



Michigan Vascular Center (MVC) - Mission Statement

MVC exists to improve the quality of life for patients by providing the most comprehensive, innovative and best possible vascular care based on sound principles of treatment.

MVC exists to render that care with compassion, respect, & integrity; exercising the best possible thought and judgment for the patient's benefit.

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SAAAVE Your Patient

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Since the month of September is designated as National Vascular Awareness month, it is important to highlight the national efforts that have been made to raise awareness of the silent, lethal disease process of abdominal aortic aneurysm. As you will see in a related article in this journal, ***One For The Ages***, the technological advances in the treatment of some of the manifestations of vascular disease such as abdominal aortic aneurysms (AAAs) are truly remarkable. However, the age old problem of the diagnosis of this disease process remains as critical and as vexing as ever.

Because an abdominal aortic aneurysm is asymptomatic in its growth, because it is very difficult to palpate due to its deep seated, retroperitoneal position and because it can be treated with great success under elective conditions whereas the results of emergent treatment are abysmal, the diagnosis and elective treatment of an abdominal aortic aneurysm become paramount for all patients. It was the realization and acknowledgement of these circumstances that led to the creation of a National Aneurysm Alliance which convinced Congress to pass the ***Screen Abdominal Aortic Aneurysms Very Efficiently (SAAAVE)*** legislation. Effective in 2007, this act made screening for abdominal aortic aneurysms a benefit in the ***“Welcome To Medicare” initial physical exam*** for all men with a smoking history entering Medicare, and for women with a family history of AAAs. The benefit carries no deductible. Recent legislation has extended the ***“Welcome To Medicare”*** physical from within six months of joining the program to 12 months. Beyond that point, the benefit is lost. .

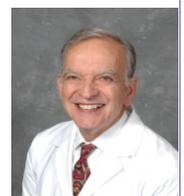
While the initial act was a landmark piece of legislation, we are now becoming painfully aware of the fact that according to recent AMA documents, only about 18% of patients entering Medicare actually undergo a ***“Welcome to Medicare”*** physical. The causes for this is unclear. Whether it is due to poor patient awareness or lack of physician involvement, is not clear. In an effort to improve the vascular health of the citizens of this community, we at the Michigan Vascular Center encourage all physicians to encourage all of their patients entering Medicare to avail themselves of the AAA screening benefit available to them under the ***“Welcome to Medicare”*** physical.

SAAAVE your patient. It's there for the patient's benefit.

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≈ Carlo A. Dall'Olmo, M.D.



Congratulations—Drs. Wilson and Becker !!!

We at the Michigan Vascular Center wish to extend our congratulations to our colleagues, David B. Wilson, MD, and Russell W. Becker, DO, for their recent acceptance into the prestigious Society for Vascular Surgery (SVS), the premier vascular society in the United States. Becoming one of only 2,400 members nationally, their accomplishment exemplifies the commitment to excellence, integrity, the pursuit of knowledge and compassion in patient care that are the prerequisites for entry into the SVS; and are the core values of the members of Michigan Vascular Center.

Both men are “board-certified” in vascular surgery. Dr. Wilson passed the American Board of Surgery’s requirements in May, 2006; while Dr. Becker was certified by the American Osteopathic Board of Surgery in March, 2007.



David B. Wilson, M.D.

We are proud to have Dr Wilson and Dr Becker continue a tradition first established in 1963 by our founder, Dr Albert J. Macksood — having physicians in our group with the highest level of training and expertise in the vascular field to treat the vascular needs of the patients of this community.



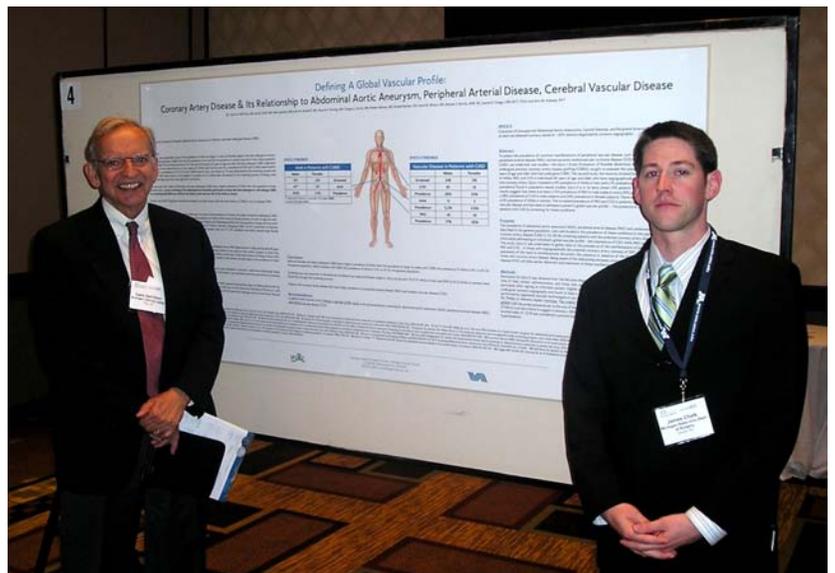
Russell W. Becker, D.O.

Dr. Dall’Olmo Presents at Society for Vascular Medicine - Annual Meeting, May 2008

Dr. Dall’Olmo presented findings of two research projects, EPICS I and EPICS II, in which patients with coronary artery disease were screened for vascular disease of the carotids, aorta, and legs. The findings suggest a 25% prevalence of carotid stenosis, a 20% prevalence of Peripheral Arterial Disease (PAD), and an increase of prevalence of AAA’s in men and women with a history of coronary artery bypass graft (CABG).

The conclusions were that those with coronary artery disease should be screened for AAA, carotid disease and PAD.

A poster presentation displayed the final results of EPICS I along with side-by-side summary results of EPICS II.



Carlo A. Dall’Olmo, M.D.
Michigan Vascular Center

James Chalk, M.D.
McLaren Regional Medical Center

MVC Wins 2 First Place "FAME" Awards

The MSU/FAME Community Research Forum is a collaborative event sponsored by Genesys Regional Medical Center, Hurley Medical Center, McLaren Regional Medical Center, and MSU/Flint Area Medical Education.

This annual event includes, on average, more than 170 oral and/or poster presentations of original research conducted by teaching facilities, resident physicians, medical students, nurses, and other health professionals. This year Michigan Vascular Center is happy to announce winning two first place awards.

Nurse Investigator Award given to Brenda Buckle, ANP, BC

"Evaluation of Unsuspected Abdominal Aortic Aneurysms In Patients Who Have Undergone Coronary Artery Bypass Grafting: EPICS I"

Authors:

Brenda Buckle, ANP, BC; Carlo Dall'Olmo, MD; John McIluff, MD; Wayne Kinning, MD; Gregory Fortin, MD; Scott Garner, MD; Robert Molnar, MD; Russell Becker, DO; David Wilson, MD; Fernando Jara, MD; Frederick Armenti, MD; Anup Sud, MD; Joanne Drago, LPN, RVT, FS; and Ann Inskeep, RVT.



Best Case Oral Presentation—First Place—James Chalk, M.D.

Coronary Artery Disease and its Association with Abdominal Aortic Aneurysms, Peripheral Arterial Disease and Cerebrovascular Disease.

James Chalk, M.D.— McLaren Regional Medical Center

Authors:

James Chalk, MD; Carlo Dall'Olmo, MD; Brenda Buckle, ANP BC; Joanne Drago, LPN RVT FS; Ann Inskeep, RVT.

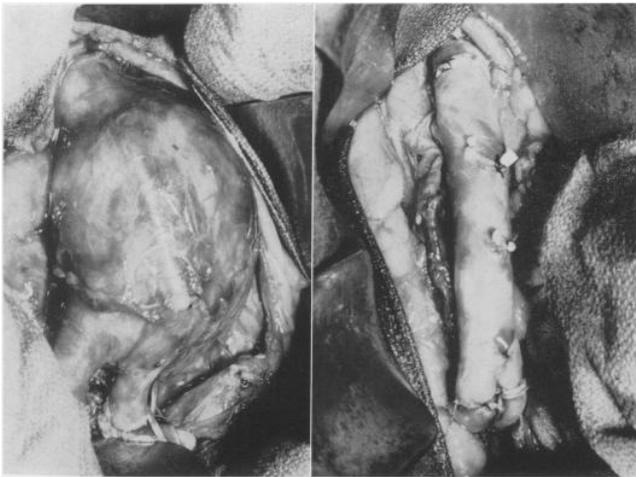
Congratulations To All !

One For The Ages Percutaneous, Endovascular AAA Repair Under Local Anesthesia

Occasionally in the evolution of specialty surgical procedures, an event transpires that on the surface seems like a logical next step yet when considered in its historical context, it is absolutely mind-boggling and merits reporting. Such is the case with the most up-to-date treatment of Abdominal Aortic Aneurysms — **an endovascular approach performed percutaneously, under local sedation!** No, your eyes did not deceive you. The operative word is **percutaneously, under local sedation!**

First performed several months ago by two of our members — Drs. Russell Becker and David Wilson — the patient was discharged the following day. How significant is this feat? Consider a bit of surgical history.

Prior to 1951, the treatment of an Abdominal Aortic Aneurysm for a surgeon was much like the famous Norman Rockwell painting of the physician sitting next to the bed of the sick child, hoping the illness would run its course, resigned to his futility in knowing he had limited treatments at his disposal. He could do no more and he knew it. So it was for the surgeon with a patient who had an aortic aneurysm. There was no treatment available because none of the graft materials, instruments, techniques and ancillary anesthetic and respiratory services had been developed. The surgeon was helpless and worse yet, he knew it.



AAA Repair 1956
Annals of Surgery 1956, Jan. 143(1) 57-64)

Then in 1951 Dr. Charles DuBoust, a French surgeon, performed the first successful abdominal aortic aneurysmectomy in Paris. Using a homograft derived from a cadaver, his successful effort ushered in the era of AAA surgery. As time passed, many advances contributed to improving the technical success of the operation. From improved anesthetic agents and respiratory advances to high quality graft materials, it became possible for even the higher risk patient to safely undergo this procedure. There remained, however, one constant — the procedures were long because the surgical techniques had not changed. It was not unusual to spend four to six hours resecting and grafting an aneurysm.



Dr. Charles DuBoust
Journal of Vascular
Surgery, Vol. 33,
Issue 4, Pg. 895. S.
Friedman

Then in 1992, Dr. Juan Parodi from Brazil introduced a new break-through approach to the treatment of an abdominal aortic aneurysm. By combining open surgical and catheter and wire techniques, Dr. Parodi created a homemade “endograft.” It was a Dacron sleeve attached to an expandable stent placed on an expandable balloon which could be directed over a wire residing within the lumen of the artery. The homemade “endograft” could thus be delivered over a wire and positioned within the aorta to replace the aneurysm. Thus began the era of the endovascular repair of an abdominal aortic aneurysm.

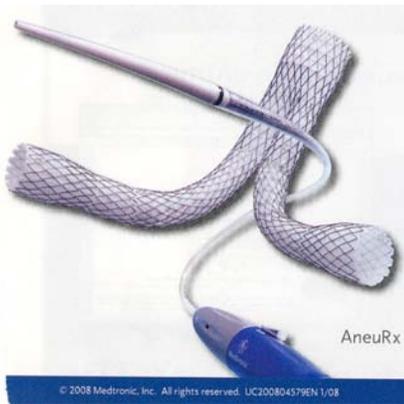
With this approach the surgical insult to the patient decreased dramatically as now only two small incisions were made — one over each femoral artery — to deliver the devices. Gone was the long abdominal incision and requisite retroperitoneal dissection! Still, patients were put to sleep for the entire procedure and open arterial surgical techniques were needed in the femoral arteries to repair the large holes made by the delivery systems. The challenge then became a technological one: developing advanced, user friendly endografts and delivery systems.

(Continued on page 5)

One For The Ages *(Continued)* Percutaneous, Endovascular AAA Repair Under Local Anesthesia

Over the past few years this challenge had been met. With miniaturized endograft delivery systems creating smaller puncture sites in the femoral arteries along with the development of arterial closure devices which can seal an arterial puncture site percutaneously, the stage was set for what was once unimaginable — the ***percutaneous repair of an abdominal aortic aneurysm under local anesthesia*** ! It required but the thought of merging the two technologies to make the impossible routine.

We at the Michigan Vascular Center are pleased to report that recently Drs. Becker and Wilson performed such a procedure on an elderly patient with multiple risk factors and a large abdominal aortic aneurysm. Having recently participated in another such intervention, I could not help but marvel about doing an aneurysm repair under local with but two small femoral artery punctures. The experience was absolutely exhilarating and mind boggling: a welcome advancement over the years and long hours spent treating aneurysms when “open” surgery was our only option.



When we shed our lead aprons and scrub gowns at the end of the procedure, we placed a simple band-aid over each femoral artery puncture site and then leaned over the drapes and informed the patient the procedure was completed. He responded with a “Thank you” and was wheeled out of the room!

One for the ages, I thought, truly one for the ages.

≈ Carlo A. Dall’Olmo, M.D.



Feedback Please !!!

Michigan Vascular Center began publication of *Vascular Voice* in May, 2006. Its purpose is to share with you developments and topics in the field of vascular surgery and vascular medicine. We hope we are meeting that goal. Your input would be very helpful to us in continuing this project.

Please send a brief E-mail with your thoughts

JoanB@MichiganVascular.com

- ? Have you found the publication helpful?
- ? Are the articles a good length, etc.?
- ? What suggestions do you have for vascular topics of interest to you?

We promise not to share your e-mail address and you will NOT receive SPAM from us.

Thank You. Your Input is Highly Valued !

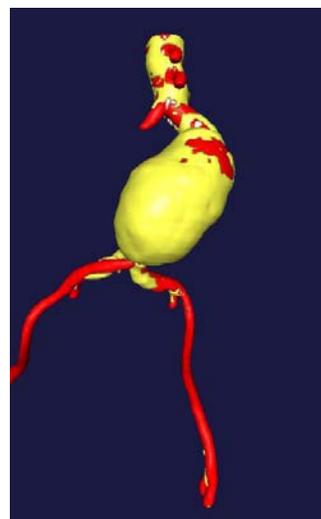
Note: Back issues are available on the Website (www.MichiganVascular.com)
For an original copy, email request indicating Volume and Issue numbers.

Pythagoras Trial Update

Despite more than a dozen years of innovations and five different commercially available products, roughly half of patients with an abdominal aortic aneurysm (AAA) still cannot have minimally invasive endograft repairs. A new device, the Aorfix by Lombard Medical, was designed to address this problem. Roughly 400 have been implanted worldwide. Currently approved for use in Europe and South America, the Aorfix is available in the U.S. only as part of the Pythagoras trial, which is expected to conclude by the end of 2008.

MVC was selected as one of only thirty sites across the U.S. to participate in this trial. Patients with highly angulated aortic “necks” between the renal arteries and the aneurysm have previously been denied endovascular repairs. This Aorfix graft is designed to achieve stable repairs in this situation, which is present in roughly 15% of those with AAA..

Our initial patient enrolled in this trial had been denied repair of her 6 cm AAA for years due to excessive medical risk for open surgery, and roughly 70 degree angulation of her aneurysm neck. This precluded successful endografting with commercially available devices. The 3-D CT-generated model of her aneurysm is shown in Fig 1. MVC Surgeons David Wilson, MD, FACS and Robert Molnar, MD, FACS implanted the device at McLaren with complete exclusion of the aneurysm. Her operation was performed through 4 cm incisions in each groin, and her convalescence has been uneventful.



Enrollment in Pythagoras nationwide has been brisk. The FDA requires only 160 patients to be treated, at which time the trial will close. MVC Surgeons will continue to offer this treatment until that time to those patients with anatomy unsuitable for standard endografting. If you are aware of a patient who has been denied an endograft repair, we would be happy to review his or her information to assess if enrollment in this trial might be a good option.

≈ David B. Wilson, M.D.

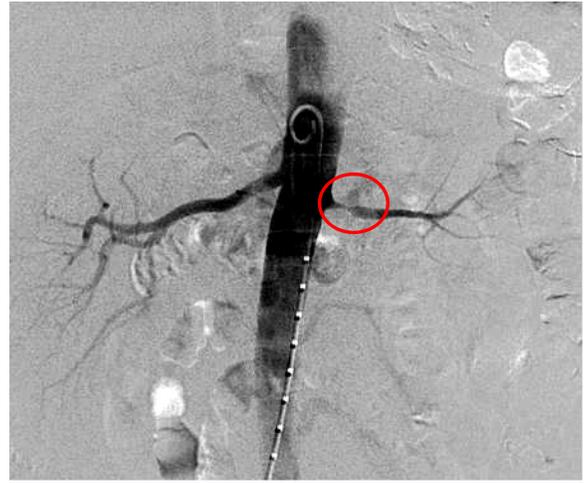


Renal Artery Stenosis—To Stent or Not To Stent? The CORAL Trial



Renal Artery Stenosis (RAS) is a common problem present in up to 5% of the American population with an incidence of approximately 7% in patients over age 65. Despite the frequency of RAS, there is generally no consensus on diagnosis, therapy, or follow-up. There have been clinical studies that support the benefit of RAS stenting as well as studies that fail to show any benefit at all. Because there has been no clear cut evidence-based guidelines established, there has generally been a “find-it, fix-it” approach by some clinicians. The most widely accepted indications for RAS stenting are either poorly controlled blood pressure or renal insufficiency in the presence of severe RAS. Having identified that there has been no consensus on the benefit for RAS stenting, are the costs associated with such therapy warranted?

To help answer this important question, The Michigan Vascular Research Center (MVRC) has begun recruitment for a multi-center clinical trial on RAS and hypertension sponsored by the National Institutes of Health. The trial, Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL), is



The First Patient Entered in the CORAL Trial
Randomized to Optimal Medical Therapy!!



Atherosclerotic RAD
Majority are ostial, extensions of aortic plaque

recruiting more than 1,000 patients at 100 sites around the United States; and we are now happy to begin enrollment. During the study, participants will be randomized to one of two groups. They will receive medication alone to control blood pressure and other risk factors, or they will be treated with medication and placement of a stent in the diseased renal artery segment(s). Participants will be followed for the duration of the six-year study to determine which treatment reduces the incidences of heart attack, heart failure, stroke and kidney failure. The primary endpoints are event-free survival from cardiovascular and renal adverse events, defined as a composite of cardiovascular or renal death, stroke, myocardial infarction, hospitalization for congestive heart failure (CHF), progressive renal insufficiency, or need for permanent renal

replacement therapy. The CORAL study will examine whether inserting a stent will lead to better overall outcomes in this patient population and help direct future therapy with evidence-based results.

We are pleased to have Drs. Nabil Zaki, M.D. (Mid-Michigan Kidney/Hypertension, PC) and Ali K. Mohammed, M.D. (Nephrology and Hypertension, PC) as co-investigators for this trial to lend their expertise with the aggressive anti-hypertensive therapy associated with the trial. If you are interested in discussing this more fully or if you have patients you would like to refer, please contact the Michigan Vascular Research Center at (810) 600-2009 and mention “CORAL”. Additional information is also available on our website: www.MichiganVascular.com or www.CoralClinicalTrial.org.

≈ Robert G. Molnar, M.D.



Michigan Vascular Research Center—Updates

Michigan Vascular Research Center (MVRC) is one of the country's most experienced sites for carotid stenting and AAA endovascular repair. Our specialists are currently participating in multiple FDA-approved trials in the following areas:

- ❖ Carotid Stenting
- ❖ AAA Endovascular Repair
- ❖ AAA Endovascular Pressure Measurement
- ❖ Iliac Stenting
- ❖ Renal stenting
- ❖ SFA Stenting
- ❖ Fistula Placement
- ❖ Stem Cell Treatment for Critical Limb Ischemia.

Our research team consists of 9 vascular surgeons, a research director, two clinical research coordinators and two research assistants. Because of Michigan Vascular Research Center's dedication and commitment toward conducting research, we were the first in the state to enroll patients in several trials.

- ◆ First in the state of Michigan to implant a FDA approved carotid stent manufactured by Guidant, Inc. in September 2004.
- ◆ First and only site in the state of Michigan to implant a superficial femoral artery drug-coated stent manufactured by Cook, Inc. in October 2005.
- ◆ First in the state of Michigan to implant a FDA approved abdominal aortic aneurysm pressure monitoring device, manufactured by CardioMEMS in June 2006. This device is used in patients who undergo endovascular repair of an AAA and measures the pressure over time within the excluded AAA for leaks.
- ◆ First in the state of Michigan to enroll a patient into the Stride Study in May 2008. The Stride Study uses the Trellis-8 system for treatment of DVT.

**MVRC
First in
Michigan
TO ENROLL
IN
Several
Trials**

List of Current Trials

MVRC has participated in many different phases of research from Phase I to Phase IV.

The following list summarizes current trials being conducted at MVRC. If you have any questions about these studies or would like to have your patient evaluated for one of these open trials, please don't hesitate to contact me at (810) 600-2009.

≈ Brenda Buckle, ANP-BC





Michigan Vascular Research Center
(810) 600-2009

Current Trials Open For Enrollment

STUDY	TYPE	DATE STARTED	ENROLLING	BRIEF DESCRIPTION
Vascutek	Fistula Graft	8/24/2008	Surgery Center or McLaren	Implantation of either the Vascutek Vascular Access Graft (Rapidax) or a standard Vascutek ePTFE Graft (Maxiflo)
Coral	Renal Stent NIH Granted Study	5/16/2008	McLaren	Renal Stent Randomized to either medical therapy or medical therapy and renal stent.
Pythagoras	AAA graft	2/15/2008	McLaren	AAA graft (≥ 60 Degree neck)
Sonic I	DVT	1/18/2008	McLaren	OmniWave for DVT
Complete	Iliac Stent	9/21/2007	McLaren	Iliac Stent
Abraxis	Revasc. SFA re-stenosis prevention with	8/17/2007	McLaren	Paclitaxel IV for SFA restenosis after PTA stenting

Continued on page 10

Current Trials Open For Enrollment

STUDY	TYPE	DATE STARTED	ENROLLING	BRIEF DESCRIPTION
Aastrom	CLI	8/5/2007	MVAC	Use of TRC Autologous Bone Marrow Cells in Patients with Peripheral Arterial Disease to Treat Critical Limb Ischemia Bone Marrow aspiration then 14 days later 20 injections into limb.
Create PAS	Carotid Stent	5/9/2007	Genesys	High Risk CAS (Carotid Artery Stenting)
Sapphire WW	Carotid Stent	2/14/2007	Genesys	High Risk CAS (Carotid Artery Stenting)
CardioMEMS	Endovascular Sensor for AAA repair with graft	8/18/2006	McLaren	All AAA undergoing EVT Graft who agree to participate
CAPTURE II	Carotid Stent	12/16/2005	McLaren	High risk CAS (Carotid Artery Stenting)
Zilver Phase II	Evaluation of the ZilverPTX Vascular Stent in the above-the-knee Fem-Pop	8/29/2005	MVAC	SFA Stenosis Randomized to receive either a Zilver PTX Drug eluting Vascular Stent or PTA. (If PTA fails may have stent placed) A lesion in each limb (total of two lesions per patient) may be treated.

Current Trials Open For Enrollment

STUDY	TYPE	DATE STARTED	ENROLLING	BRIEF DESCRIPTION
Pivotal	Small AAA Graft vs. Surveillance (randomized)	6/8/2005	McLaren or Genesys	Surveillance vs AAA Graft Tx of AAA early 4.0 to 5.0 cm. Pt. must be willing to be randomized Follow-up is 60 months.
CoSmic	AV Fistula Covered Stent to exclude pseudoaneurysms	4/15/2005	Yes McLaren	AV Fistula - Stent to exclude pseudoaneurysm.
EPICS II	AAA Study Pt. with Coronary Artery Disease	8/1/2004	MVC	Coronary Artery Disease $\geq 50\%$ stenosis diagnosed upon Cardiac Cath. Looking for incidence of AAA, Carotid Stenosis & PAD.

Meet the MVRC Research Team



Left to Right: Jill George, BS, CCRC; Linda Reynolds, CRA; Brenda Buckle, ANP-BC (Director) Joan Brown, CRA; Maureen Angles, CRA



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The Surgery Center)



VeinSolutions
Leaders in Genetic & Therapeutic Vein Care

VeinSolutions

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MVC Core Values

- We are a professional organization –a team– working equally in a common cause: To provide the best possible vascular care for the physicians, patients, and institutions of our community.
- We share a commitment to excellence in the vascular care of patients through the pursuit of knowledge, communication, innovation, and research.
- We value our employees and incorporate them into our team.
- We commit to each other to honor & pursue these values.

AFFILIATE



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