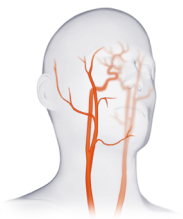
MEDISTIM

Quality Assessment in Vascular Surgery



CEA

Reduce risk of stroke

Peripheral Bypass

Secure short & long-term graft patency

AV Access

Improve maturation rate

Guidance & Completion Control in Vascular Surgery

Medistim technology is a versatile tool in various vascular procedures

The need to measure blood flow intraoperatively has become evident during the development of reconstructive arterial surgery.

Some 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. In every surgery case, vascular surgeons strive for a properly perfused end organ, for sufficient flow in the graft, and for the reconstruction to be free of technical errors.

Transit time flow measurement (TTFM) directly measures the volumetric flow through vessels which provides immediate results of a reconstruction, where a technical failure may jeopardize an otherwise successful operation.

Numerous clinical publications document the link between intraoperative TTFM values and graft patency predictions.

To help locate and understand technical imperfections, high frequency ultrasound (HFUS) can image the areas of concern and reveal morphological issues for immediate correction before closure. Several publications report an increase in intraoperative revision rate with the help of ultrasound imaging, thereby reducing the number of post-operative graft failures.

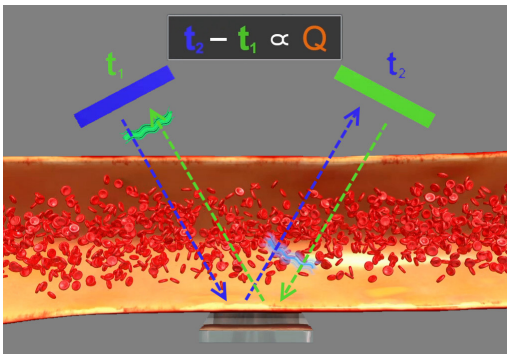
The Medistim MiraQ™ Vascular system offers both TTFM and HFUS modalities in one system. Surgical findings can be documented through flow tracings and images provided by the system, and surgeons can leave the operating room with the assurance that the construct is functioning well.

Intraoperative quality assessment and ultrasonic surgical guidance can greatly increase the patients' probability of a positive outcome and lessen the chance for additional and unnecessary surgical re-interventions.

TTFM - a proven technology

TTFM technology provides:

- Objective and reliable data
- Robust and user independent
- Easy to use

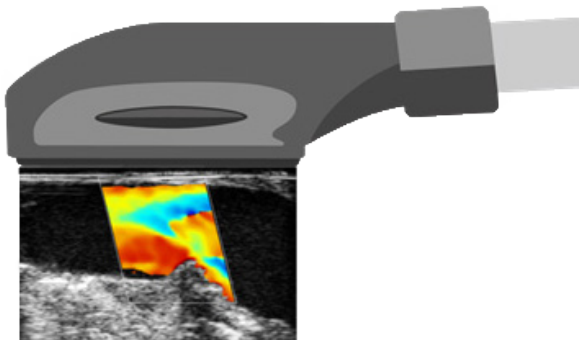


The TTFM principle is based on measuring the difference between upstream and downstream transit time of a wide ultrasound beam. The transit time difference is directly proportional to the blood volume flow. This measurement principle gives an accurate quantification of the real time volume flow that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

High-frequency Ultrasound imaging

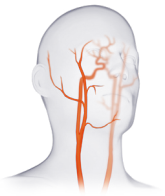
Medistim HFUS provides:

- High-resolution, near-field images during surgery
- Probe head designed for small incisions
- Reusable and sterilizable probe



Ultrasound imaging generates images by transmitting ultrasound pulses and receiving echoes from the pulses as they travel through the body. The received echoes are used to create an image of the target area. The color flow mode uses the Doppler principle to detect and visualize blood flow. Pulsed Wave (PW) Doppler uses the same principle to estimate blood flow velocity.

Carotid Endarterectomy Verification



Reduce risk of stroke

HFUS is your completion control every time. Superior to angiography in detecting defects, simply image the carotid area and undo technical imperfections before closure. Reveal flow issues after CEA with TTFM; high flow may be a predictor of cerebral hyperperfusion syndrome (CHS).

Purpose

Reduce the risk of stroke

Considerations

- Reduce risk of perioperative stroke with appropriate quality control and monitoring strategies during surgery [2, 7, 8, 9]
- 10% of the findings required immediate revision after ultrasound imaging revealed unexpected lesions [5, 6]
- High flow may be a predictor of hyperperfusion risk (> 500 ml/min) [3, 4]

Solution

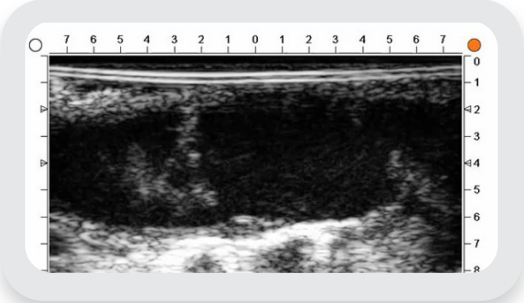
Completion control

- Use imaging after CEA to visualize the lumen
- Look for imperfections that can lead to thrombus formation
- Make sure all the relevant obstructions are removed to avoid risk of perioperative stroke
- Check post CEA flow to assess risk of hyperperfusion or other flow issues

ESVS 2017 Guidelines

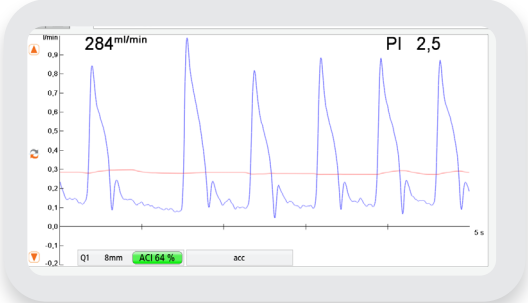
"Reliance on a single monitoring or quality control strategy is unlikely to make any difference because of the multiple causes of perioperative stroke." [1]

Example 1: Completion control with HFUS



Case from the CIDAC trial where angio showed no defect while a newly formed thrombus was visible with ultrasound leading to immediate revision. [10]

Example 2: Flow assessment



Completion TTFM is routine in many hospitals. Normal ICA (internal carotid artery) flow is recommended to be in the range of 100-500 ml/min. [9]

Courtesy of Prof. Hans-Henning Eckstein
Technical University of Munich, Germany

Peripheral Bypass Verification

Control the flow and save the patient's leg

The primary aim with peripheral bypass surgery is to secure both short and long term graft patency. Use TTFM as completion control every time. If inadequate flow improvement, investigate causes with HFUS for immediate correction.

Purpose

Increase blood flow to lower limbs

Considerations

- Reduce risk of amputation due to critical limb ischemia (CLI), and save the leg
- Intraoperative graft volume flow is a predictor of bypass occlusion after infrainguinal bypass [11, 12, 14, 17]
- Increase quality of life for patients with severe PAD, for improved mobility
- Health economy considerations, with PAD being a burden to society

Solution

Secure short and long term graft patency

- Assess the hemodynamics and vessel morphology intraoperatively with TTFM and HFUS [16]
- If low flow, assess further with HFUS [13, 15]
- Redo anastomosis or repair other technical imperfections before completion

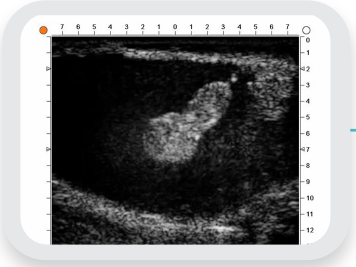
Intraoperative Quality Control with TTFM

Artery	Low Flow ml/min
Iliac arteries	< 300
Common femoral artery	< 200
Popliteal bypass	< 100
Crural bypass	< 80
Inframalleolar bypass	< 50

Table 1: An overview of estimated low flow values developed in clinical practice after routine use of TTFM in >8000 bypasses performed at Helsinki University Hospital. [9]

Case: Low flow assessment

Following vessel closure, TTFM served as first quality control. The results indicated poor flow and high PI in the superficial femoral artery (SFA), and led to further imaging of the vessel.



Intraoperative detection of a flow-obstructing flap during femoral thromboendarterectomy. The pulse in the superficial femoral artery was good. This finding led to an immediate revision.

Completion control with TTFM post revision showed improved flow and PI.

Courtesy of Prof. E.S. Debus
University of Hamburg, Germany

AV Access Verification

Improve maturation rate for best patient care

Control blood flow volume with TTFM as completion control every time. At low flow investigate causes with HFUS for immediate corrections.

Purpose

Develop a well-functioning vascular access for hemodialysis

Considerations

- Get the patient ready for dialysis within 4-6 weeks
- Adequate AV flow increases chance of a successful maturation [19, 22, 23, 24, 26, 27]
- Reduce the risk of primary failure rate, which can vary between 5-30 % [21]
- Exclude disease in the vein and technical errors with the anastomosis [18]

Solution

Improve maturation rate

- Completion control with TTFM
- If low flow, use HFUS to assess defects [25]
- Correct if needed before closure for best possible outcome
- At high flow (>800 ml/min), assess risk for steal syndrome [20]

Intraoperative Quality Control with TTFM

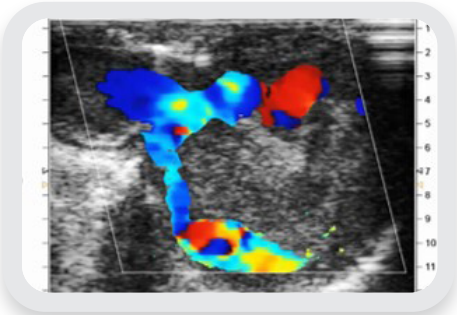
Artery	Low Flow ml/min
Radiocephalic AVF [9]	< 200
Brachiocephalic AVF [18]	< 280

Table 2: Shows estimated definition of low flow TTFM values developed in clinical practice. [9, 18]

Example 1: Completion control with TTFM

Use completion TTFM to ensure that the flow is adequate to increase the chance of a successful fistula maturation. The flow measurement indicates normal flow for radiocephalic fistula, according to literature. [18, 19, 22, 23, 24]

Example 2: Anastomosis assessment



Completion control of the anastomosis with HFUS revealed a thrombus in a native radiocephalic arteriovenous fistula (AVF).

Courtesy of Prof. Alexander Meyer. Klinik für Viszeral- und Gefäßchirurgie Johanniter Krankenhaus Rheinhausen, Germany

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AV Access

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Medistim High-frequency Ultrasound Imaging Probe™*

Medistim Vascular TTFM Probe™*

Medistim QuickFit™ TTFM Probe*

*Probes to be used with Medistim MiraQ™ or VeriQ™ systems.

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