Vascular Surgery: Physician and Patient Education on Novel Procedures

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A Thesis Submitted to the Faculty of

The College of Health Sciences and Technology

In Candidacy for the Degree of

MASTER OF FINE ARTS
In
Medical Illustration

Vascular Surgery: Physician and Patient Education on Novel Procedures

by

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7/15/2020
Vascular Surgery: Physician and Patient Education on Novel Procedures

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ABSTRACT

Carotid artery disease accounts for 20-30% of all strokes in the western world, and while several surgical procedures have been developed and utilized for decades as a means of treatment, each method comes with its own set of drawbacks (Saw et. al., 2007). A novel procedure, known as transcarotid artery revascularization (TCAR), seeks to mitigate the shortcomings of these previous surgical approaches.

The illustrations depicting the TCAR procedure are intended to assist in the education of surgeons and operating room staff who are responsible for carrying out the procedure. The Vascular Surgery Department at the University of Rochester Medical Center intends to present these illustrations during vascular surgery conferences, and for continuing medical education.

Thoracoabdominal aortic aneurysms (TAAAs) present another common vascular morbidity for the aging population. Physician-Modified Endografts (PMEGs) are an alternative to traditional open surgery for the repair of TAAAs. The procedure to deploy them is minimally invasive, requiring catheters in the arm and groin rather than a large incision down the midline of the body. They are also a viable alternative to company-manufactured endografts (CMEs) when case urgency precludes a long manufacturing time (Oderich et. al., 2019).

The PMEG illustrations are intended for use in a patient education pamphlet. The University of Rochester Medical Center is not currently participating in an investigational device exemption (IDE), though a proposal to the FDA is in the works. Presently, patients desiring an endovascular approach can either be enrolled in an IDE trial at another location, or they can consent to receiving a PMEG at the University of Rochester, despite the lack of IDE.
INTRODUCTION

Over 795,000 people have a stroke each year in the United States. 140,000 of these strokes lead to death, accounting for 5% all deaths (Stroke Facts, 2020). Around 87% of all strokes are ischemic, while the remaining result from intracerebral hemorrhage. According to Saw et. al. (2007), “stroke is the third leading cause of death, and the principal cause of long-term disability.”

Carotid artery disease accounts for 20-30% of all strokes, although etiology differs by race. The transcarotid artery revascularization procedure was developed as a minimally invasive surgical treatment for carotid artery stenosis. Studies have shown that it reduces perioperative ischemic events compared to transfemoral carotid artery stenting, as it reverses blood flow and avoids crossing the aortic arch and atherosclerotic lesion (Schermerhorn, M., & Liang, P., 2019).

The TCAR procedure demonstrates reduced mortality and morbidity when compared to transfemoral carotid artery stenting (tfCAS), and equivalence to carotid endarterectomy (CEA), the current “gold standard” in the treatment of coronary artery disease (Schermerhorn, M., & Liang, P., 2019). Moreover, the TCAR procedure is significantly less invasive than CEA, with a shorter healing period, and fewer opiates prescribed (Balceniuk et. al., 2020).

The TCAR illustrations depict the surgical procedure, and are meant to be studied in conjunction with other learning material. Upon review, surgeons are expected to have acquired the capacity to more accurately and confidently perform the TCAR procedure.

The yearly incidence of new thoracoabdominal aortic aneurysms in the western world ranges from 0.4 to 0.67 percent. Incidence drastically increases in people over the age of 60, from 55 per 100,000 in cohorts aged 65 to 74, to 112 per 100,000 in cohorts aged 75 to 85, and
finally to 298 per 100,000 in people aged 85 and over. Aortic aneurysms are among the top 15 causes of death, and are more common in men and those who smoke or have comorbidities such as high blood pressure (Chung, 2020) (Thoracic Aortic Aneurysm Surgery, 2019).

Physician-modified endografts have evolved as an alternative treatment to open surgical repair in urgent cases where company-manufactured endografts cannot be completed on time, at centers where company-manufactured endografts are not available, and when patient age and/or comorbidity precludes open repair (O’Donnell et. al., 2019a). Studies have shown these endografts to be at least equally effective, if not better at treating aneurysms than open repair (O’Donnell et. al., 2019b).

Illustrations depict common aortic aneurysm extents, as well as the methods used to create PMEGs. They will serve to educate patients on their treatment options.

Both the transcarotid artery revascularization (TCAR) procedure and physician-modified endograft (PMEG) investigation were chosen as the focus of this thesis due to their promising initial results and novelty within the field of vascular surgery. They demonstrate at worst equivalence, and at best superiority to current standard treatment options for carotid artery disease and thoracoabdominal aortic aneurysms, respectively.
SCIENTIFIC BACKGROUND

A. Transcarotid Artery Revascularization Procedure

Stroke is the most common cause of death in the United States, and a significant proportion of strokes are due to carotid artery disease. Carotid artery disease occurs when the lumen of one or both carotid arteries narrows due to the buildup of atherosclerotic plaque. This narrowing impedes blood flow to the brain, which can cause transient ischemic attacks (TIAs) at first, and strokes later on. A stroke involves the necrosis of brain tissue, and can be caused by either the near to complete occlusion of the carotid artery by the atherosclerotic lesion, or by a smaller piece of plaque rupturing off of the main lesion. This smaller piece of plaque is referred to as an embolus, and can travel further into the brain to occlude a smaller artery (Carotid artery disease, 2020).

When lifestyle changes and medications are not enough to mitigate the effects of carotid artery disease, surgery becomes the next best option. The “gold standard” for surgical intervention is carotid endarterectomy (CEA) (Schermerhorn et. al., 2020). The CEA procedure begins with a longitudinal incision on the neck that extends above and below the atherosclerotic lesion, often beginning behind the ear and ending at the superior border of the clavicle. The artery is then exposed and incised, clamps are placed above and below the lesion, and a shunt is placed so that blood can continue to flow to the brain. The endothelium containing the plaque is removed. The vessel is then stitched closed, often with the addition of an organic or artificial patch to widen the lumen of the artery (Carotid Endarterectomy, 2015).

A different approach in the management of carotid artery disease consists of deploying a stent via a catheter placed in the leg or groin. This approach is known as transfemoral carotid
artery stenting (tfCAS). A catheter containing a stent is threaded through the aorta, where it traverses the aortic arch and enters the carotid artery, initially passing through the atherosclerotic lesion to deploy an umbrella mesh that acts as a distal protection device. The lesion is then stented, sometimes with aggressive ballooning prior to stent deployment in an effort to further widen the arterial lumen (Schermerhorn, M., & Liang, P., 2019).

The most recent surgical addition to carotid artery disease treatment is known as transcarotid arterial revascularization, or the TCAR procedure. It is less invasive than CEA, with a smaller transverse incision in the neck that is more well-hidden upon healing. A micropuncture needle and dilator are used to gain access to the arterial lumen, rather than a long incision. Clamps are typically placed above and below the atherosclerotic lesion. A reverse-flow suction device is place in the artery, which temporarily reroutes arterial blood through a mesh filter before draining into a femoral vein. The mesh filter has 200-micron diameter pores which capture both macro and microemboli that would have otherwise traveled to the brain or heart to cause infarctions. A stent is then deployed to widen the lumen (The TCAR Procedure, 2020).

Manufactured by Silk Road Medical, the ENROUTE® Transcarotid Neuroprotection and Stent System has been shown to be a successful alternative to tfCAS, showing lower rates of perioperative stroke and myocardial infarction (MI), which were previously due to manipulation of a diseased aortic arch, and crossing the atherosclerotic lesion prior to the deployment of a distal protection device (Schermerhorn, M., & Liang, P., 2019) (Schermerhorn et. at., 2019) (Malas et. al., 2019). Moreover, a study by Bonati et. al. (2010) found that the use of distal protection devices during tfCAS actually increased the incidence of periprocedural stroke and MI when compared to foregoing a protection device.
Many studies have shown tfCAS to result in higher rates of ischemic lesions than CEA, including Bonati et. al. (2010), Bijuklic et. al. (2012), and Zhou et. al. (2012). The TCAR procedure has been shown to be at least as effective as CEA in preventing strokes, and the first ROADSTER Study (2016) by Silk Road actually showed lower 30-day stroke rates for TCAR patients when compared to CEA. Moreover, both ROADSTER (2016) and ROADSTER 2 (2019) studies have shown lower rates of cranial nerve injury in TCAR patients compared to CEA, likely due in part to a smaller initial incision. Furthermore, both ROADSTER trials recorded the time of flow reversal to average 10-11 minutes, in comparison to an average CEA clamp time of 31 minutes. Similarly, Schermerhorn et. al. (2020) found that overall procedure time for TCAR was on average 33 minutes shorter than CEA.

The most important consideration regarding the above-mentioned studies is that the patients undergoing the TCAR procedure were on average older, with more comorbidities that precluded them from undergoing CEA or tfCAS (Malas et. al., 2019) (Schermerhorn et. al., 2020). Despite this, they still had the same or better outcomes on average than lower-risk patients. These studies demonstrate that the TCAR procedure is a viable alternative to tfCAS and CEA in patients whose anatomy permits stenting.

**B. Physician-Modified Endografts**

The aorta is the largest artery in the body, supplying oxygenated blood to the head, limbs, torso, and majority of internal organs. Thoracoabdominal aortic aneurysms (TAAAs) occur when a section of the aorta weakens and bulges outward. Small-diameter and slow-growing aneurysms are less likely to cause problems, but those that burst or begin to leak can be life-threatening. Aneurysms larger than 5.5 cm more often require surgical intervention to stabilize the vessel and prevent future morbidity and mortality (Abdominal Aortic Aneurysm).
Some TAAAs are so common that they are classified into their own “extents”. An extent I aneurysm involves the descending aorta, beginning at the level of the left subclavian artery and ending around the level of the celiac trunk. Extent II aneurysms also involve the upper reaches of the descending aorta, though they extend caudally to the bifurcation of the iliac arteries. Extent III aneurysms involve the lower descending aorta and extend to the iliac bifurcation. Extent IV aneurysms involve only the abdominal aorta. Extent V aneurysms are the smallest, involving the lower descending aorta and upper abdominal aorta (Thoracoabdominal Aortic Aneurysm, 2019).

The traditional surgery for TAAAs is an open surgery requiring a longitudinal incision that spans most of the abdomen. The aorta is clamped above and below the aneurysm, and the vessel is opened via a longitudinal incision. A fabric graft is stitched into the endothelium of the vessel to take pressure off of the aneurysm by redirecting blood flow. The aorta is then stitched closed, along with the overlying layers of muscle, fat, and skin (Abdominal Aortic Aneurysm, 2010).

Endovascular repair of TAAAs is becoming more common, especially in older patients and those with comorbidities who are not good candidates for open surgery. Endografts, also known as stent grafts, combine bare metal stents with fabric sheaths, and act in a similar manner as the grafts that are placed during open surgery. However, deployment of an endograft requires only a small incision in the upper groin for infrarenal aneurysms, and one to two incisions in the groin and upper arm(s) for more extensive aneurysms involving aortic vessels such as the renal arteries, superior mesenteric artery, and celiac trunk. The endograft is placed using one or more catheters that are threaded through these incisions (O’Donnell et. al., 2019a).

One endovascular approach that involves more extensive aneurysms utilizes multiple endografts of varying diameter that begin at or above the level of the main graft and run along the sides of the aneurysm, extending into the implicated branching vessels. These grafts are
referred to as parallel endografts, and are categorized on the basis of their deployment as chimney, periscope, snorkel, or sandwich techniques. They are typically deployed transbrachially via catheters (Ullery, 2016). While these are effective for patients with unusual anatomy or in cases requiring surgical intervention where fenestrated grafts are not available, the proximal zone does not have a tight seal due to the circular profile of the endografts. Blood can still pressurize the aneurysm, clotting within the spaces between the grafts and potentially embolizing thereafter (Minion, 2012).

Another endovascular technique is the use of company-manufactured endografts (CMEs) with fenestrations, scallops, and/or branches at the level of the target vessels. These endografts more closely mimic the natural anatomy of the aorta when compared to parallel endografts, and they have a tighter proximal seal. Physician-modified endografts (PMEGs) are similar in structure to CMEs, though they are created in the operating room by the surgeon at the time of the operation. Both CMEs and PMEGs are created using 3D reconstructions of patient-specific data from computed tomography angiography (CTA) (Oderich et. al., 2019).

The creation of PMEGs begins with the removal of an FDA-approved endograft from its deployment sheath. The surgeon then uses an electrocautery device to burn holes at the level of the vessels to be included into the graft, and creates a watertight seal by stitching a stainless-steel ring around the opening. The endograft is then re-sheathed and deployed into the aorta transfemorally. Smaller endografts are placed through the preceding fenestrations into the target vessels transbrachially (Minion, 2012).

There are several important differences between CMEs and PMEGs. To begin, CMEs are produced under strict quality control guidelines and overwatch, while PMEGs are produced by surgeons with variable experience and skill. However, the production time for CMEs is
anywhere from 8-12 weeks, while PMEGs can be created within several hours (Dossabhoy et. al., 2020). A turnaround period of several months is not always feasible, especially in patients whose aneurysms are leaking or have burst.

A study by O’Donnell et. al. (2019b) found higher perioperative rates of stroke, MI, and other major adverse cardiac events (MACEs) in patients treated with parallel endografts compared to PMEGs and CMEs. The study also found slightly lower rates of perioperative death and MACEs with PMEGs compared to both CMEs and parallel endografts. Interestingly, one study by Lederle et. al. (2012) found a perioperative survival advantage for endovascular repairs, but this advantage declined and eventually disappeared within 3 years for older patients (for whom endovascular repair was expected to benefit more greatly). A different study by O’Donnell et. al. (2019a) found greater 3-year mortality rates in endovascular-repair patients than in open-repair patients. However, this study also found open surgical repair to be associated with longer operation times and hospital stays, a greater incidence of post-operative renal and intestinal dysfunction, greater incidence of MI, and higher volume of blood lost. It is important to note that these studies are confounded by both the learning curve associated with endovascular repair, and the fact that patients undergoing endovascular repair tended to be older and have more comorbidities than those undergoing open repair.

Case urgency, patient anatomy, target vessel patency, and prior surgery dictate which surgical approach to use. Parallel endografts are better suited for patients with caudally directed renal arteries, hostile iliofemoral access, target vessel stenosis, close proximity of superior mesenteric artery to most cranial renal artery, aortic tortuosity, and prior aortic reconstruction. CMEs and PMEGs are more beneficial to patients with diseased or challenging aortic arches, cranially directed renal arteries, upper extremity occlusive disease, and proximal renal branching.
Open repair is best suited for patients whose anatomy precludes reasonable accessibility both transbrachially and transfemorally (Ullery, 2016).

C. Illustrations

It is difficult to find any illustrations of the TCAR procedure outside of frames captured from the animation made for Silk Road. There are a scant amount of illustrations regarding PMEGs, though most only involve pararenal and juxtarenal aneurysms, and don’t include production steps.
BODY OF WORK

A. Goals of the Artwork

The illustrations of the TCAR procedure are intended to be used to educate vascular surgeons and operating room staff. They will be used during vascular surgery conferences and for continuing medical education.

The illustrations of aortic aneurysms and the process used to create PMEGs are intended for use in patient education. The University of Rochester is planning to enroll in an FDA trial, and needs resources to assist their patients in making informed decisions regarding their treatment options.

B. Illustration Process

Illustrations of the TCAR procedure were initially created using Procreate software on an iPad Pro. It is often easier to blend colors in Procreate than in Adobe Photoshop, where they tend to only be pushed around but not quite brought together. Procreate allows for the production of a more believable transition zone between adjacent colors. A female family member, aged 63, was used for the orientation slide, as the incidence of carotid artery disease increases significantly after the age of 60. Upon completion in Procreate, the images were then brought into Adobe Illustrator for the addition of rounded black rectangles to separate them into steps, as Procreate has only rudimentary capabilities in that regard. The surgical instruments were also created in Adobe Illustrator, for a crisper feel than that which can be accomplished in raster software. Each slide was then brought into Adobe Photoshop for the creation of instrument cast shadows.

These illustrations were made to fit into 16” x 9” PowerPoint slides. The orientation slide is meant to highlight key anatomical features, including the common carotid artery as it branches
off of the brachiocephalic trunk, its bifurcation into the internal and external carotid arteries, the internal and external jugular veins branching off of the subclavian vein, the vagus nerve, and the sternum and clavicle. It was conjointly decided that the orientation slide and the subsequent slide containing the initial surgical steps would be rendered in full color, but that the background saturation in the remaining slides would be reduced in order to emphasize the surgical field. No text was added to the slides since they were to be used in a PowerPoint, where text can be added and removed as necessary.

**Introduction slide?**

*If you wanted to make a title slide or something.*

Figure I. Initial development of orientation slide. Saturation and placement of anatomy was adjusted.
Figure II: Initial slide ideas.
Illustrations of the aortic aneurysms were made in Procreate. The three illustrations depicting the creation of the PMEG were then brought into Adobe Photoshop and run through a bevel and embossing filter to increase contrast and 3D effect. The different aneurysms were made from the same base illustration of an aorta, with modifications to the location and extent of the aneurysm, as well as slight modification of the positioning of the branching vessels.

The body was drawn from a male model in his early 30’s. The saturation of the body in the initial and final two images was reduced in order to draw attention to the aorta, and the kidneys were added for additional viewer orientation, though their opacity was reduced as well. The aorta and body were placed in a ¾ position for optimal viewing. The kidneys were excluded from the illustrations of each aneurysm to focus the viewer on the aneurysm itself. Intercostal arteries were added as a reminder to the surgeon to discuss potential spinal cord ischemia with patients. An extent 3 aneurysm was chosen for the illustrations depicting the deployment of the PMEG due to the involvement of the celiac trunk and superior mesenteric artery. The branching arteries in these images were lightened to differentiate them from the darker aneurysm. The steps detailing the creation of the PMEG were redone as the initial illustrations were mediocre.

Figure III: Evolution of PMEG creation steps.
Figure IV. Development of the aorta from first to final draft.

Figure V. Change in skin saturation in orientation image.
Figure VI. Development of PMEG illustration.
CONCLUSION

Vascular diseases affect a significant proportion of the adult and elderly population. It is vitally important that physicians, surgeons, and staff have the materials necessary to understand and accurately carry out life-saving procedures. It is equally important that patients are provided adequate educational material in order to make informed decisions regarding their healthcare options. The illustrations of the TCAR procedure engage and inform healthcare providers with the intent of educating them on the mechanisms of a procedure that they will be performing. The PMEG illustrations convey significant information to patients about their TAAA treatment options without being overly gory. Patients will be able to give informed consent, should they desire to enroll in an FDA trial or receive a PMEG without enrolling.

I am curious to see where both TCAR studies and PMEG IDE trials go in the future. Once surgeons master the PMEG learning curve, how will outcomes differ from those in current and previous studies? Will TCAR end up replacing tfCAS in most situations, and open repair in cases where patient anatomy is conducive to stenting?

Overall, I have tremendously enjoyed my time working with the vascular department at the University of Rochester. Everyone I have worked with has been so kind, informative, and understanding. This collaborative experience has been unlike any I have yet encountered, and I hope to continue working with the team in the future.
Figure 1. TCAR Orientation. This first slide shows an anterior view of the neck with the patient’s head rotated laterally. Important structures are highlighted, including the common carotid artery as it branches into the internal and external carotid arteries (red), internal and external jugular veins (blue), vagus nerve (yellow), manubrium and clavicle (pale tan), and sternocleidomastoid muscle (very translucent dark red).
Figure 2. TCAR Initial Steps. The first step depicts the marking in black of the superior aspect of the clavicle and the two heads of the sternocleidomastoid muscle. The site of incision is marked in a dashed yellow. The second step depicts the initial incision and dissection with a Bovie cautery device as the skin around the incision is retracted. The third step shows the elevation of the common carotid artery using umbilical tape, and the placement of a purse string suture which will be used to close the artery at the end of the surgery.
Figure 3. TCAR Cannulation Steps. This slide depicts the cannulation steps required to gain access to the carotid artery. An initial micropuncture needle is followed by an arterial dilator, and finally the larger flow reversal sheath is placed into the artery which remains elevated.
Figure 4. TCAR Cooley Vascular Clamp. A slide to highlight proximal placement of a specific clamp that the vascular team at the University of Rochester prefers to use during the procedure. White space was left above the clamp for text to be inserted and altered as desired.
Figure 5. TCAR Apparatus. This slide shows the flow reversal apparatus in its entirety. Blood is redirected away from the head through a mesh filter which traps emboli that could otherwise lead to a stroke or MI. Blood then drains into a femoral vein.
Figure 6. TCAR Balloon and Stent. This slide depicts balloon expansion of the stenotic arterial lumen, followed by stent placement.
Figure 7. TCAR Silk Road Clamps. This image shows typical placement of Cooley Vascular Clamps for proximal and distal atherosclerotic lesions within the carotid artery.
Figure 8. PMEG Normal Aorta.
Figure 9. TAAA Proximal Arch.
Figure 10. TAAA Entire Aorta.
Figure 11. TAAA Extent II.
Figure 12. TAAA Extent III.
Figure 13. TAAA Extent IV.
Figure 14. TAAA Extent V.
Figure 15. TAAA Infrarenal.
Figure 16. PMEG Custom 3D Printed Jig to assist in intraoperative fenestration placement.
Figure 17. PMEG Fenestration Creation with electrocautery.
Figure 18. PMEG Fenestration Reinforcement with suturing to make a watertight seal.
Figure 19. PMEG Deploying. The main stent is deployed transfemorally, and branches, in this case to the celiac trunk, superior mesenteric artery, and renal arteries, are added transbrachially. The PMEG is deployed in a staged fashion.
Figure 20. PMEG Deployed.
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