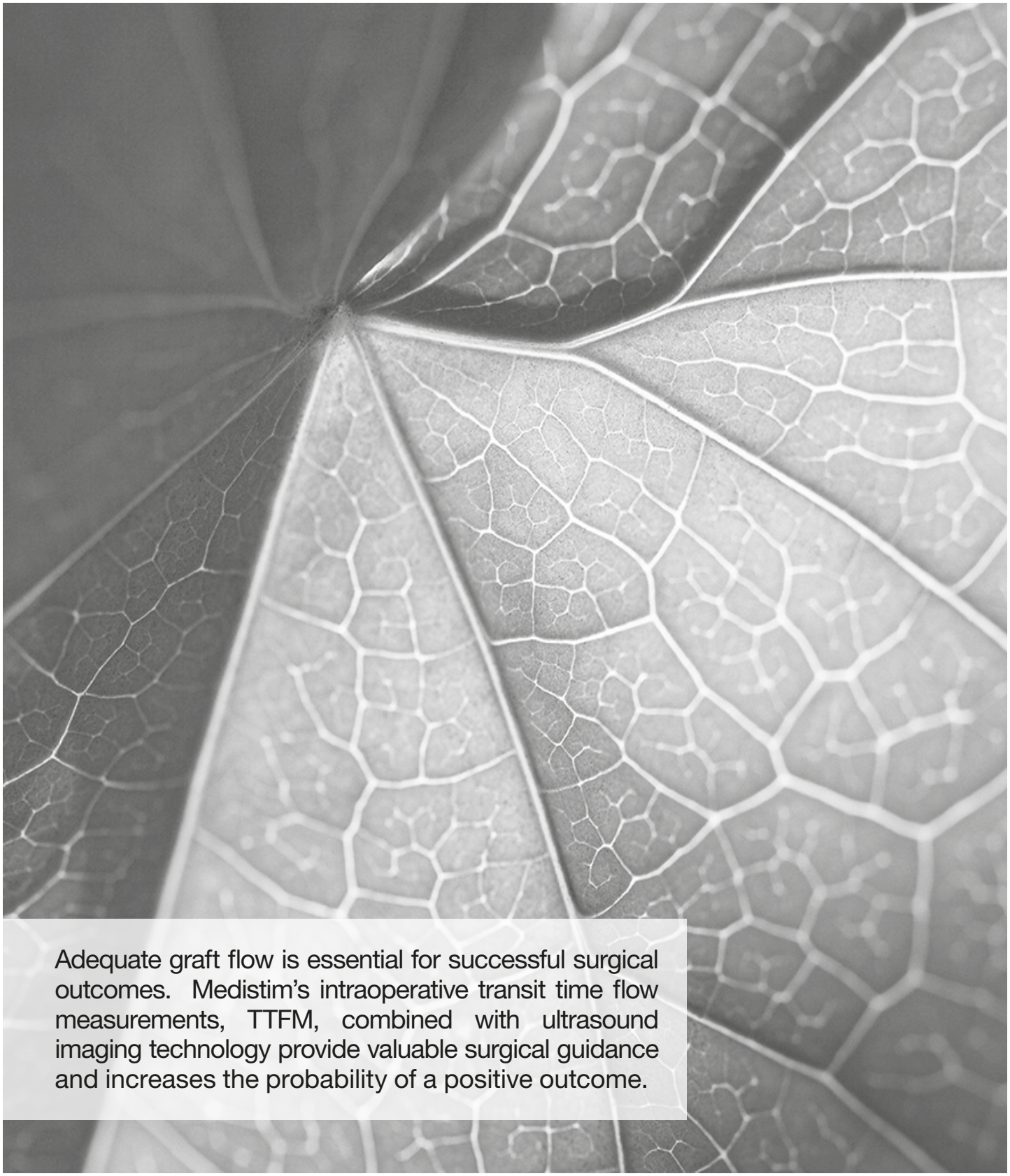
Quality Assessment in Vascular Surgery



Adequate graft flow is essential for successful surgical outcomes. Medistim's intraoperative transit time flow measurements, TTFM, combined with ultrasound imaging technology provide valuable surgical guidance and increases the probability of a positive outcome.

Benefits of Performing Quality Assessment in Vascular Surgery

For the Patient

Performing perioperative quality assessment using Medistim technology can greatly increase the patients' probability of a positive outcome and lessen the chance of additional and unnecessary surgical reinterventions.

For the Surgeon

Medistim technology provides objective, quantifiable feedback on how well a graft is functioning during an operation. Surgeons can leave the operating room with the assurance that the construct is functioning well. All surgical findings can be documented through the flow tracings and images provided by the Medistim system.

For the Payer

Intraoperative ultrasound imaging using a Medistim system during CEA can substantially lower the rate of perioperative stroke and mortality and can be more cost-effective than either completion angiography or no operative imaging.[1]

Why measure flow in Vascular Surgery?

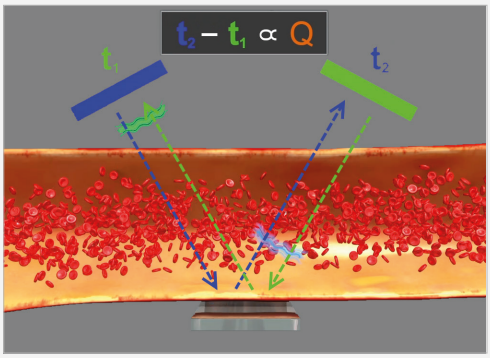
The need to measure blood flow intraoperatively became apparent during the development of reconstructive arterial surgery. Many surgeons still rely on pulse palpation as an index of flow, but a vessel can pulsate even when there is no blood flowing through it. The pulse may even increase if the vessel occludes distal to the palpation site, though admittedly not for long.

The primary aim of transit time flow measurement (TTFM) is to obtain information on the immediate results of the reconstruction, where a technical failure may jeopardize an otherwise successful operation.

To eliminate technical failures, intraoperative quality control of the reconstruction is important. Furthermore, such investigations can also be helpful in planning the procedure and in giving an indication of the long-term prognosis of the operation.

Documentation

The Medistim systems will store accurate flow analysis and produces a single documented report. This can be used as evidence of graft patency as records for referring physicians and for preparing publications.



TTFM

The TTFM principle is based on measuring the difference between upstream and downstream transit time of a wide ultrasound beam. The transit time difference is directly proportional to the blood volume flow. This measurement principle gives an accurate quantification of the real time volume flow that compliments the ultrasound imaging.

References

1. Cost-effectiveness of intraoperative imaging in carotid endarterectomy. Burnett MG, Stein SC, Sonnad SS, Zager EL. Department of Neurosurgery, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, USA.
Neurosurgery. 2005 Sep;57(3):478-85; discussion 478-85. Burnett MG.

Carotid Endarterectomy Verification

See the invisible and undo technical imperfections before closure

Medistim's systems offer the unique combination of flow measurement (TTFM) and high frequency ultrasound imaging guidance to help reduce and minimize the risk of postoperative neurological issues.

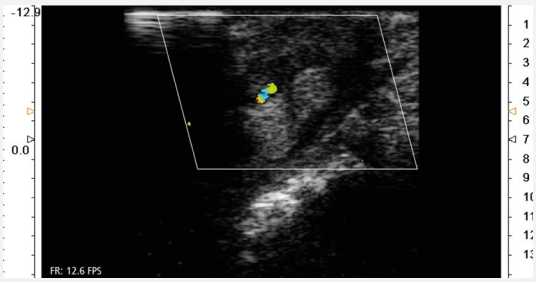
Vascular surgeons should use Medistim systems for quality assurance during carotid endarterectomy (CEA) to get immediate feedback on their work. When technical defects go undetected, patients are at risk of postoperative stroke. Medistim technology gives surgeons the opportunity to revise on the spot.

The use of ultrasound imaging as a quality assessment tool has proven effective in revealing technical imperfections in >10% of cases, leading to immediate revision.[2]

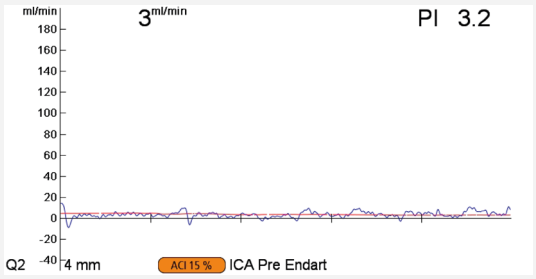
Ultrasound imaging is a valuable tool for visualization and evaluation of the stenosis and the completed endarterectomy. [3,4]

An image of the anastomosis reveals otherwise unseen imperfections and gives the surgeon the chance to correct before closure.

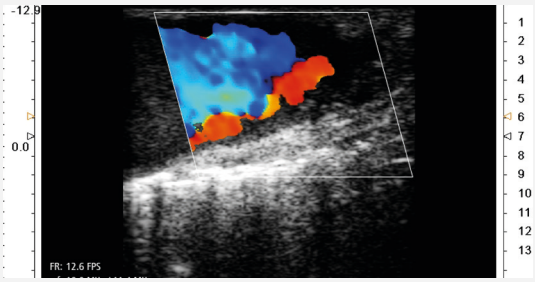
Graft patency is the predominant predictor of early neurological events.



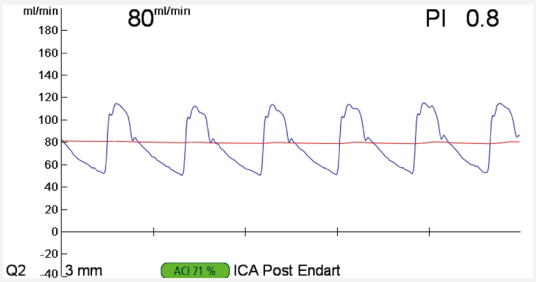
Pre-endarterectomy imaging



Pre-endarterectomy flow measurements



Post-endarterectomy imaging



Post-endarterectomy flow measurements

References

2. Intraoperative Duplex Ultrasonography in Carotid Endarterectomy: The Impact on Indication for Immediate Revision and Intermediate-term Outcome.
Ott C, Heller G, Odermatt M, Furrer M.
VASA, May 2008; 37: 151-156. Department of Surgery, Kantonsspital Graübunden, Chur, Switzerland.

3. Will carotid thromboendarterectomy remain competitive? Influence of intraoperative duplex ultrasound quality control.
H.W. Kniemeyer, C. Sporkmann, H. Beckmann, R. Marti¬nez, U. Sabin-Luzius, A. Salem, A. Soliman, A. Pühler.
Chirurg 2007 · 78:236–245 DOI 10.1007/s00104-006-1287-z. Springer Medizin Verlag 2007.

4. Cost-effectiveness of intraoperative imaging in carotid endarterectomy.
Burnett MG, Stein SC, Sonnad SS, Zager EL. Department of Neurosurgery, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, USA.
Neurosurgery. 2005 Sep;57(3):478-85; discussion 478-85. Burnett MG.

Peripheral Bypass Verification

Control the flow and save the patient's leg

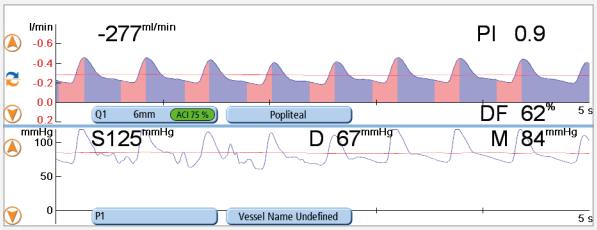
Medistim offers a unique intraoperative quality assessment system combining flow measurements with imaging for immediate feedback and the chance to revise before closure.

Volumetric flow values have proven to be an important factor for predicting graft longevity.[5] Good graft function increases the likelihood of saving the patient's leg.

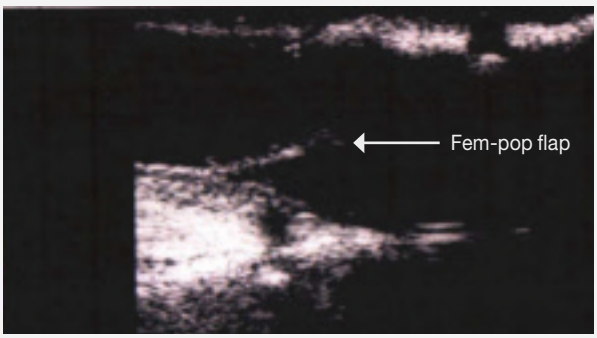
The risk of early postoperative occlusion is significantly increased if the basal blood flow after femoropopliteal reconstruction is less than 100 ml/min or the Papaverine-induced flow (intra-arterial injection of 40mg papaverine) is less than 200 ml/min.[5]

Capturing an image of the anastomosis using the Medistim system can reveal otherwise unseen imperfections inside veins and arteries. Medistim systems give surgeons the chance to correct imperfections before closure.

With graft patency being the predominant predictor of long-term survival after vascular surgery, surgeons can insure improved patient outcomes using this unique quality assessment device.



Sample tracing femoropopliteal bypass graft post Papaverine



Imaging example of a femoropopliteal flap

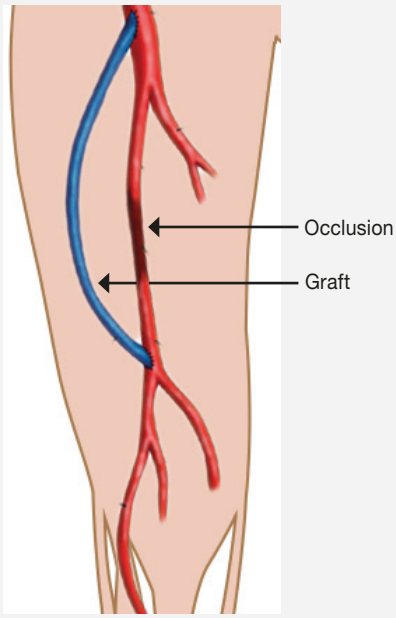


Diagram of femoropotliteal bypass

References

5. Methods for the Evaluation of Vascular Reconstruction
Einar Stranden,Department of Vascular Diagnosis and Research,Aker University Hospital, Oslo, Norway
Heart Drug 2004;4:201–217, DOI: 10.1159/000082191.

AV Access Verification

Control the flow and increase the probability for a long lasting shunt

Using Medistim systems for quality assessment during AV access surgery provides immediate feedback on how well a graft is functioning. If needed, revisions can be made before closure.

In AV access surgery, a non-maturing fistula due to low blood flow can require reintervention and prolonged use of a central dialysis catheter; if the flow is too high, there is a risk of hand ischemia and heart failure.

Patients with chronic renal failure often have a reduced quality of life. Performing quality assessment during AV access surgery will protect the patients against unnecessary re-interventions and improve their quality of life.

Flow quantification is a valuable tool for surgeons performing AV access surgery. The use of transit time flow measurements in combination with common qualitative assessment methods allows surgeons to leave the operating room with great confidence that their patient will have the best possible outcome.

Several studies have shown that volumetric flow rates are predictive of surgical outcomes. In fistulas using the radiocephalic artery, minimum flow rates between 100cc and 200cc/min are shown to have an increased likelihood of reaching maturity.[7, 8, 9,10]

Flow reduction using intraoperative access flow monitoring is an effective and durable technique allowing for the correction of distal ischemia and cardiac insufficiency in patients with a high-flow autogenous access. The desired postoperative access flow of 400 mL/min is not associated with an increased risk of thrombosis.[6]

Measuring flow with Medistim systems and quality assessment verification tools will increase the probability for a long lasting shunt and minimize the chance for reinterventions.

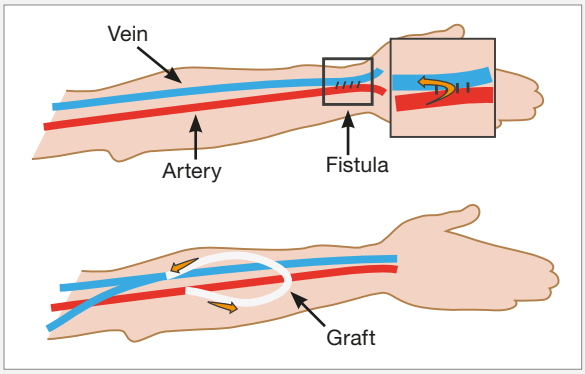


Diagram of AV access

References

6. Flow Reduction in high-flow arteriovenous access using intraoperative flow monitoring.
Juergen Zanow, MD, Karen Petzold, MD, Michael Petzold, MD, Ulf Krueger, MD, and Hans Scholz, MD, Berlin, Germany.
J Vasc Surg 2006;44:1273-8.91.

7. Correlation of intraoperative blood flow measurement with autogenous arteriovenous fistula outcome.
Chia-Hsun Lin, MD, Chai-Hock Chua, MD, Shou-Shan Chiang, MD, Jer-Young Liou, MD, Huei-Fong Hung, MD, Chung-Hsin Chang, MD, Taipei, Taiwan.
J Vasc Surg 2008;48:167-72

8. Predicting Arteriovenous Fistula Maturation with Intraoperative Bloow Flow Measurements.
Scott S. Berman, MD, FACS, Bernardo Mendoza, MD, Alex Westerband, MD, FACS, Rhonda C. Quick, MD, FACS, Tucson, Arizona, USA.
J Vasc Access. 2008 Oct-Dec;9(4):241-7.

9. Is intra-operative blood flow predictive for early failure of radiocephalic arteriovenous fistula?
François Saucy, Erik Haesler, Claude Haller, Sébastien Déglise, Daniel Teta, and Jean-Marc Corpataux, Lausanne, Switzerland.
Nephrol Dial Transplant (2010) 25: 862-867

10. Prognostic value of intraoperative blood flow measurements in vascular access surgery.
Christopher P. Johnson, MD, Young-ran Zhu, MD, Carrie Matt, BS, Corey Pelz, MS, Allan M. Roza, MD, and Mark B. Adams, MD, Milwaukee, Wisconsin, USA.
Surgery. 1998 Oct;124(4):729-37; discussion 737-8

Medistim Probes

With Medistim TTFM and Ultrasound Imaging probes, volumetric blood flow can be accurately measured through exposed arteries, veins, and conduits during surgical procedures.

Medistim QuickFit™ TTFM Probes - PS Probe Series

Probe name	Probe sizes (mm)	Part numbers*
QuickFit™ TTFM Probes	**1.5**	**PS101011, PS101012**
	2	**PS100021, PS100022**
	3	**PS100031, PS100032**
	4	**PS100041, PS100042**
	5	**PS100051, PS100052**
	7	**PS100071, PS100072**

Medistim Vascular TTFM Probes - PV Probe Series

Probe name	Probe sizes (mm)	Part numbers*
Vascular TTFM Probes	**1.5**	**PV101011**
	2	**PV100021**
	3	**PV100031, PV100032**
	4	**PV100041, PV100042**
	5	**PV100051, PV100052**
	6	**PV100061, PV100062**
	8	**PV100081, PV100082**
	10	**PV100101, PV100102**
	12	**PV100121, PV100122**
	14	**PV100141, PV100142**
	16	**PV100161, PV100162**

**Part numbers that end with 1 indicate probes without handle and part numbers that end with 2 indicate probes with handle*

Medistim Ultrasound Imaging Probe

Probe name	Part Number	System Compatibility	Technical Specifications
L15 High-frequency Ultrasound Imaging Probe	**EL100015**	**MiraQ™, VeriQ C™**	128-element transducer operates at frequencies from 8 - 18 MHz. Suitable for direct cardiac contact (CF). The following imaging modes are supported: • **B-Mode** • **CFM – Color Flow Mapping** • **PW – Pulsed Wave Doppler**

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All products mentioned in this brochure are in compliance with the European Medical Device Directive 93/42/EEC. Please refer to the User Manual for indications, contraindications, warnings, precautions, and further specifications and descriptions. Specifications may be changed without notice. For a list of flow probes for other applications, contact your Medistim representative.

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