

## Carotid Stenting is inferior to Carotid Endarterectomy in the Low Physiologic Risk population: Results of the National Inpatient Sample, 2004-7

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**Objective:** The SAPPHERE trial established that Carotid Artery Stenting (CAS) is not inferior to Carotid Endarterectomy (CEA) for high surgical risk patients. The CREST trial has shown CEA have a lower stroke rate than CAS, at the expense of higher cardiac complications. The objective of this study is to evaluate the nationwide performance of CAS and CEA in both high (HR) and low physiologic risk (LR) patients, outside of the clinical trial setting.

**Methods:** Data from the National Inpatient Sample (NIS) was pooled for patients undergoing carotid intervention from 2004-7. HR was defined as pre-existing cardiac disease (CHF, valvular disease), or COPD. Stroke, death, myocardial infarction and complication rates were determined in both HR and LR populations. Multivariate regression analysis was performed to determine adjusted odds of stroke and death.

**Results:** From 2004-7, CEA was performed in 490,665 patients (HR 30.6%) and CAS in 50,283 patients (HR 31.2%). Unadjusted stroke/death rates were higher for CAS vs CEA in both HR and LR groups (table). Myocardial infarction rates were equivalent in the HR population and slightly higher for CAS in LR population. Combined complication rates were higher after CEA vs CAS, mainly due to pulmonary and renal complications. Multivariate regression analysis revealed adjusted odds of stroke/death were increased for CAS (OR 1.36, CI 1.28-1.45). HR patients had an equivalent odds of stroke/death after CAS (OR 1.10, CI 0.99-1.28), while LR patients had an increased odds (OR 1.56, CI 1.45-1.67).

**Conclusions:** This nationwide, real-world study supports the use of CAS in the HR population undergoing carotid intervention. However, the LR population is at higher risk of stroke and death after CAS, when compared to CEA. Contrary to the CREST results, both carotid procedures can be performed with equivalent cardiac morbidity.

Chi-square analysis of Carotid Interventions						
	<b>High Risk</b> (165,741)			<b>Low Risk</b> (375,207)		
Outcome %	<b>CEA</b> (150,053)	<b>CAS</b> (15,688)	<i>P-value</i>	<b>CEA</b> (340,612)	<b>CAS</b> (34,595)	<i>P-value</i>
Stroke/Death	4.60 (6,908)	6.14 (964)	<0.001	3.61 (12,286)	5.91 (2,044)	<0.001
Stroke/Death/MI	7.84 (11,765)	8.99 (1,410)	<0.001	5.52 (18,797)	8.27 (2,861)	<0.001
<b>Complications, % (#)</b>						
Myocardial Infarction	3.61 (5,416)	3.45 (541)	0.312	2.06 (7,012)	2.66 (921)	<0.001
Pulmonary	3.02 (4,529)	1.01 (158)	<0.001	1.04 (3,540)	0.39 (136)	<0.001
Renal	0.73 (1,092)	0.41 (65)	<0.001	0.72 (2,437)	0.16 (54)	<0.001
Combined complications	6.56 (9,838)	4.52 (709)	<0.001	3.56 (12,121)	3.12 (1,081)	<0.001

## **EEG Monitoring With SSEP Obviates Need For Shunting In CEA, Even With Stroke**

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**OBJECTIVE:** The utilization of selective cerebral shunting during carotid endarterectomy (CEA) has been predicated on surrogate measures such as contralateral carotid occlusion, back pressure measurements, patient's motor and cognitive function with regional anesthesia or recent stroke. This study analyzed the need for shunting in CEA where comprehensive electroencephalography (EEG) monitoring with somatosensory evoked potentials (SSEP) was the sole determinant of the necessity of a shunt.

**DESIGN:** A retrospective review was performed in a single institution of all consecutive CEAs performed between September 2002 and March 2010. The decision for carotid shunting was based only on changes in continuous EEG dynamics reflecting ischemia as assessed intraoperatively by a neurologist. SSEP were used in a portion of cases as a functional confirmation of EEG findings. No other factor influenced the need for a shunt. Patient demographics including age, degree of internal carotid artery (ICA) stenosis, pre-operative neurologic symptoms and medications were reviewed. 30-day outcomes including stroke, TIA, death, and other major complications were tabulated.

**RESULTS:** A total of 163 patients [100 (62.5%) men; mean age 69.4 years, (range 44-91)] underwent a total of 169 carotid endarterectomies. Of the total arteries treated, 76 (45%) were symptomatic of which 66 (39%) had a documented stroke. A total of 20 patients (11.8%) had high-grade contralateral (80-99%) ICA stenosis and 12 (7%) had contralateral ICA occlusion. Only 2 shunts (1.2%) were used. The 30-day stroke, TIA, death rates were 4(2.3%), 0(0%), 2 (1.2%) respectively. There was 1 intra-operative stroke and the remainder of the 3 strokes occurred within 30 days. None of the patients with contralateral occlusion or contralateral high-grade ICA stenosis had EEG changes necessitating a shunt.

**CONCLUSION:** Continuous EEG monitoring with SSEP dramatically reduces the need to place a shunt during CEA. Recent stroke, contralateral ICA occlusion or contralateral high grade ICA stenosis are not an indication for intra-operative shunting. Shunting for CEA should be vanishingly rare. EEG with SSEP should be considered the gold standard for monitoring of cerebral perfusion during CEA.

## Spatial Distribution Of Microemboli Following Carotid Interventions

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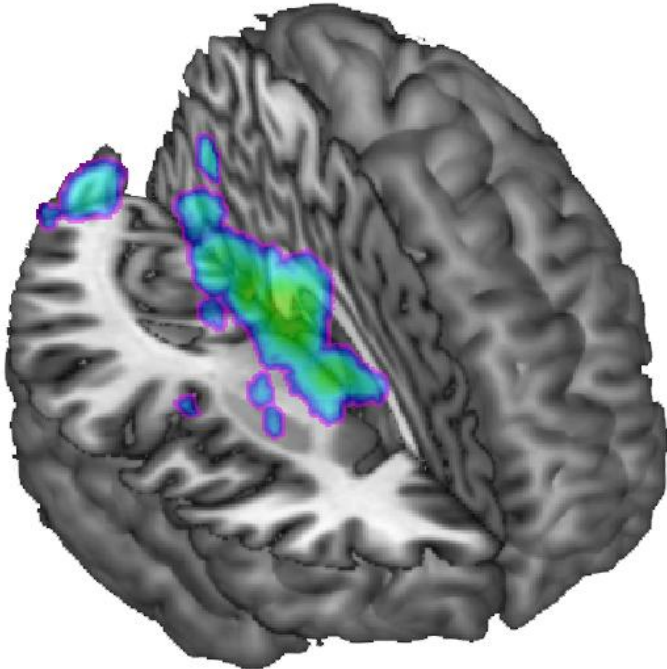
**Background:** Despite absence of clinically evident neurologic symptoms, subclinical microemboli during carotid interventions are common. Characterizing the typical locations of these lesions is an important step in identifying neural systems vulnerable to disruption. The purpose of this study was to examine the distribution of microemboli following carotid interventions using a novel imaging analysis program.

**Methods:** Patients who received both pre- and post-operative MRI evaluations for carotid interventions at a single academic institution from 2002 to 2008 were retrospectively evaluated. Microemboli were defined by new hyper-intensities on postoperative diffusion weighted MRI sequence (DWI) with corresponding decreased diffusion on ADC map. Microemboli regions of interest (ROI) were manually defined (MRICron) and normalized using SPM5 along with ADC images. ROIs were smoothed using a conservative Gaussian distribution (FWHM = 6mm) with FSL and input to a modified version of the Anatomic Likelihood Analysis (ALE) algorithm, in which a voxel-wise statistic was computed to derive a measure of agreement across images.

**Results:** Inter-rater reliability was first established between a board certified neuroradiologist with experience detecting microemboli and a novice rater trained to adequate inter-rater reliability with respect to microembolus volume ( $R^2=.99$ ) and spatial overlap (similarity index= .80). Among a total of 160 patients who underwent carotid interventions and received both preoperative and postoperative MRI studies, 81 patients had new postoperative DWI-lesions. Areas with a high degree of convergence across ROIs included the anterior and posterior cingulate, middle frontal gyrus, insula, basal ganglia, and occipital areas (Brodmann areas 18 and 19) (Figure 1).

**Conclusion:** Regions vulnerable to microemboli include those implicated in executive control and motor planning/speeded responses (anterior cingulate, middle frontal gyrus, basal ganglia) and memory (posterior cingulate). This finding forms a basis of selecting an appropriate set neuropsychological battery to accurately evaluate cognitive effects of microemboli.

**Disclosure:** The content was partially presented as a poster in Human Brain Imaging 2009



## Contemporary Management of Aberrant Right Subclavian Arteries

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**Background:** Aberrant origin of right subclavian arteries represents the most common of the aortic arch anomalies. This variant has few published series to guide management. Our goal was to review treatment options and results for these potentially complex reconstructions.

**Methods:** A retrospective review was performed on all patients with the diagnosis of aberrant right subclavian artery at our institution from January 2003 through July 2009.

**Results:** Nineteen patients, which comprises one of the largest series reported, including 9 males and 10 females (mean age 40.6 years, range 7-77) were diagnosed with an aberrant right subclavian artery. Fourteen (74%) were diagnosed incidentally, but 5 (26%) had symptoms of either dysphagia, upper extremity ischemia, or both. Computed tomography was most commonly used to establish the diagnosis (15 patients, 79%). Magnetic resonance imaging established the diagnosis in 3 patients (15%) and standard angiography in one (5%). A Kommerell's diverticulum (KD) was the most common associated anomaly (5 patients, 26%). All 5 patients (100%) with a KD required intervention for either symptoms or aneurysmal degeneration. Intervention was performed in 10 patients (53%) including carotid subclavian bypass in 5 (50%), carotid subclavian transposition in 3 (30%), ascending aorta to subclavian bypass in 2 (20%). Four patients (40%) had additional intervention for management of aneurysmal disease of the aorta or KD with open aortic replacement in 2 (20%) and aortic endografting in 2 (20%). There was one perioperative death (10%) in a patient undergoing aortic arch debranching with placement of an aortic endograft. Eighteen patients were alive without symptoms after a mean follow up of 38 months.

**Conclusions:** Aberrant right subclavian arteries are most commonly found incidentally with computed tomography. The presence of a KD appeared to correlate with the need for intervention. Patients with no symptoms with the absence of a KD can safely be followed.

## Clinical Outcomes and Implications of Failed Infrainguinal Endovascular Stents

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**Objective:** While the influence of initial TASC II classification has been clearly shown to influence the primary patency of infrainguinal stenting procedures, its effect on outcomes once stent failure has occurred is less well documented. It is the objective of this paper to determine whether clinical outcomes and implications of anatomic stent failure vary according to initial TASC II classification

**Methods:** Results were analyzed by TASC II classification. Kaplan-Meier survival curves were plotted and differences between groups tested by log rank method. A Cox proportional hazards regression model was used to perform the multivariate analysis

**Results:** During a five year period, 239 angioplasties and stents were performed in 192 patients. Primary patency was lost in 69 stented arteries. Failure was due to one or more hemodynamically significant stenoses in 43 patients, and occlusion in 26 patients. After primary stenting, limbs initially classified as TASC C & D were more likely to fail with occlusion ( $p < .0001$ ), require open operation ( $p = .032$ ), or lose runoff vessels ( $p = .0034$ ) than those classified as TASC A or B. In two patients initially classified as TASC C, stent failure changed the level of open operation to a more distal site. Percutaneous re-intervention was performed on 35 limbs. Successful re-intervention improved the patency of TASC A & B lesions to 92%, 85%, and 64% and TASC C & D lesions to 78%, 72%, and 50% at 12, 24, and 36 months respectively. Initial TASC classification was highly predictive of first anatomic failure ( $p < .0001$ ), but it did not predict the durability of subsequent catheter based re-intervention ( $p = .32$ ). Ten patients with stent failure required operation and five underwent amputation, all had failed with occlusion. Overall limb salvage was 89% and peri-procedural mortality was 0.4%.

**Conclusions:** Following primary stenting of the SFA and popliteal artery, lesions classified as TASC C or D are more likely to fail with occlusion, lose runoff vessels, and alter the site of subsequent open operation than their TASC A & B counterparts. Although these complications are infrequent they may negatively impact later attempts at revascularization and this must be considered when deciding upon the proper treatment strategy for patients with infrainguinal occlusive disease.

## Intraoperative Thrombolysis and Laser Atherectomy: Effective Treatment for TASC C and D Lesions in Critical Limb Ischemia

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**Objective:** We postulate that catheter directed intraoperative thrombolysis in conjunction with laser atherectomy is a safe and effective treatment of TASC C and D critical limb ischemia.

**Methods:** We retrospectively analyzed 411 patients who underwent 670 percutaneous, lower extremity interventions from September 2004 to October 2009. Indications for intervention were limb salvage (98.7%) and claudication (1.3%). TASC C lesions were present in 40.9% of patients and TASC D lesions in 59.1%. Gender was 51.0% male and 49.0% female. Average age was  $69.5 \pm 12.0$  years, range: 30 to 97 years. Risk factors included hypertension (87.8%), diabetes (70.2%), coronary artery disease (56.4%), tobacco abuse (54.8%), hyperlipidemia (49.4%), COPD (36.6%), congestive heart failure (26.3%), renal insufficiency (23.7%), history of myocardial infarction (21.3%), history of TIA or CVA (20.0%), atrial fibrillation (16.6%), dialysis (16.0%), morbid obesity (14.9%), arrhythmia (7.3%), and pacemaker (6.1%). All procedures involved catheter directed arterial infusion of 2 to 10mg of tissue plasminogen activator into the lesion and laser atherectomy: 647 extremities required balloon angioplasty, and 326 extremities required stenting.

Technical success required completion of the intended procedure. Clinical success required no deaths, strokes, myocardial infarctions, bleeding requiring transfusion, thromboemboli, infection, respiratory complications, or reinterventions within 30 days. Follow-up was at 24 hours, 30 days, 6 months, and then q 6 months. Kaplan Meier analysis was used for patency, limb salvage, and survival rates.

**Results:** Technical success rate was 96.6%. Clinical success was 83.0%. Within 30 days post op, 6.2% required repeat intervention; 4.2% required amputation; 3.3% experienced post-operative complications; including bleeding requiring transfusion (1.1%), thromboemboli (1.0%), infection (0.7%), respiratory complications (0.4%), and myocardial infarction (0.1%); and 3.3% died. Patency, limb salvage, and survival rates are listed in Table 1.

**Conclusions:** The combination of thrombolysis and laser atherectomy is safe and effective in treating TASC C and D lesions in this high-risk group of patients with critical limb ischemia.

Patency, Limb Salvage, and Survival Rates						
	1 Mo.(%)	3 Mo.(%)	6 Mo. (%)	12 Mo. (%)	24 Mo. (%)	48 Mo. (%)
Primary	89.5	79.6	66.4	50.4	43.3	26.5
Primary Assisted	91.5	82.2	71.0	59.3	51.7	35.8
Secondary	94.9	90.0	84.3	82.6	78.0	71.2
Limb Salvage	96.3	92.7	88.7	86.7	81.3	74.5
Survival	96.7	89.9	86.1	78.6	69.9	62.4

## Deep Venous Thrombosis (DVT) In Critically Ill Trauma Patients: There Are No Low Risk Patients

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**Objective:** American Chest Physician (ACP) guidelines stratify DVT risk in trauma patients based on injury pattern and medical prophylaxis. Screening is recommended only for highest risk groups. Many screening studies for DVT have not investigated calf vein DVTs (CVDVT) and did not exclusively target critically ill patients. Given new ACP guidelines recommending treatment of calf vein DVT, we investigated the efficacy of duplex ultrasound screening (DUS) of critically ill trauma patients for all lower extremity DVTs, including CVDVT, regardless of injury pattern, risk factors, or medical prophylaxis.

**Methods:** The records of 264 intensive care unit trauma patients who received DUS screening for lower extremity DVT were examined for data on high risk injuries, DVT risk factors, and LMWH prophylaxis.

**Results:** 40 (15.2%) patients had DVTs found on DUS screening, 25 (62.5%) were CVDVT, and 30% of all DVTs were diagnosed within 1 week of admission. Patients without high-risk injuries receiving LMWH had a 13.5% DVT rate, which did not differ significantly from the 19.7% DVT rate in high-risk injury patients not receiving LMWH ( $p=0.667$ ). Patients without high-risk injuries, and receiving LMWH, had high rates of DVT even excluding other DVT risk factors.

**Conclusions:** Lower extremity DVT is common in critically ill trauma patients, particularly in the first week following injury, regardless of injury pattern, DVT risk factors, or medical prophylaxis. Previous studies have underestimated DVT rates by not investigating CVDVTs. We recommend early DVT screening of all critically ill trauma patients.



## **Endovenous Ablation of Incompetent Perforator Veins Is Effective Treatment for Recalcitrant Venous Ulcers**

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**Objectives:** Endovenous closure of incompetent saphenous veins has been reported to facilitate venous ulcer healing; however, there is little information about the effectiveness of perforator ablation (PA) in healing recalcitrant venous ulcers. We report our experience with PA with venous ulcers unresponsive to prolonged compression therapy.

**Methods:** Patients with nonhealing venous ulcers of > 3 months duration underwent duplex ultrasound to assess their lower extremity venous system for incompetence of superficial, perforating, and deep veins. Patients who had either no saphenous incompetence or persistent ulcers after saphenous ablation underwent PA of incompetent perforating veins > 3mm that demonstrated reflux; initial treatment was performed on the perforator vein adjacent to the ulcer with additional incompetent veins treated if ulcer healing failed.

**Results:** Fifty-six ulcers with 74 associated incompetent perforating veins were treated with PA in 44 patients with CEAP 4 (9%), 5 (6%), and 6 (85%) recalcitrant venous ulcers. Treated incompetent perforator veins were located in the medial ankle (67 %) and calf (33%). Initial success of PA, assessed by post-procedure duplex ultrasound, was 55 %; reported complications of catheter site skin necrosis (0%), infection (0%), nerve injury (0%) did not occur; 18% of patients required more than one procedure for perforator closure; 73% had eventual successful perforator closure. Failure of perforator closure occurred in 27% and was associated with intercurrent illness, patient non-compliance, and patient death from unrelated causes. Of patients who healed their ulcers, the healing occurred at a mean of 2.3 months; an average PA of 1.5 incompetent veins per ulcer were required for healing.

**Conclusions:** This experience demonstrates both the feasibility and effectiveness of PA for a selected group of patients with venous ulcers who fail conventional therapy with compression.

## Early Results of a Highly Selective Algorithm for Surgery on Patients with Neurogenic Thoracic Outlet Syndrome: A Prospective Analysis

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**OBJECTIVE:** Neurogenic thoracic outlet syndrome (nTOS) encompasses a wide spectrum of disabling symptoms that are often vague and difficult to diagnose and treat. We developed and prospectively analyzed a treatment algorithm for nTOS utilizing objective disability criteria, TOS-specific physical therapy, radiographic evaluation of the thoracic outlet, and selective surgical decompression.

**METHODS:** Patients treated for nTOS from 2000-2009 were reviewed (n=84). In Period 1, most patients were offered surgery with documentation of appropriate symptoms. A prospective observational study began in 2006 (Period 2), aimed to determine which patients benefitted from surgical intervention. Evaluation began with a validated QuickDASH (QD) quality-of-life scale (0-100, 100=worse) and duplex imaging of the thoracic outlet. Patients then participated in physical therapy (PT) for 2-3 months and were offered surgery if there was documented improvement in symptoms.

**RESULTS:** 34 patients underwent 1st rib resection in Period 1 (68% female, mean age 39, 18% athletes, 15% workers comp). In operated patients undergoing duplex imaging, 40% showed compression of their thoracic outlet on provocative positioning. Based on subjective improvement of symptoms, 59% of patients at 6 months had a positive outcome. In Period 2, 50 consecutive patients were evaluated for nTOS (62% female, mean age 35.4, 36% athletes, 14% workers comp) with a mean pre-PT QD score 55.5. All patients were prescribed PT, and 21 (42%) were eventually offered surgical decompression (SURG) based on compliance with PT, interval improvement on QD score, and duplex compression of the thoracic outlet. Differences between the SURG and non-SURG cohorts are shown in the Table. At 6 month follow-up, 93% of patients expressed symptomatic improvement with the mean post-op QD score decreasing to 23.3 (p=.01)

**CONCLUSIONS:** This highly-selective algorithm for nTOS surgery leads to improvement in overall success rates documented subjectively and objectively. Compliance with TOS-specific PT, improvement in QD scores after PT, radiographic impingement, young age, and competitive athletics are associated with improved surgical outcomes. Long-term studies will be necessary to document sustained symptom relief and to determine who the optimal surgical candidates are.

Prospective analysis of 50 patients evaluated for nTOS			
Period 2 (n=50)	SURG (n=21)	Non-SURG (n=29)	p-value
Age	27.9	40.9	.0002
% female	61.9%	62.0%	NS
% competitive athlete	61.9%	17.2%	.002
% history of trauma	57.1%	17.2%	.006
% workers compensation	9.5%	17.2%	NS
Duplex obliteration of thoracic outlet	75%	60.7%	NS
Pre-PT QuickDASH	56.5	54.9	NS
Post-PT QuickDASH	49.3	48.4	NS
% improved after PT	76%	21%	.001

## **Infraclavicular First Rib Resection for Focused and Effective Treatment of Venous Thoracic Outlet Syndrome**

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**Objective:** Thoracic outlet decompression is an effective and durable treatment for venous thoracic outlet syndrome (VTOS), but there is no consensus regarding the optimal operative approach. Transaxillary, supra- or para-clavicular approaches are most commonly employed, based largely upon surgeon preference. However, unlike other forms of thoracic outlet syndrome, the pathology in VTOS is centered in the anteriorly located costoclavicular space. Therefore, we have adopted a focused infraclavicular approach with intraoperative venography that provides excellent access to the axillo-subclavian veins and the costoclavicular space for effective treatment of VTOS patients.

**Methods:** 32 consecutive patients underwent infraclavicular thoracic outlet decompression between June 2005 and March 2010. All patients presented with symptomatic subclavian vein thrombosis, including 8 (25%) with acute (<14d) and 24 (75%) with sub-acute or chronic (>14d) thrombosis. 28 (88%) underwent catheter-directed thrombolysis pre-operatively, often prior to referral to our institution.

**Results:** Infraclavicular first rib resection and intraoperative venography was technically successful in all patients. Adjunctive procedures included balloon angioplasty in 19 (59%) and venous stent placement in 1 (3%). 4 patients with chronic vein occlusion or stenosis underwent partial division of the manubrium, vein reconstruction (patch angioplasty in 2 and interposition bypass in 2), and temporary AV fistula creation. 31 (97%) patients had patent veins at discharge.

**Conclusions:** The infraclavicular approach facilitates focused and effective treatment of patients with VTOS. It provides direct exposure to the costoclavicular space for first rib resection and venolysis, and provides versatility for vein reconstruction if needed. Moreover the infraclavicular approach avoids unnecessary exposure of the brachial plexus and sacrifice of venous collaterals, making it an excellent approach for the treatment of VTOS.

## Long-term Impact of a Preclinical Endovascular Skills Course on Medical Student Career Choices

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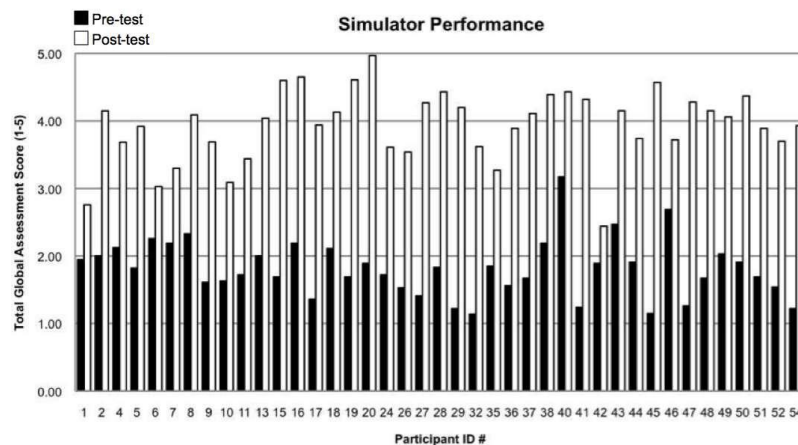
**OBJECTIVE:** Surging interest in the 0+5 integrated vascular surgery residency and successful recruitment of the top students in medical school requires early exposure to the field. We sought to determine the impact of a high-fidelity simulation-based preclinical endovascular skills course on medical student performance and ultimate career specialty choices.

**METHODS:** 53 preclinical medical students enrolled in an 8-week VS elective course from 2007-2009. Students completed a baseline and post-course survey and performed a renal angioplasty/stent procedure on an endovascular simulator (pre-test). A curriculum consisting of didactic teaching covering peripheral vascular disease and weekly mentored simulator sessions concluded with a final graded procedure (post-test). Long-term follow-up surveys 1-3 years after course completion were administered to determine ultimate career paths.

**RESULTS:** Objective and subjective performance measured on the simulator and through structured global assessment scales improved in all students from pre- to post-test (see Figure), particularly with regard to technical skill and overall procedural competency ( $p < .001$ ). Prior to enrolling in the course, 8.5% of the students expressed high interest in VS, and after completing the course 70% were seriously considering VS as a career option ( $p = .0001$ ). More than 95% responded that endovascular simulation increased their knowledge and interest in VS. In long-term follow-up, 67% were still considering VS, with other top career choices including surgical subspecialties (76%), interventional cardiology (52%), and interventional radiology (38%). Most respondents indicated major reasons for continued interest in VS were the ability to practice endovascular procedures on the simulator (81%) and mentorship from VS faculty (38%).

**CONCLUSIONS:** Basic endovascular skills can be efficiently introduced through a simulation-based curriculum and leads to improved novice performance. Early exposure of preclinical medical students provides an effective teaching and recruitment tool for procedural-based fields, particularly surgical subspecialties. Mentored exposure to endovascular procedures on the simulator positively impacts long-term medical student attitudes towards vascular surgery and ultimate career choices.

## Global Assessment Scores



## Impact of Simulation in Physician Training During Initial Performance of Thoracic Endovascular Aneurysm Repair (TEVAR)

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**OBJECTIVES:** The use of simulated environments for the interactive education and training of physicians is being embraced. This study was undertaken to evaluate the first use of medical simulation in TEVAR physician training to determine its impact on initial procedure performance.

**METHODS:** 1,211 physicians underwent training with a Talent thoracic prosthesis prior to performance of TEVAR between July 2008 and December 2009. Group I (n= 548) had only on-site in-service, Group II (n=663) completed an on-line didactic, attended a day course which included lectures and performance of at least 2 simulated TEVAR cases, and prostheses in-service. Complications during initial TEVAR cases between Group I (n=322) and II (n=172) were then compared.

**RESULTS:** Table 1

**CONCLUSIONS:** Physicians with limited TEVAR experience who underwent simulation-assisted training prior to initial TEVAR performance had significant less total number of complications as experienced physicians who did not undergo simulation training. Mostly due to a significant reduction in deployment related complications (Type I endoleaks) and stroke incidence.

TEVAR Complications			
	Group I # (%)	Group II # (%)	p
Procedure Mortality	39 (12)	17 (10)	0.55
Inaccurate Delivery (58)	43 (13)	15 (9)	0.14
Misaligned Deployment (32)	25 (8)	7 (4)	0.12
Positioning Difficulties (40)	30 (9)	10 (6)	0.23
Type I Endoleak (45)	36 (11)	9 (5)	0.03
Type III Endoleak (10)	7 (2)	3 (2)	0.99
Kink (9)	5 (2)	4 (2)	0.72
Deployment Complications	146	48	0.0002
Rupture	10 (3)	5 (3)	0.99
Pre-Operative (15)	8 (2)	10 (6)	0.08
Vessel Rupture (18)			
Vascular Bypass Conversion (10)	7 (2)	3 (2)	0.99
Surgical Conversion (4)	3 (1)	1 (1)	0.99
Occlusion (13)	11 (3)	2 (1)	0.24
Vascular Complications	39	21	0.91
Paralysis (14)	8 (2)	6 (3)	0.57
Stroke (10)	10 (3)	0 (0)	0.02
Neurological Complications	18	6	0.38
TOTAL # OF COMPLICATIONS	242	92	<0.0001

## A Comparison between Single and Two Stage Brachiobasilic Arteriovenous Fistulas

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**Objectives:** Controversy exists as to whether the brachiobasilic arteriovenous fistula (BBAVF) should be performed in one or two stages. We compare primary failure rates, as well as primary and secondary patency rates of one and two-stage BBAVF.

**Methods:** Patients undergoing one and two-stage BBAVF at two institutions were compared retrospectively with respect to age, sex, body mass index, use of preoperative venous duplex ultrasound, diabetes, hypertension, and causes of end stage renal disease. Categorical variables were compared using chi-square and Fisher's exact test, whereas the Wilcoxon-rank sum test was used to compare continuous variables. Primary and secondary patency rates were assessed using the Kaplan-Meier survival analysis and the Cox-proportional hazards model.

**Results:** 90 patients (60 one-stage and 30 two-stage) were identified for the study. Mean follow up was 14.2 months and the mean time interval between the first and second stage was 11.2 weeks. Three patients in each group required procedures to maintain assisted primary patency. Although no significant difference in early failure existed (one-stage 22.9% vs. two-stage 9.1%,  $p = 0.2$ ), the two-stage BBAVF showed significantly improved primary patency (hazard ratio 0.31; 95% CI 0.09-0.99;  $p=0.048$ ) and significantly improved secondary patency (hazard ratio 0.18; 95% CI 0.04-0.84;  $p=0.03$ ). Mean primary patency for one stage BBAVF was 72.3 weeks and two-stage was 138 weeks (1 SD;  $p=0.05$ ). Mean secondary patency was 94 weeks and 139 weeks, respectively (1 SD;  $p=0.05$ ). In addition, primary patency at one year for one and two-stage stage BBAVF was 78% and 84%, respectively ( $p=0.05$ ). Functional primary patency at one year for one and two-stage BBAVF was 61% and 88%, respectively ( $p=0.05$ ). Complication rates were not statistically different (each greater than  $p=0.11$ ).

**Conclusions:**

Patency rates appear to be improved with the two-stage BBAVF. There is no difference in complication rate. Optimal surgical technique for patients undergoing BBAVF for dialysis are discussed. Longer-lasting hemodialysis access improves patient outcome and decreases morbidity associated with dialysis.

## Efficiency of the KDOQI Guidelines For Vascular Access In An Academic Setting

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**Background:** The National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (KDOQI) for Vascular Access guidelines state that late-stage chronic kidney disease (CKD) patients should undergo native arteriovenous fistula (AVF) creation at least 6 months before the anticipated start of hemodialysis (HD) treatments to obviate the need for other vascular access types.

**Objective:** Determine the incidence of HD, the functional patency, and associated morbidity of AVFs in late-stage CKD patients placed according to KDOQI.

**Methods:** Consecutive patients with late-stage CKD who underwent 'first-time' index AVF creation using K/DOQI guidelines for anatomy between January 2003 and December 2007 at three tertiary academic centers were retrospectively evaluated. Baseline demographics, index AVF type, and clinical comorbidities were recorded. Patients were stratified into one of four groups (A-D) over the follow-up course based on the patency of their index AVF and whether or not they began HD. The ideal primary outcome was AVF maturation and use for HD (Group A; cumulative functional patency). Other outcomes included AVF patency but no HD (Group B), HD with AVF failure (Group C), or no HD and AVF abandonment (Group D). Secondary endpoints were time to first cannulation, complications, and secondary interventions.

**Results:** Index AVFs were created (46% forearm and 54% upper arm) in 150 CKD patients (85% male, median age 63 years). At a median follow-up of 10 months, 74 (49%) patients were receiving HD and 48 (65%) were using their index AVF (Group A), while 26 (35%) were not (Group C). Thirty-four (23%) patients never initiated HD treatments, but had a viable AVF. AVF abandonment was 51%. Mean maturation time of all index AVFs that were cannulated was 285 days (range 30 to 1265 days). Complications encountered were: maturation failure for cannulation (15%), focal stenosis requiring intervention (13%), inadequate flows on HD (9%), steal syndrome (9%), and thrombosis (8%). Cumulative functional patency for all index AVFs was 19% and 27% at 6 and 12 months respectively with a mean number of two interventions per AVF (range 1 to 10). Mortality for the group during the study was 23%.

**Conclusion:** AVF creation in late-stage CKD patients has sobering results. This calls into question the wisdom of early AVF planning in this population.

**Serum Metalloproteinases MMP-2, MMP-9 and Metalloproteinase Tissue Inhibitors (TIMP) in patients are associated with Arteriovenous Fistula Maturation**

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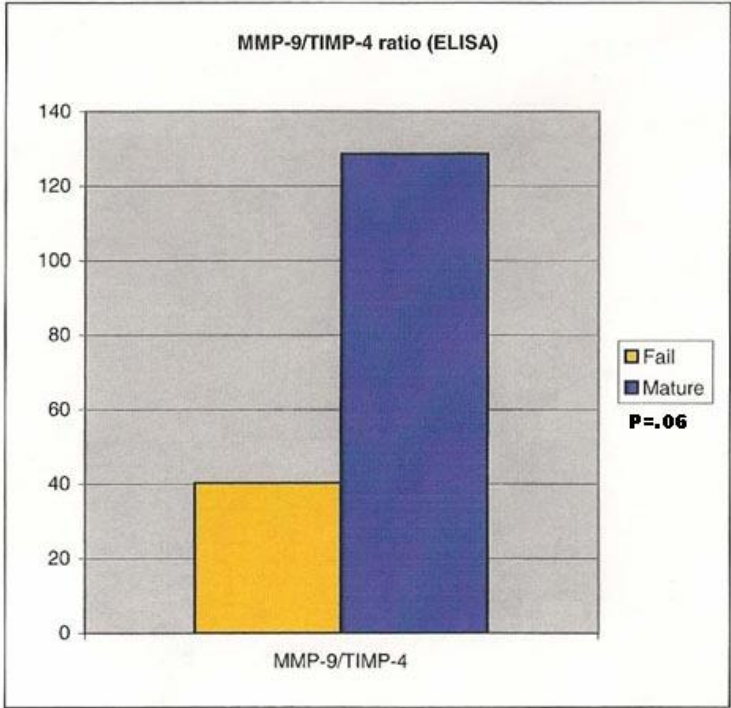
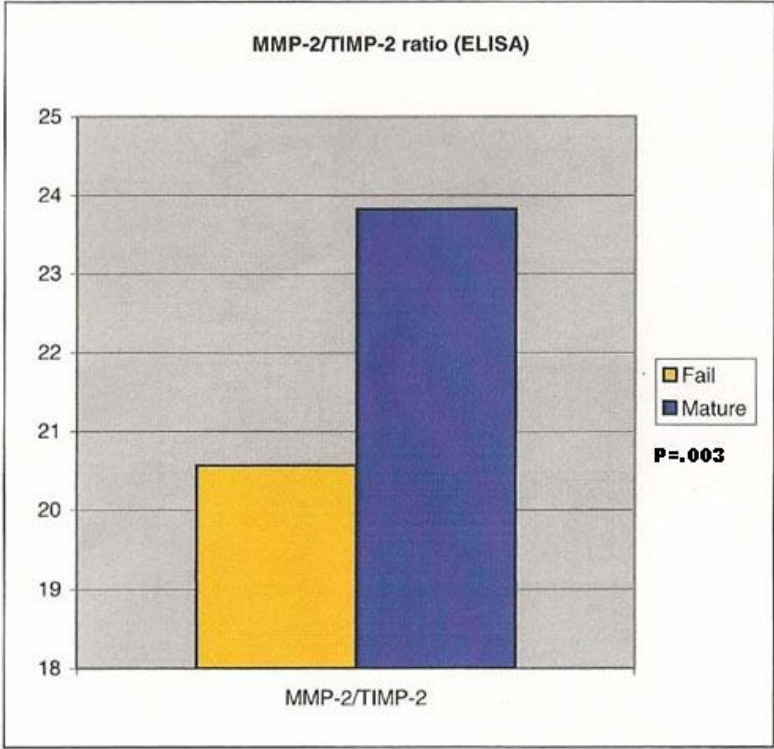
**Objective:** Many vascular surgeons construct arteriovenous fistula (AVF) for hemodialysis access as the primary choice access. However, a significant number of AVF fail to mature leading to patient frustration and repeated operations. MMP activity, particularly MMP-2 and MMP-9 are considered important for AVF maturation. We therefore sought to identify whether serum MMPs could serve as a biomarker for predicting future successful AVF maturation.

**Methods:** Patients with chronic renal insufficiency requiring long-term access had blood collected at the time of surgery. Serum was separated from whole blood by the use of an ultracentrifuge at 1000g for 10 minutes. Serum aliquots were then frozen at -80C until used for analysis. MMP-2, MMP-9, TIMP-2, and TIMP-4 were assayed using the ELISA technique. Patients were divided into failed and matured groups depending upon clinical endpoints. Successful maturation was considered in patients who had at least 3 successful hemodialysis access episodes. MMP/TIMP ratios were calculated as an index of the MMP axis activity since MMP activity parallel alterations in their TIMPs.

**Results:** Twenty patients were enrolled, 13 patients had successful maturation and 7 had failure of AVF maturation. Significantly higher serum levels of MMP-2/TIMP-2 was found in patients who had AVF that matured compared to those that failed ( $P=.003$ ). Similarly, a trend towards increased serum levels of MMP-9/TIMP-4 were found in patients with successful AVF ( $P=.06$ ) (See Figure).

**Conclusions:** These data show that serum MMPs and the associated inhibitors could potentially play a role as a biomarker for future AVF maturation.





## Blunt Abdominal Aortic Injury

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**Objective:** Blunt Abdominal Aortic Injury (BAAI) is rare with fewer than 200 cases in the current reported world literature. It is most often seen in high speed motor vehicle collisions, and associated with major blunt intra-abdominal injury and thoraco-lumbar fractures. We report our institutional experience over the past decade.

**Methods:** Of the 141 cases with blunt aortic injury presenting from 1999 to 2008, we retrospectively reviewed all cases with BAAI. Data collected included demographics, mechanism of injury, associated injuries, ISS, type of intervention, procedural complications, and subsequent CT imaging.

**Results:** We identified 17 cases of BAAI. Average age was 32 years old (range 6-79). Forty-one percent were women, and 71% due to motor vehicle collisions. Forty percent were hypotensive upon presentation. Average ISS was 49 (range 16-75). Associated abdominal injuries were seen in 81% and over half had associated spine injuries. Injury presentation ranged from intimal tears (29%), intimal flaps >10mm (29%), pseudoaneurysms (18%), to free rupture (24%). Treatment was non-operative in 24%, and operative in the majority of cases: 41% open aortic repair, 29% endovascular repair, and one hybrid repair with visceral debranching. Overall mortality was 29%, with the majority occurring in the emergency department. Free aortic rupture mortality was 100% by hospital day 4. Procedure-related complications were one endoleak treated with another stent graft, and visceral bypass thrombosis in the hybrid repair case, leading to death. Follow-up imaging was available in 80% of cases. All intimal tears treated non-operatively healed, a large intimal flap treated non-operatively remained stable, and 6 patients who underwent repair of their aortic injury had complete resolution and healing of their injury.

**Conclusions:**

This is one of the largest series described in the literature. BAAIs range from small intimal tears to free rupture with outcomes correlating with injury severity. Non operative management was successful in the cases of intimal tears. Free rupture is associated with the highest mortality risk. For all other categories of aortic injury, successful repair correlates with a favorable prognosis.

## **Failure to Rescue: Physician Specialty and Mortality After Reoperation for Abdominal Aortic Aneurysm (AAA) Repair**

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**Objectives:** Complications after AAA repair resulting in reoperation contribute to mortality, but have not been well-studied. Mortality after reoperation is termed failure to rescue, and may reflect differences in outcome directly related to management of the complication. This study describes the relationship between reoperation and mortality, and demonstrates the effect of physician specialty on reoperation rates and failure to rescue after AAA repair.

**Methods:** Data was extracted for 2616 patients who underwent intact AAA repair in 2005-2006 from a standard 5% random sample of all Medicare beneficiaries. Patient demographics, co-morbidities, type of repair and specialty of operating surgeon were collected. Primary outcomes were 30-day reoperation and 30-day mortality. Logistic regression analysis identified characteristics predicting reoperation.

**Results:** A total of 156 reoperations were required in 142 (4.2%) patients. Early mortality was far more likely after reoperation (22.5% vs. 1.5%;  $p < .0001$ ). Of patients requiring reoperation, those requiring two or more interventions had an even higher mortality (54% vs. 20%;  $p = .0007$ ). Despite equivalent need for reoperation among specialties (vascular surgeons 5.2%, others 5.6%,  $p = .67$ ), the mortality after reoperation was nearly half for vascular surgeons compared with other specialties (16.2% vs. 32.3%;  $p = .04$ ). The most common reason for reoperation was arterial complications (35.8%; mortality 39.3%), which also accounted for the largest difference in mortality between vascular surgeons (30.7%) and other specialties (52.0%).

**Conclusions:** Postoperative complications requiring reoperation dramatically increase mortality after AAA repair. Lower mortality following reoperation in patients managed by vascular surgeons reflects the importance of specialty vascular care. Failure to rescue contributes to the difference in outcome given equivalent complication rates.

## **Clinical Outcomes and Volumetric Analysis of Endoluminal Exclusion of Acute Complicated Type B Descending Thoracic Aortic Dissections**

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**Objective:** Late clinical outcomes and structural changes within aorta after thoracic endovascular aortic repair (TEVAR) for acute complicated type B descending thoracic aortic dissections (ADTD) remain unknown. The goal of the study is to review and analyze the clinical outcomes and the volumetric data of patients with ADTD.

**Methods:** 41 consecutive patients with ADTD, all with at least 1 yr follow-up, were treated as a part of a single center FDA-approved IDE from 2002 to 2009. Indications were malperfusion (n=17), rupture (n=12), chest pain (n=6), acute enlargement (n=4), and uncontrolled hypertension (n=2). Duration of symptoms was 14 days or less. 3-D M2S CT reconstructions were analyzed for aortic volume and diameter changes, regression of the false lumen and expansion of the true lumen.

**Results:** 32 (78%) patients required emergent surgery, with 1 death at induction. Procedural success rate was 97%. The 30-day mortality was 14% for malperfusion, 25% for rupture and 0% for all others, with the late mortality of 0%, 25%, and 25% respectively. Mean follow-up was 18 mo. Permanent stroke and paraplegia rates were 4.9% (n=2) and 0%. 10 of 18 secondary interventions were performed for 5 proximal endoleaks, 1 distal cuff endoleak, and 4 distal reperfusion. For patients without endoleaks (n=33), the true lumen volume grew by 29% at 1 mo, 51% at 1 yr, and 80% at 5 yrs. Volume regression of the false lumen was 69%, 76%, and 86%, respectively. The true lumen volume did not change at 1 mo or 1 yr in the endoleak group (n=7) but increased 50% at 2 yrs following secondary intervention. A 10% reduction of abdominal aortic volume distal to endograft occurred over 5 yrs in the absence of endoleaks.

**Conclusions:** TEVAR offers a promising solution to patients with ADTD. Aortic morphologic changes occur shortly after TEVAR and remain predictable up to 5 yrs with continuous expansion of the true lumen and regression of the false lumen. A lack of increase in the true lumen volume is associated with endoleaks or distal reperfusion.

**Gender-based Outcomes Following Endovascular Repair Of Degenerative Thoracic Aneurysms.**

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Sponsored by: Peter Schneider, MD

**Objective:** The extent to which patients' gender influences endograft treatment of TA has not been reported. The current study analyzes the influence of gender on the endovascular management of thoracic aneurysms.

**Methods:** A total of 421 patients (265 males [M] and 156 females [F]) were enrolled as part of the TAG (WL Gore, Flagstaff, AZ) thoracic stent graft trials. Pre-operative risk factors, intra-operative events, and 365 day follow-up data were analyzed.

**Results:** The mean maximal aneurysm diameter was comparable (M63 vs. F60 -mms;  $p=0.09$ ). Among 22 different pre-operative risk factors evaluated females had a lower incidence of prior vascular procedures ( $p=0.004$ ), and a trend was noted towards lower coronary artery disease and smoking ( $p=0.09, 0.08$ ). Mean proximal and distal landing zone diameters and iliac access diameters (M9.2 vs. F7.6-cms) were smaller in women ( $p<0.001$ ). Conduits were required more frequently among female patients (M6% vs. F24%;  $p<0.001$ ). Local access site complications were significantly higher in female patients, majority related to vascular trauma (M2% vs. F12%). Overall length of stay was prolonged in female patients (M4.8 versus F5.5 days;  $p=0.001$ ). However, this did not result in any difference between genders in the technical success rate (device delivery and successful aneurysm exclusion) or any other major adverse event rate ( $p=0.82$ ) at 30 and 365 days. Survival at one year was comparable (M91% vs. F87%;  $p=0.229$ )

**Conclusion:** No significant difference in major end points was noted at the 1-month and 1-year on gender based analysis for thoracic stent graft therapy. Local access complications may have been related to the smaller access vessels diameter for female patients. A great attention to detail for the access site in female patients and a lower threshold for elective conduit maybe a more prudent approach.

## **Translumbar Embolization for type 2 Endoleaks after EVAR: A Multicenter Retrospective Review**

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**Objective:** Translumbar embolization (TLE) of type II endoleaks has been described for the treatment of enlarging aneurysms following EVAR. This technique is reported to have a very high rate of technical success and durability. The purpose of this study is to review our experience with TLE in controlling type II endoleaks, in arresting the increase in aneurysm growth, and limiting the need for subsequent intervention.

**Methods:** A retrospective case review was performed on thirteen patients with CT and/or angiographically confirmed type II endoleaks who underwent TLE at two separate institutions. Patients were treated with combinations of stainless-steel coils, Onyx, Cyanoacrylate (NBCA), Thrombin, and/or Poly vinyl alcohol (PVA) beads. Success was defined as clear resolution of the type II endoleak and/or an aneurysm diameter that was either stable or decreasing. Failure of the technique was defined as any persistent leak, an enlarging aneurysm sac, or the need for secondary intervention.

**Results:** Thirteen patients underwent TLE for type II endoleaks associated with aneurysm enlargement. In two of the patients who underwent translumbar puncture, no endoleak could be identified, and no treatment was performed. TLE was successful in only five (45.5%) of the remaining eleven patients. Six patients (54.5%) had unsuccessful TLE. Of the six treatment failures; two patients required repeat interventions, two patients required open surgical repair (one for rupture), one patient suffered colonic ischemia requiring resection, and one patient has a persistent type II endoleak.

**Conclusions:** Our experience contrasts with previously published studies in that less than half of the patients treated had successful resolution of their endoleak with TLE alone. While TLE is a useful technique for the management of type II endoleaks, many patients will require subsequent procedures. Close surveillance of patients following TLE is imperative to identify the patients who will require additional intervention.

The practice gap addressed is the difficulty in obtaining adequate results using TLE in treating endoleaks. A small number of previously published studies showed high success rates. By identifying a lower success rate for TLE, we hope to impress the importance of vigorous surveillance following the procedure.

## The Transition from Custom-Made to Standardized Multi-Branched Thoracoabdominal Aortic Stent Grafts

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**Objective:** To compare the branch morphology and short-term outcome of endovascular aneurysm repair using custom-made versus standardized multi-branched thoracoabdominal stent grafts.

**Methods:** Custom-made stent grafts (CSG) with patient-specific cuff locations were compared to standardized stent grafts (SSG) with uniform cuff locations. Data on patient demographics, aortic morphology, component use, and outcome were collected prospectively. Final branch length (cuff to target artery orifice) and branch angle (cuff orientation to target artery orientation) were determined using 3-D reconstruction of computed tomographic angiograms (CTA).

**Results:** Since 1/2008, 24 patients underwent endovascular repair using 13 CSG (10 in 2008, 3 in 2009) and 11 SSG (1 in 2008, 10 in 2009). 2 SSG were excluded from analysis: one has yet to undergo CTA, the other had crossed renal branches due to problems traversing a previously reconstructed aortic arch. All stent grafts were implanted successfully. There were no perioperative deaths. All branches were patent on the initial postoperative CTA. There were no statistically significant differences between the CSG and SSG groups in terms of patient demographics, procedural details (operation length, fluoroscopy time, contrast volume, blood loss), or mean branch length and angle (Table 1).

**Conclusions:** The substitution of SSG for CSG had no effect on the complexity of the procedure, the final branch morphology, or the perioperative outcome. The availability of an off-the-shelf SSG will broaden the application of endovascular TAAA repair by eliminating manufacturing delays.

Target Artery	Mean Branch Angle (degrees)			Mean Branch Length (mm)		
	CSG (sd)	SSG (sd)	p-value	CSG (sd)	SSG (sd)	p-value
CA (n=22)	14.5 (13.3)	20.4 (11.2)	0.29	25.1 (15.7)	20.2 (8.1)	0.40
SMA (n=22)	25.6 (18.6)	17.3 (17.6)	0.31	27.0 (12.5)	19.6 (3.0)	0.10
RRA (n=21)	25.3 (19.9)	25.0 (14.6)	0.96	23.5 (11.3)	24.9 (11.6)	0.78
LRA (n=21)	26.1 (23.0)	28.7 (25.0)	0.81	25.3 (8.4)	27.3 (10.6)	0.64
All (n=86)	22.8 (19.0)	22.9 (17.6)	0.98	25.3 (12.0)	23.0 (9.1)	0.33

Table 1. Comparison of branch morphology between custom-made and standardized stent grafts.

### **The Hybrid Procedure: Arch and Visceral/Renal Debranching Combined with Endovascular Repair for Thoracic/Thoracoabdominal Aortic Aneurysms**

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**Objective:** To report a single-center experience using a hybrid procedure (open debranching followed by endovascular aortic repair) for treatment of thoracic/thoracoabdominal aortic aneurysms.

**Methods:** From 2005-2010, 48 patients (31 male, mean age 71) underwent a hybrid procedure for thoracic/thoracoabdominal aortic aneurysms. Thirty-day/in-hospital morbidity/mortality; and late endoleak, graft patency and survival were analyzed. Graft patency was assessed by CT, angiography or duplex ultrasound.

**Results:** Hybrid procedures were employed to treat 24 thoracic, (11 arch, 13 descending), 19 thoracoabdominal, (Crawford type I - III: 3, type IV: 7, type V: 9), and 5 para-anastomotic aortic aneurysms. The hybrid procedure involved debranching arch vessels (47) or visceral/renal vessels (73) using bypass grafts followed by endovascular repair. Eighty percent of debranching and endovascular repair procedures were staged with an average interval of 25 days. Major 30-day/in-hospital complications occurred in 38% of patients and included bypass graft occlusion (4), endoleak reintervention (2), and paraplegia (1). Thirty-day/in-hospital mortality was 4.2%, secondary to bowel ischemia in one patient and aneurysm rupture in the other. Over a mean follow-up of 13 months, 3 type II endoleaks required four interventions. Seven patients died: sepsis (1), respiratory failure (1), and unknown cause (5). There were no documented aneurysm related deaths or new graft/limb occlusions. Primary bypass graft patency was 96%. 1-year and 3-year actuarial survival was 85% and 67%, respectively.

**Conclusions:** The hybrid procedure for the treatment of thoracic/thoracoabdominal aortic aneurysms is a competitive alternative to traditional open repair and endovascular repair with branched stent-grafts. The results reported above validate this approach for the short-mid term, however longer follow-up is required to appraise its durability.