac arteries or in Dacron (in the event the patient has had a previous or concomitant aortic or aorto-iliac reconstruction).
    - Untreatable branch vessel stenosis.
    - Anatomy that would not allow maintenance of at least one patent hypogastric artery.
    - Signs that the inferior mesenteric artery is indispensable (i.e. angiographic visualization or a large IMA, filling of SMA via collaterals, stenosis of celiac or SMA or oblique views) and the indispensible IMA is not amenable to treatment with a graft branch or fenestration.
    - Branching, duplication, aneurysm or untreatable stenosis of the celiac, SMA or renal arteries that would preclude implantation of the investigational devices.

Once the participant has signed the approved informed consent, the following tests will be done to determine final subject eligibility and which device will be used: Clinical Exam, Blood Tests, CT angiography with 3D reconstruction (with and without contrast).

Potential patient participants will be given detailed information that complies with IDE requirements and adheres to standard healthcare communications. They will also be directed to standard resources, such as clinicaltrials.gov, with text such as the following:

> Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies [https://clinicaltrials.gov/ct2/about-studies/learn].

N. Treat patients

Procedures will be performed in the Hybrid endosuite at Tampa General Hospital. The primary investigator will treat each patient as appropriate, using these techniques:

- Standard femoral artery access will be via percutaneous access or open femoral access. In cases where the femoral artery is not of adequate caliber, iliac conduits may be used.
- Brachial artery access will be also via percutaneous or open access at the antecubital fossa or axillary artery. A 90cm 7F Cook sheath will be advanced into the descending thoracic aorta.
- Stiff guidewires (Lundquist) will be inserted form each femoral access site into the ascending aorta.
- Build a 4 branch (depending on patency of celiac artery, Superior mesenteric artery, and bilateral renal arteries)) universal converter using existing endograft contralateral limb (based on design from phase 1.). The limb will be partially deployed in sterile environment to expose the distal aspect of the stent graft. 3 or 4 branches (6mm PTFE – Gore grafts 15mm to 30 mm) will be sewn to each other and to the distal end of the graft using 5-0 Gore suture to create a secure attachment between each branch and the endovascular graft. Each branch will be pre-cannulated with a 300cm SV-5 0.018 guidewire.
- The branched limb will then be introduced into a delivery sheath over the stiff guidewire(22 F 55cm Gore Dry-Seal sheath).
- Using standard EVAR techniques the bifurcated aortic endograft (EVAR), either Cook Zenith, Medtronic Endurant or Gore Excluder (C3) will be inserted into the thoracic aorta under fluoroscopic guidance form the contralateral femoral access site. The distal aspect of the contralateral limb will be placed anteriorly 3-4 cm from the celiac artery origin.
- Through the contralateral femoral access the contralateral gate will be cannulated and the Glidewire exchanged for a Lundquist wire.
- The branched limb will then be advanced into the contralateral gate and deployed.
- From the brachial approach the first 0.018 wire will be snared using an endovascular snare. After capturing the wire a 7F 90cm Cook sheath will be advanced through the branch.
- Using a selection of glidewires and catheters the celiac artery will be cannulated. The appropriately sized (10% bigger than target artery) celiac artery bridge stent (Gore Viabahn) will be advanced over a SV-5 wire and deployed with 2-3cm into the celiac artery and complete overlap into the branch limb. The stent graft will then be balloon dilated with a matched size angioplasty balloon.

- The subsequent branches (SMA and renals) will be sequentially snared, catheterized, and stented using the same techniques as above.
- Once all limbs are completed, final imaging using contrast angiography will be performed to demonstrate graft limb patency and exclusion of endoleaks. The remainder of the TAAA will be treated by placing a uniiliac of bifurcated endograft in the ipsilateral limb and extending it to a healthy landing site in the distal aorta of iliac arteries.

O. Follow up with patients

The participants will be followed for 2 years. All subjects will have peripheral blood collected at designated study visits: 1 month, 6 month, 12 months and annually. Peripheral blood will be collected by standard venipuncture. All subjects will also have CT angiography at 1 month, 6 months, 12 months, and annually.

If patients require additional surgical intervention due to device failure or surgical complications, these procedures will be performed as necessary.

Patient outcomes will be tracked and evaluated as shown in Table 2.

P. Evaluate clinical performance

The primary investigator and a team of scientific experts will review post op CT scans for device successful implantation, branch cannulation, branch patency, freedom from endoleaks and aneurysm shrinkage and successful aneurysm exclusion, and for renal function.

Treatment success is defined as procedural technical success and patent treated branch vessels at 12 months post procedure, device integrity, and freedom from both reintervention and aortic enlargement ≤5mm as compared to baseline at 12 months post primary procedure.

Technical success is defined as successful exclusion of the diseased aortic segment without a clinically significant type I or type III endoleak and patent treated branch vessels at the end of the procedure without the need for unanticipated corrective interventions.

Q. Evaluate Post-op Data

Patient data will be further evaluated and statistically analyzed for the primary and secondary outcome measures shown in Table 2.

R. Pursue publication

Results of the IDE and data findings will be submitted for publication to a peer-reviewed endovascular journal.

PROTECTION OF HUMAN SUBJECTS

Phase 1 of the research (corresponding with Research Aims 1 and 2) will be conducted in the CAMLS Innovation Center and does not require human subjects.

Phase 2 of the research (corresponding with Research Aim 3) will involve up to 20 adults with thoracoabdominal aortic aneurysm (TAAA) who will receive endovascular aneurysm repair (EVAR) at Tampa General Hospital using an off-the-shelf infrarenal endovascular stent graft that has been modified using the universal multi-branch converter under a Physician Sponsored Investigational Device Exemption.

Appropriate patients at Tampa General Hospital and University of South Florida Health clinical practice will be approached for recruitment and consent purposes, and their outcomes will be followed for two years.

Patient participation eligibility criteria is noted in section M, above.

Information and materials collected during this study will be used for this study only. This point will be made clear during the consent process, and included in written consent forms.

PATIENT RISKS AND MITIGATION

RISKS:

Confidentiality: Certain aspects of the subjects' medical history and demographics will be collected for this study. Loss of privacy may lead to problems with insurability or social stigmatization. Also, some of the laboratory evaluations being performed may potentially indicate an immune dysfunction. Loss of privacy in regards to this information may also lead to problems with insurability.

Venipuncture: There may be discomfort associated with obtaining peripheral blood via venipuncture. Venipuncture also carries the risk of developing a hematoma at the site of the puncture and a <1% risk of developing an infection at the site of puncture.

Surgical risk: Risks specific to this surgery are [15,62,63,64,65[62636465]]

- Risk of blood clots that may travel to the lungs
- Breathing problems
- Infection, including in the lungs, urinary tract, and belly
- Heart attack or stroke
- Reactions to medicines
- Bleeding around the graft that requires more surgery
- Bleeding before or after procedure

- Blockage or slippage of the stent
- Damage to a nerve, causing weakness, pain, or numbness in the leg
- Kidney failure, possibly requiring dialysis
- Poor blood supply to legs, kidneys, or other organs
- Problems getting or keeping an erection
- Narrowing or blockage of branch stents requiring reintervention
- Endovascular surgery is not successful and patient requires open surgery
- Gastrointestinal event
- Paraplegia / paraparesis
- Death

Mitigation of patient risks:

The Tampa General Aortic Center is a multidisciplinary center specializing in complex aortic reconstructions. Our physicians have extensive experience with endovascular treatment of aortic aneurysms. All these procedures will be performed by experienced staff in a state of the art Hybrid suite to minimize radiation exposure.

All procedures will be reviewed by the team and the PI and performed by the PI per protocol. Experienced anesthesia and ICU teams will assist in the care of these patients. All patients will have a prophylactic spinal drain placed to mitigate the risk of spinal cord ischemia and be monitored peri-operatively based on strict protocols for spinal ischemia risk.

Contrast volume and concentration will be kept to a minimum to avoid renal dysfunction.

RISKS TO PROJECT

Performance of Phase 2 is contingent on approval of the IDE. The PI has access to a Society of Vascular Surgery IDE application template which has been used successfully. He will also have the support of this organization in completing this application. The process of testing a simulated mechanical model and gathering data during Phase 1, and prior to the IDE application, will expedite the process.

DATA SAFETY AND MONITORING

Information will be stored in an encrypted (meeting mandated IT security standards) password-protected database and will contain subject identifiers such as name, address, date of birth, and medical record numbers. This information is necessary to maintain contact with the subjects during the full 2 years of the study. Only the primary investigator and members of the research team that will contact the subjects will have access to information linked to subject identifiers.

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