MEDISTIM

Guidebook - Vascular

IMPROVE YOUR INSIGHTS

Intraoperative guidance and quality assessment using TTFM and HFUS

"The practical recommendation is that TTFM completion control can and should be utilized at the end of virtually every open or hybrid vascular surgical operation."

Vikatmaa & Albäck, 2018[1]

This guidebook is written by Medistim for the medical community with information and guidance on how to use our systems and probes during vascular surgery. The content is based on clinical experience and published articles and is not intended to be a substitute for medical advice, diagnosis or treatment. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of the individual patient. Please refer to the Medistim Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and further specifications and descriptions. Copies of this guidebook can be ordered at medistim.com.

1. Table of Contents

1. Introduction

Medistim background

Medistim launched its first flowmeter based on transit time flow measurement (TTFM) technology in 1994 (CardioMed). Since then, the company has developed several generations of quality assurance equipment. Medistim introduced the first ultrasound imaging probe approved for direct contact with the heart in 2009, and is currently the only supplier in the world that can offer a user friendly integrated TTFM and intra-operative high frequency ultrasound (HFUS) imaging system.

Medistim technology is a versatile tool in various vascular procedures. Surgical findings can be documented through flow tracings and images provided by the system. Medistim's TTFM probes utilize transit time technology to accurately measure blood volume flow intraoperatively. The imaging functionality provides the surgeon with both guidance before and during surgery and the opportunity to uncover the cause of poor blood flow measurements. Combining the spatial information from ultrasound imaging and quantitative data from TTFM enables the surgeon to make informed decisions, and revise when necessary.

Medistim provides reusable TTFM probes, a sterilizable ultrasound imaging probe and a Doppler probe. Most of the TTFM probes are available with or without a handle.

To measure blood flow with TTFM is a standard clinical practice in many countries and supported by numerous publications documenting the clinical value.

Medistim High-frequency Ultrasound Imaging Probe™

Medistim MiraQ™ Vascular System

Medistim Vascular TTFM Probe™

Medistim Doppler probe

Medistim QuickFit™ TTFM Probe

Objective

The objective of this guidebook is to provide a comprehensive overview of the Medistim TTFM and HFUS technology and to provide information on how to interpret measurements and images. The information provided is recommended to be used together with Medistim's online learning platform, EduQ *(medistim.com/education).*

Why perform TTFM and HFUS?

The authors of the initial quote in this guidebook explain this well: "Early graft failure after a vascular reconstruction leads to re-operations and may have catastrophic consequences for the patient, especially in cases of delayed diagnosis. It is thus crucial to control patency related issues and quality of the reconstruction intraoperatively. At the end of a vascular reconstruction, the flow in a graft should be sufficient and the reconstruction should be free of technical errors. Simple pulse palpation and inspection are not sufficient methods." [1]

Three areas of vascular surgery will be covered in this guidebook: Peripheral Bypass, AV Access and Carotid Endarterectomy.

Peripheral Bypass

The use of TTFM and HFUS during peripheral bypass will assist in hemodynamic assessments and predict graft patency. Any technical issues may be discovered and handled during the procedure and improve the patient's outcome. In 2000, the following statement from Albäck et al. was published: "Graft flow and maximal flow capacity are good predictors of the 1-year graft patency of femoro-crural bypasses."[19] Ihlberg et al. later concluded: "Intraoperative graft volume flow is a predictor of bypass occlusion after infrainguinal bypass. In addition, this study verifies an association between the development of clinically evident graft stenoses and low graft flow." [20]

AV Access

Arteriovenous fistulas (AVF's) for hemodialysis are associated with high primary failure rates. After performing a search on MEDLINE giving statistics from 7393 AVF's, Meyer et al. concluded with a 23% primary failure rate. In their latest publication, they state that the intraoperative measurement of the blood flow in the outflow vein has been identified as the unique significant parameter for the fistula maturation. Additionally, the reason for low flow in the outflow vein may be found and corrected by using HFUS during the AVF creation.[13]

Carotid Endarterectomy

The ESVS Guidelines state that the 30-day risk of stroke after Carotid Endarterectomy is between 3,2% and 6,2%. The risk of hyperperfusion syndrome is about 1%.[23]

Burnett et al. found in 2005 that using HFUS as completion control after CEA lowers the rate of perioperative stroke and mortality and is significantly more cost-effective than either completion angiography or no operative imaging.[3] Later studies have indicated that HFUS could be considered as an alternative intraoperative morphologic assessment tool in carotid surgery. TTFM may be useful to test the adequacy of the carotid reconstruction regarding normalized ICA flow.[23]

Other vascular procedures

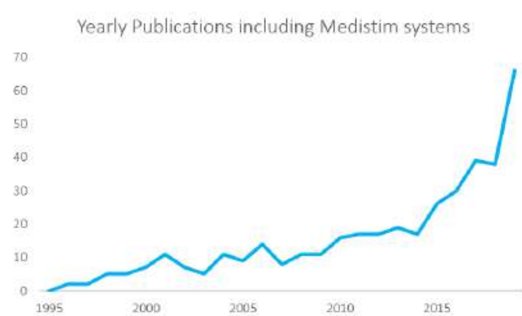
The technology may be used in several other vascular procedures like abdominal vascular surgery and aortic arch surgery. At the end of this booklet, we will include some examples from the use of TTFM and imaging in Femoral endarterectomy and Meso-Rex shunt.

Documentation

The Medistim systems can store accurate flow analysis and produce a single documented report. All measurements may be saved and later selected to prepare a customized report. This can be used as evidence of intraoperative quality control, as records for referring physicians, and for preparing publications.

Body of evidence

Documentation on the benefits of using TTFM and HFUS technology in vascular surgery is growing. There are currently over 60 clinical publications that include the use of Medistim TTFM and HFUS devices during vascular applications. Below is a curve showing the cumulative number of publications including Medistim systems from all applications. Medistim continuously monitors the field for new clinical data.



Peripheral Bypass

2019 Joint Guidelines of SVS, ESVS and WFVS

Global Vascular Guidelines on the management of chronic limb-threatening ischemia [5]

Recommendation 6.42
"Perform intraoperative imaging (angiography, DUS, or both) on completion of open bypass surgery for CLTI and correct significant technical defects if feasible during the index operation."

Recommendation Grade 1 (Strong),
Level of evidence C (Low)

SVS
Society for Vascular Surgery

ESVS
European Society for Vascular Surgery

WFVS
World Federation of Vascular Societies

Carotid Endarterectomy (CEA)

2023 ESVS Guidelines

Clinical practice guidelines on the management of atherosclerotic carotid and vertebral artery disease [7]

"QC is not the same as monitoring. The role of monitoring is to ensure adequate brain perfusion, (especially during clamping or shunting), using TCD, CEA under LRA, stump pressure, ICA backflow or near infrared spectroscopy. Loss of cerebral electrical activity is assessed by somatosensory evoked potentials (SSEPs) or EEG. The aim of QC is to identify and correct technical error, such as embolisation during carotid mobilisation (TCD), ensuring the shunt is functioning (TCD, CEA under LRA), identifying luminal thrombus before flow restoration (angioscopy), identifying luminal thrombus after flow restoration (DUS, angiography), diagnosing intimal flaps (angioscopy, DUS, angiography), diagnosing residual stenoses (DUS, angiography) and diagnosing the rare patient thrombosing the operated ICA during neck closure (increasing embolisation followed by declining MCA velocities on TCD)."

The authors refer to the Meta-analysis by Knappich C et al. published in 2021 as the basis for this new recommendation"

Recommendation 77 (New)
"For patients undergoing carotid endarterectomy, intra-operative completion imaging with angiography, duplex ultrasound or angioscopy should be considered in order to reduce the risk of peri-operative stroke."

Class IIa, Level B

ESVS
European Society for Vascular Surgery

AV Access

2011 Guidelines by DGG
Vascular shunt surgery [6]

"Ischemia caused by high flow (>800 ml/min for AV fistula, >1.200 ml/min for prosthetic shunts) need to be reduced in a step-wise manner, using intraoperative flow measurements (to around 400 ml/min for AV fistula and 750 ml/min for prosthetic shunts)."

DGG
Deutsche Gesellschaft
fur Gefasschirurgie

2018 ESVS Clinical Practice Guidelines [7]

Recommendation 25
"If after creation of a vascular access, there is no thrill or a bruit in the region of the anastomosis, further investigations should be considered."

Class IIa, Level C

ESVS
European Society for
Vascular Surgery

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3. Abbreviations

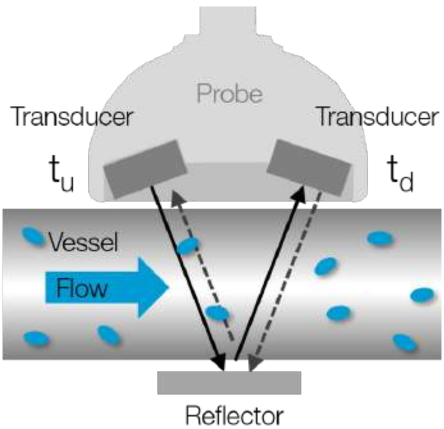
ACI	Acoustic Coupling Index
AV	Arteriovenous
AVF/FAV	Arteriovenous Fistula
CABG	Coronary Artery Bypass grafting
CCA	Common Carotid Artery
CEA	Carotid Endarterectomy
CFM	Color Flow Mapping
CHS	Cerebral Hyperperfusion Syndrome
DF	Diastolic Filling
DM	Diabetes Mellitus
DSA	Digital Subtraction Angiography
ECA	External Carotid Artery
ECG	Electrocardiogram
eGF	Estimated Graft Flow
GF	Graft Flow
GQ	Graft Quality
HD	Hemodialysis
HFUS	High Frequency Ultrasound
ICA	Internal Carotid Artery
IDUS	Intraoperative Duplex Ultrasound
IUS	Intraoperative Ultrasound
mGF	Measured Graft Flow
OFG	Optimal Flow Grafts
PB	Peripheral Bypass
PI	Pulsatility Index
PRF	Pulse Repetition Frequency
PSV	Peak Systolic Velocity
PW	Pulsed Wave
ROI	Region of Interest
SFA	Superficial Femoral Artery
SFG	Suboptimal Flow Grafts
SMA	Superior Mesenteric Artery
SMV	Superior Mesenteric Vein
SVG	Saphenous Vein Graft
TGC	Time Gain Compensation
TTFM	Transit Time Flow Measurement

4. Transit Time Flow Measurement (TTFM)

4.1 Principles of TTFM

With TTFM, ultrasound is used to measure blood flow volume directly. This differs from the Doppler principle. TTFM is based on the fact that the time required for ultrasound to pass through blood is slightly longer upstream (t_u) than downstream (t_d).

$$\text{Flow (Q)} = \text{Constant} \times (t_u - t_d)$$



The TTFM probes fit around the vessel, and selecting an appropriate probe size ensures the correct measurement conditions. Two ultrasound transducers fire ultrasound pulses in opposite directions through the bloodstream. Both pulses travel the same distance, but due to the bloodstream, the time from transmission to when the pulse is received will be different. The difference in transit time is recorded by the system and is directly proportional to the blood volume flowing through the measurement area (ml/min). The Constant is unique for each probe and is set during the manufacturing process.

Using the wide beam ultrasound principle, volume flow can be measured regardless of the vessel diameter or flow velocity, as long as the whole cross section of the vessel remains inside the measurement area of the probe. [11]

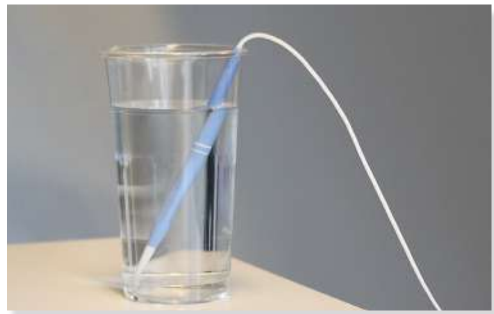
4.2 How to measure

The following section will describe the most important factors necessary for performing TTFM.

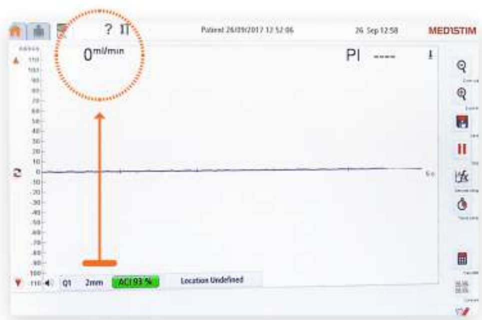
Perform functionality test before surgery

Before using a TTFM probe, a functionality test must be performed to ensure that the probe and system are functioning optimally.

1. Connect the probe to the system and place the probe stationary in a plastic container with sterile saline solution. Due to their acoustic properties, glass and metal containers can disturb the measurement. If using one, line the bottom with cotton balls or gauze.



2. Verify good Acoustic Coupling Index (ACI). The indicator should be green and display a value of >90%. If the ACI is below 90%, try stirring the liquid with the probe to dislodge air bubbles and recheck the ACI.
3. Check that the offset in mean flow (red line) is close to zero.



Zero point offset

4. If the ACI is less than 90% and/or the offset is large, try plugging the probe into a different channel or try a different probe.

Acoustic Coupling Index (ACI) during surgery

To verify that the measurement is reliable during surgery, the ACI needs to be greater than 30%. It is important to have a green or yellow ACI when measuring TTFM. Red or orange ACI may lead to inaccurate and inconsistent measurements.

ACI 50-100 % Good

ACI 30-50 % Suboptimal

ACI 10-30 % Unacceptable

ACI 0-10 % No measurement

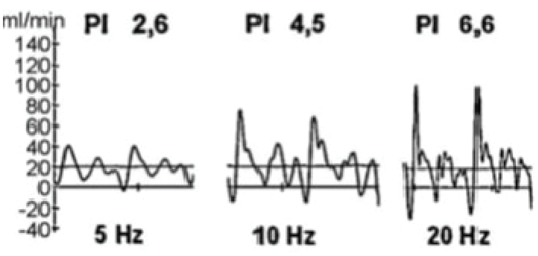
Red Line

The red horizontal line on the screen is the average mean flow, calculated over the last 7 seconds. It is possible to change this preset in the settings of the system. Wait 7 - 10 seconds for the red line to flatten out before saving. Probe repositioning must be followed by an additional 7 seconds waiting period. Pressing “Save” will save up to the last 60 seconds of the measurement.

Filter setting

The default and recommended filter setting for Medistim systems is 20Hz. A lower filter setting will result in a “smoother” TTFM curve and lower PI, making it important to adjust the expectation of PI. The reference values presented later in this guidebook are based on using the 20Hz filter setting.

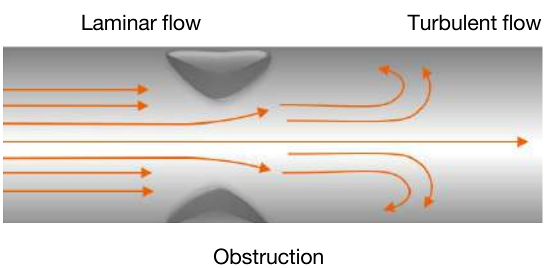
Nordgaard et al. have studied the effect on PI from different filter settings, illustrated by the figure below. [10]



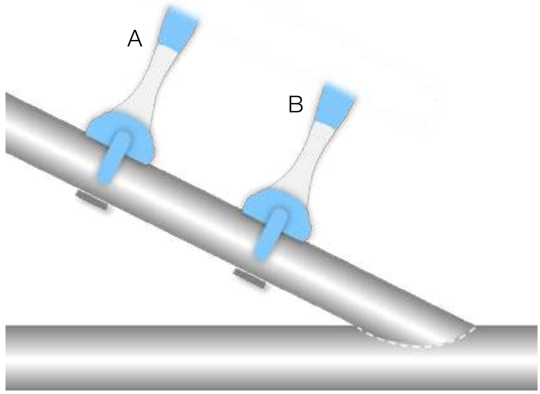
A lower filter setting may camouflage important information while a too high filter setting may include too much noise.

Probe placement

Place the probe near the anastomosis you want to examine, as turbulence will be more easily detected when the probe is placed near any narrowing in the vessel.



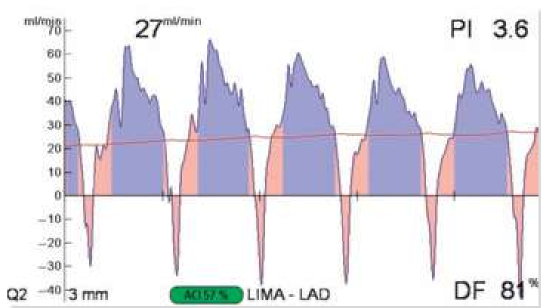
In some cases, the probe needs to be placed more proximally (A) to avoid displacement of the anastomosis. Note that the mean flow may remain the same, but the flow curve and PI may differ with a more distal placement (B) of the probe.



The TTFM examples below, illustrate how the placement of a probe affects TTFM parameters. These examples show similar mean flow but a difference in PI.

Although these readings are from a CABG case, the relevance of correct probe placement is illustrated.

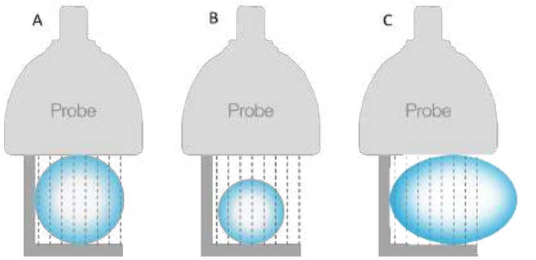
A. Probe placed proximally on the graft



B. Probe placed distally on the graft.

Select correct probe size

In order to achieve correct measurements, it is important to choose the right probe size. The probe should be placed so it wraps around the vessel in a way that it does not compress, bend or twist the vessel itself. Different probe sizes are available to optimize contact between the vessel and the probe. If the ACI is low, the space between probe and vessel may be filled with a coupling agent like saline or ultrasound gel.



Place the probe with the arrow in the expected blood flow direction. A Negative value for flow indicates either a reverse placement of the probe or net retrograde flow.

For probes with handle, the neck of the probe can be bent for easier attachment, but avoid bending the neck of the probe handle all the way to 90° as this will weaken the wire inside the probe unnecessarily and may lead to breakage. Probes are also available without a handle to accommodate for placement on vessels that are difficult to reach.

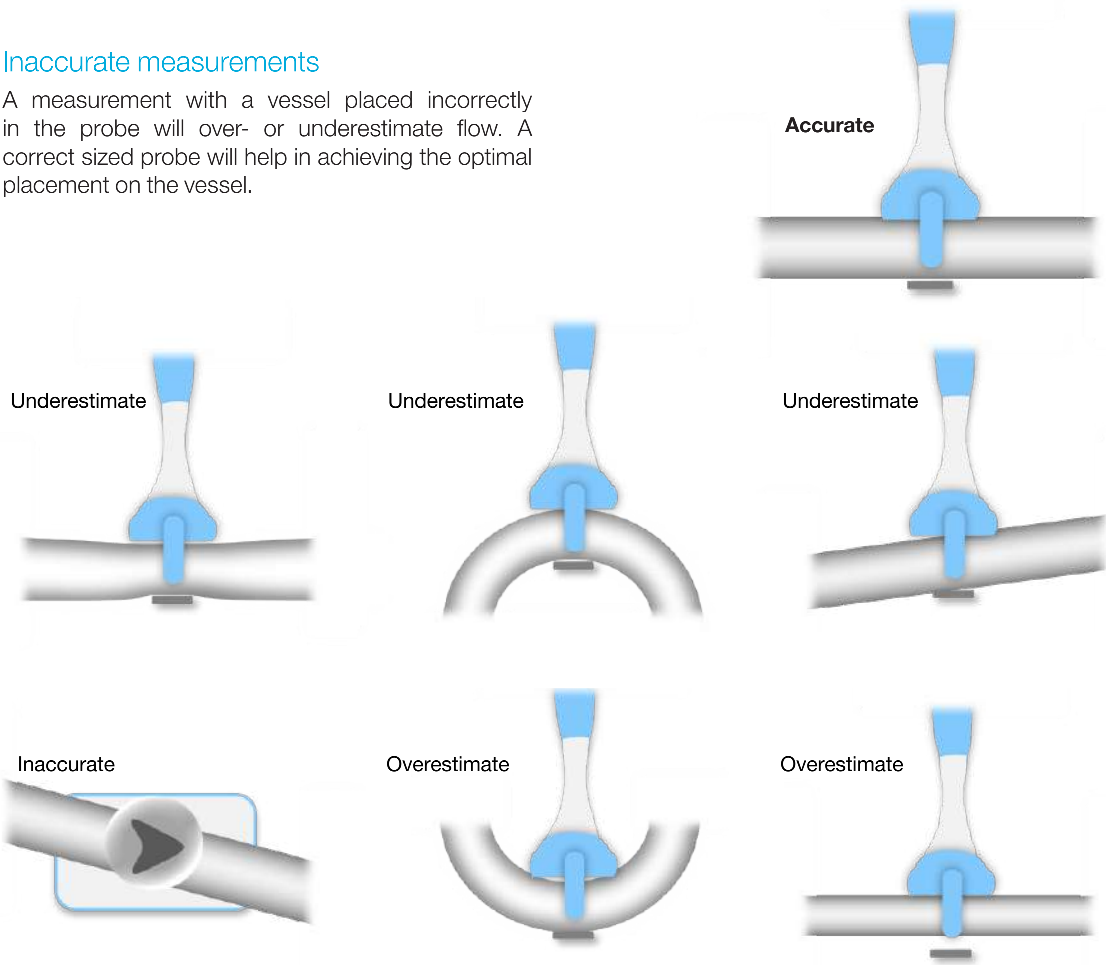
A. Correct probe size will provide a reliable measurement.

B. A probe that is too large will give poor contact with the vessel and a correct alignment of the graft is more difficult.

C. A probe that is too small will compress the vessel and flow will be underestimated.

Inaccurate measurements

A measurement with a vessel placed incorrectly in the probe will over- or underestimate flow. A correct sized probe will help in achieving the optimal placement on the vessel.



Situations that may provide inaccurate measurements.

4.3 TTFM parameters

To assess flow volume and/or the patency of a graft, several parameters should be evaluated.

Mean flow

Mean flow is the numerical value of the red horizontal line. Factors influencing mean flow are blood pressure, size of the vessel, the quality of the vascular bed, the size of the native vessels and possible spasm in the graft or native vessels. Mean flow expectations should be adjusted according to these factors. A low mean flow value in itself is not an indication of a compromised graft, but only part of the diagnostic information.

Pulsatility Index (PI)

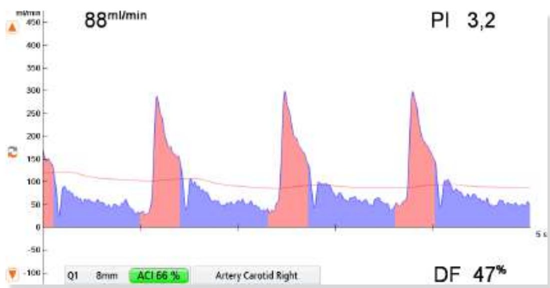
Pulsatility index, or PI, is defined as the difference between the maximum and minimum flow divided by the mean flow. A large difference between the maximum and minimum flow will lead to a high PI value.

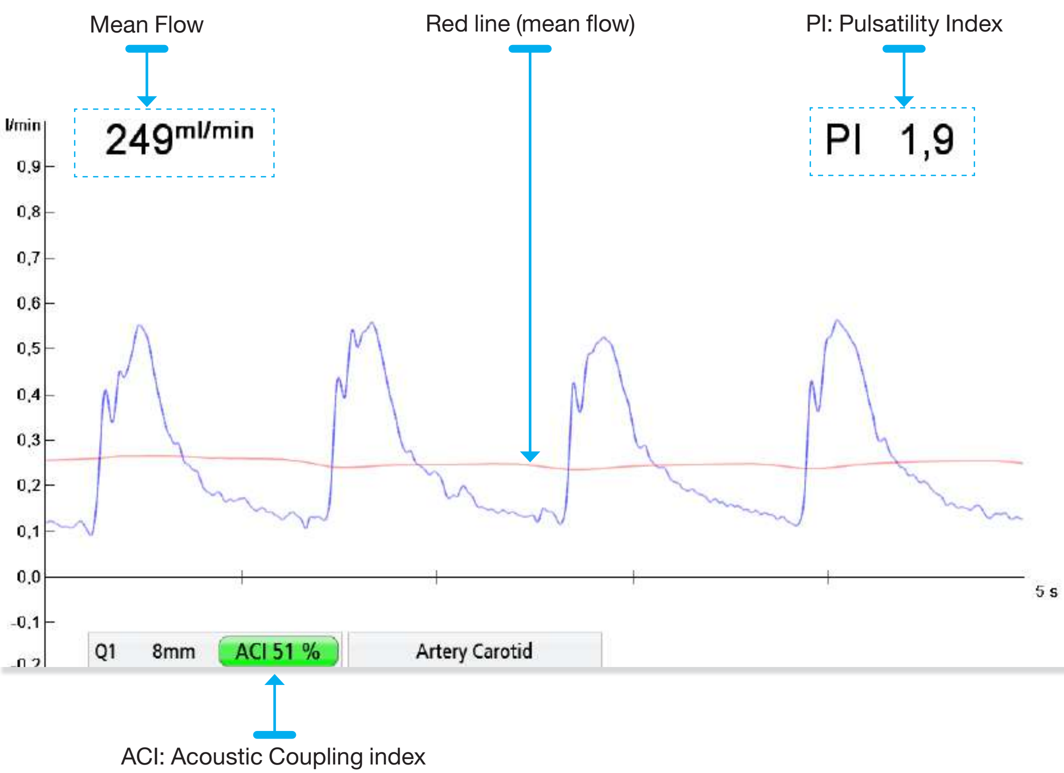
$$PI = \frac{\text{Maximum Flow - Minimum Flow}}{\text{Mean Flow Volume}}$$

Turbulence results in elevated PI and spikes in the flow tracing. If the probe is positioned over an internal valve of a saphenous vein graft, the PI may be elevated due to turbulent flow. Reposition the probe to see if PI improves. Before making the final decision to redo an anastomosis, wait a few minutes to allow the flow to normalize and measure again. Spasm in an arterial graft or the perfused bed can cause a decrease in flow with an increase in PI.

Diastolic vs systolic flow

The standard MiraQ Vascular comes with 2 flow channels and 1 pressure channel. Optional AUX channel will allow for the connection of the ECG. Connecting the ECG will change the flow curve so that the systolic and diastolic flow is filled in with pink and blue color, respectively. This feature gives helpful information during CABG surgery but is possibly less relevant during vascular surgery.





4.4 Reference values

There are currently no official guidelines for reference values for TTFM during vascular applications. Medistim refers to published peer-reviewed articles and guidelines to suggest reference values for different applications.

Note that there are multiple factors that can affect the flow volume. Physiological factors like spasm in the graft or native vessels, blood pressure and run-off in the vessel bed will affect the flow volume. The size of the vessels and a patient's weight are also factors that will affect the flow volume.

Vessel issues such as thrombus formation, twists or kinks of the vessel, or air bubbles and misapplied stitches will reduce the flow. Poor TTFM readings may also be a result of an incorrect measurement technique. Therefore, it is important to keep all of these factors in mind when assessing the vessels after surgery and before closure.

In the table below, Vikatmaa and Albäck (2018) have suggested values for low, normal and high flow values in different vessels.[1] These numbers are based on vast experience from over 8,000 peripheral bypasses and 1000 carotid endarterectomies performed. The abstract from this publication can be found in Chapter 12.1 of this Guidebook.

Suggested reference values

Rough estimates of low, normal and high flow values in different arteries and reconstructions (ml/min). There is no high-quality scientific evidence to support these values. These figures should be seen as a suggestion developed in clinical practice after routine use of TTFM at the end of nearly all open arterial operations in this unit since the early 1990's.

	Low flow (ml/min)	Normal (ml/min)	High (ml/min)
ICA	<100	100–300	500
Axillary artery	<100	100–500	>500
Radiocephalic FAV	<200	>300	>1000
A. hepatica/lienalis	<100	>150	>500
SMA	<200	>400	1000
A. renalis	<150	200–400	>500
Iliac arteries	<300	500–2000	>1000
CFA	<200	300–1000	>700
Popliteal bypass	<100	>100	>300
Crural bypass	<80	80–200	>200
Inframalleolar bypass	<50	>50	>200

ICA internal carotid artery, SMA superior mesenteric artery, CFA common femoral artery, FAV arteriovenous Fistula.

4.5 Insufficiency / Backflow

Spikes in the TTFM pattern below the X-axis show retrograde flow. To check the amount of backflow, the “Calculate” function needs to be selected in the menu. The parameter “Insufficiency” (insuf.) shows the percentage of backflow in the vessel.

Retrograde flow may be a sign of flow obstruction. The backflow will then usually be accompanied with suboptimal TTFM parameters, like low flow and high PI.

Choose “Calculate” in advanced mode to view Insuf. (Backflow%).

4.6 Synthetic grafts

The Medistim TTFM probes are calibrated to be used on biological vessels (native or e.g. bovine). High acoustic impedance in synthetic graft materials may make it difficult to perform reliable TTFM even if the acoustic coupling (ACI) is acceptable. If possible, graft flow should be measured on a native vessel close to the synthetic graft. Not all synthetic graft types will impact TTFM and HFUS.

There are four main types of synthetic grafts:

PTFE (Polytetrafluoroethylene)

Newly inserted PTFE and ePTFE (Expanded PTFE) grafts are not eligible for TTFM or HFUS due to air in the material that will interfere with the ultrasound transmission. The graft has to be heavily pinched or clamped with a soft vascular clamp in order to push the air from the prosthesis wall, a practice that might damage the prosthesis and therefore should be questioned.[1]

Dacron (Polyethylene)

A polyethylene prosthesis has less air in the wall and TTFM may be performed about 15 min after blood has been released to the prosthesis and has saturated the graft material.[1]

Polyurethane

Performing TTFM and HFUS on polyurethane grafts is unproblematic.

Hybrid grafts

Synthetic grafts coated with endothelial cells may provide adequate ultrasound transmission for TTFM to be performed.

Mistakes to avoid

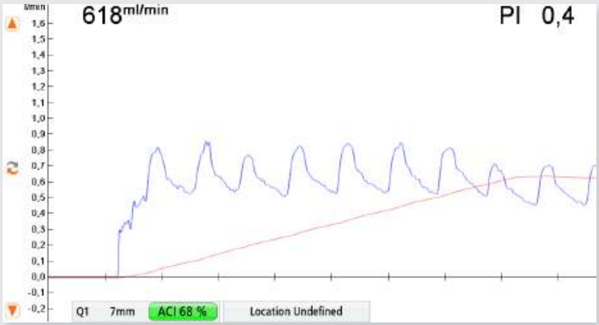
In order to achieve reliable transit time measurements, the ACI must be yellow or green and the red line must be horizontal.

Below are some examples of suboptimal flow measurements:

In this case, the ACI was orange (below 30%), meaning that the measurement was not reliable. The low ACI may be caused by using the wrong size TTFM probe, not applying enough gel/fluid in the probe/vessel contact area or by air or by fat caught between the probe and the vessel.

Motion artifacts may result in a lower mean flow value and a higher PI value. The curve from this case showed that the TTFM probe had been moved during the measurement. If this happens during a measurement, wait 7 seconds before saving for more correct flow and PI values.

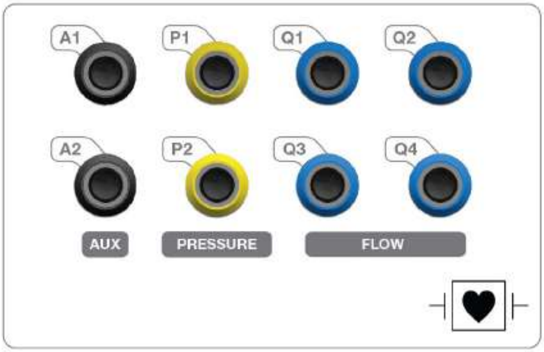
In this measurement, the red line was not yet completely horizontal. The surgeon should wait until the red line has flattened out to get a reliable measurement before saving.

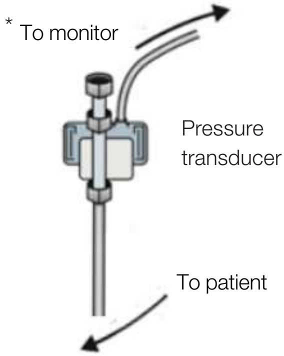


5. Pressure Measurements

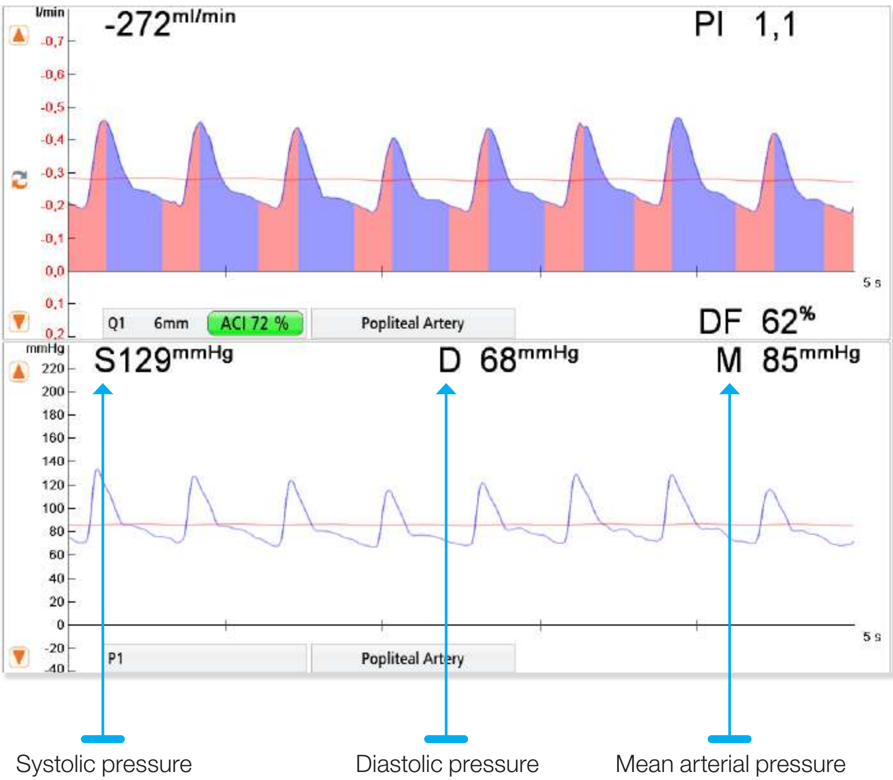
The pressure inputs (P1, P2) allow connection of pressure transducers for direct monitoring of the patient's blood pressure*. The Medistim MiraQ Vascular device can be delivered with up to two pressure inputs.

Flow will vary proportional to systolic pressure. If a dedicated direct pressure measurement is not needed, the auxiliary channels (A1, A2) can be used to interface a pressure signal from another device. The MiraQ system provides all the information on the same screen with up to four flow channels and two pressure channels simultaneously.





As illustrated below, the MiraQ system will provide information on systolic, diastolic, and mean arterial pressure in addition to flow. In this example, ECG is connected.



6. High-frequency Ultrasound (HFUS)

6.1 Principles of HFUS

Background

Medistim launched the first system with high-frequency ultrasound (HFUS) imaging in 2009, offering an added value to intraoperative guidance and quality control.

The L15 imaging probe for use with VeriQ C and MiraQ systems.

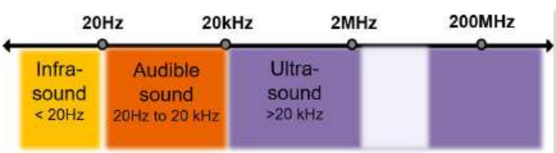
The previously mentioned quote from Vikatmaa and Albäck (2018) supports the use of HFUS during vascular procedures:

"High quality intraoperative ultrasound should be readily available in all operating theaters performing vascular surgery. With a high frequency (>15MHz) superficial transducer the visibility of anastomoses, dissection flaps and other anatomical structures is excellent in the simple B-mode. By adding pulsed wave Doppler and flow velocity measurements, local stenosis can be accurately detected." [1]

The authors of the recent CIDAC paper have compared angiography with HFUS and found HFUS to be more sensitive and reliable when it comes to detecting defects after carotid endarterectomy.[2] The abstract of this publication can be found in Chapter [11] of this guidebook.

Ultrasound

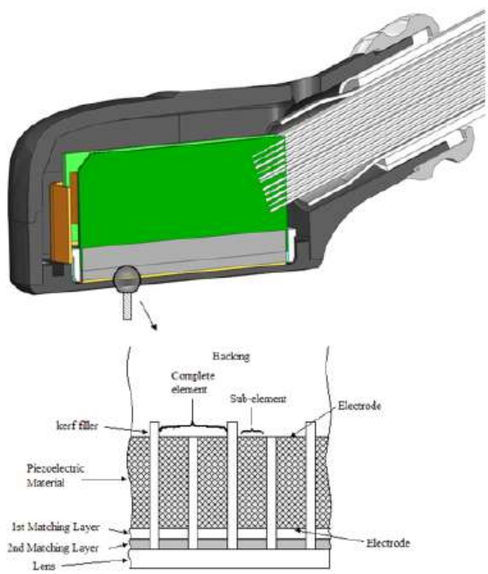
Ultrasound consists of sound waves with frequencies higher than 20 kHz.



Diagnostic ultrasound has frequencies between 1 and 30 MHz.

Higher frequency of ultrasound will provide higher image resolution with lower penetration. Lower frequency will give more depth, but lower resolution.

The L15 imaging probe contains 128 piezoelectric elements. It has a frequency range from 11 to 18 MHz, with a center frequency of 15MHz. The probe is designed to provide high resolution images in the extreme near field (0-20 mm).



128 element linear array imaging probe.

Image / ultrasound reflection

Different tissues appear differently on the screen of the ultrasound system. Fluids appear dark, solid organs appear gray, and air and bone appear white.

When a sound wave hits a boundary, some of the energy of the wave will be reflected back to the probe. How much of the wave that is reflected depends on the type of boundary. High reflection will appear white, while low reflection will appear black on the image created.

Percentage of energy reflected at tissue interfaces: [12]

Muscle/blood	0,07
Soft tissue/water	0,23
Fat/muscle	1,08
Bone/fat	48,91
Soft tissue/air	99,90

Coupling agents

It is important to remember that ultrasound will not penetrate air, so the use of gel or fluid is necessary to obtain good contact with the tissue examined. Moisture on the tissue surface may be enough, but often an optimal image is achieved by adding some type of moisture like saline, blood or ultrasound gel indicated for intraoperative use. The illustration below shows how using enough gel will avoid compressing the vessel.

Left probe figure illustrates an optimal amount of gel applied between the probe and target vessel. Right probe figure illustrates how too little gel can lead to compression of the vessel.

Another technique is to fill the operating wound with saline during imaging. This is especially useful when it is difficult to reach the target area with the imaging probe.

6.2 Imaging views

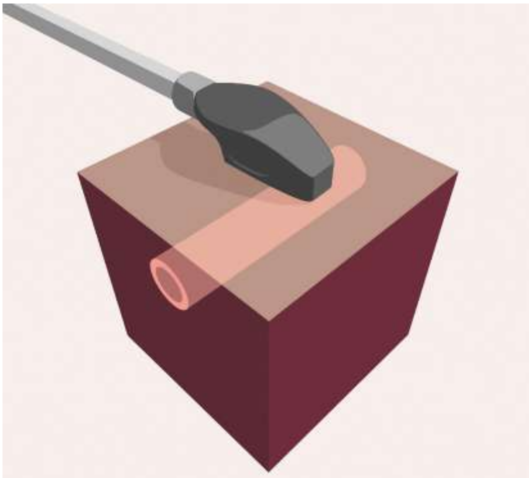
There are two main views for imaging: transverse and longitudinal. The easiest way to image a vessel is to locate it in transverse view and then rotate the imaging probe for a longitudinal view.

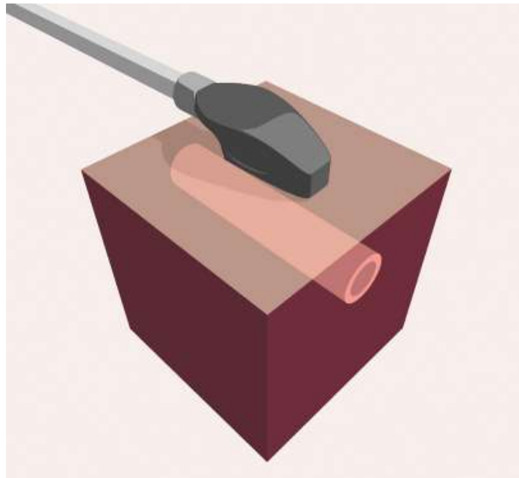
Transverse / cross section scanning

View to locate vessels and look for optimal anastomotic site as well as to check anastomosis.

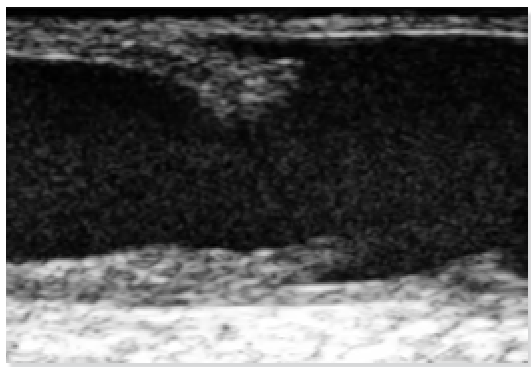
Longitudinal scanning

View to evaluate calcifications or obstructions and to check anastomosis.

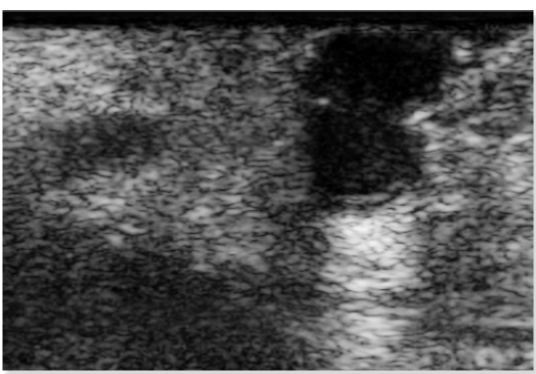




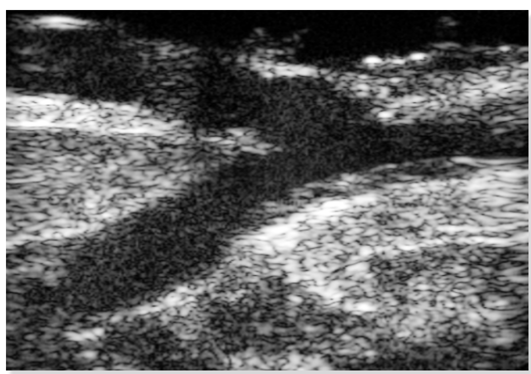
Transverse view of a vessel.



Longitudinal view of a vessel.



Transverse view of an anstomosis.



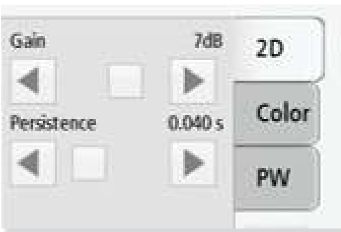
Longitudinal view of an anastomosis.

6.3 HFUS modalities and settings

There are three imaging modalities available on the Medistim system: 2D mode, Color Flow Mapping (CFM), and Pulsed Wave Doppler (PW). The modes may be changed by selecting the different tabs in the top right corner on the screen.

2D-Mode (B-Mode, Grayscale imaging)

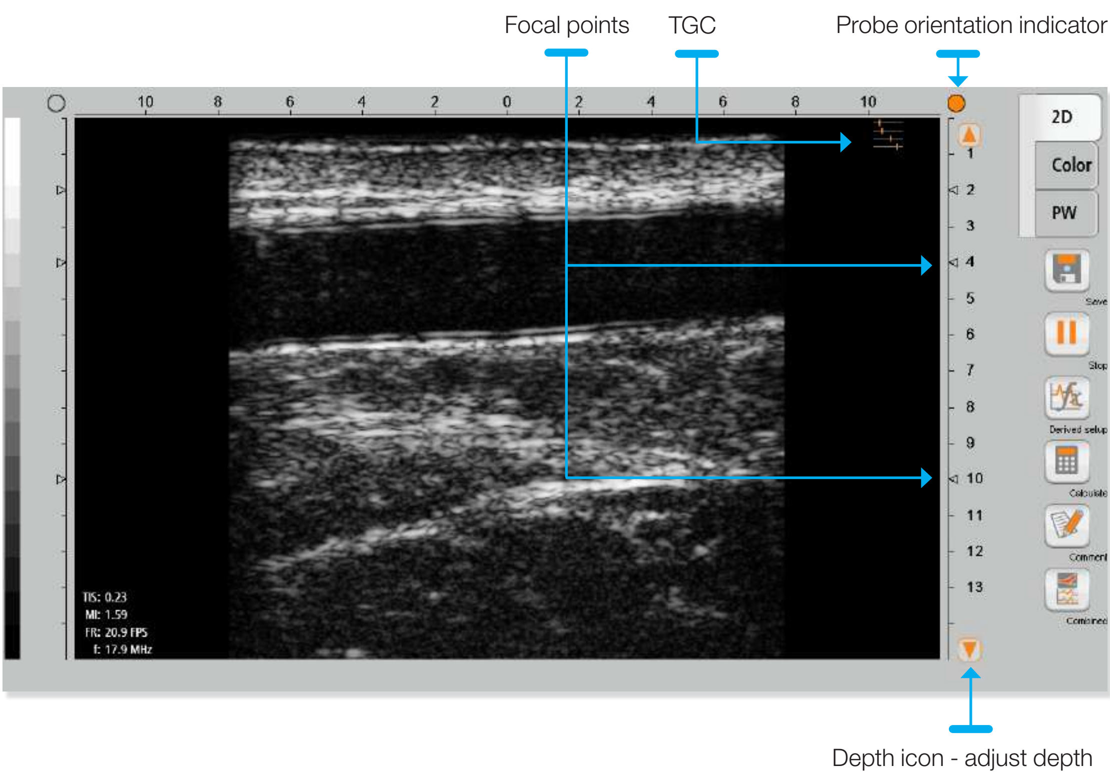
B-Mode provides the highest frame-rate which is useful when you need to view the anatomy, examine structures and find defects. In this mode, you can also adjust the gain and persistence. Gain adjusts the brightness in the displayed image. Persistence provides a temporal average filter to decrease random noise in the image.



Focal Points make the image sharper at the defined depth. It is possible to select up to four focal points, but using all of them will reduce the frame-rate. Focal points are already set on the different preset options, but can also be set manually.

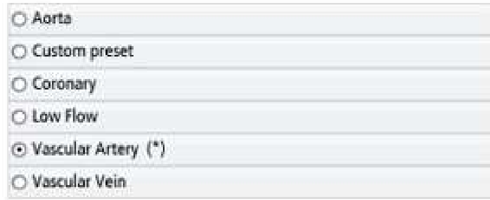
Time gain compensation (TGC) adjusts the gain for specific sections in the image and allows different gain settings for different parts of the image. To access these, press the TGC icon to access the TGC slider controls.

Screen elements in 2D-Mode



Imaging presets

The systems have presets stored for different applications. Selecting the appropriate preset minimizes the need for further imaging optimization. The low flow preset is meant for imaging of low flow velocities, typically in small vessels. There is also an option to create a custom preset to store individual preferences.



Spatial Compound imaging

Spatial compound imaging is a method that acquires images from several different angles and combines them to produce a single image. This reduces the speckle and improves the definition of tissue planes, generally decreasing image noise and improving image quality. Imaging artifacts like wall shadowing and enhancements will be less prominent in compounded images.

For users that prefer the traditional image with more speckle, the compounding can easily be switched off.

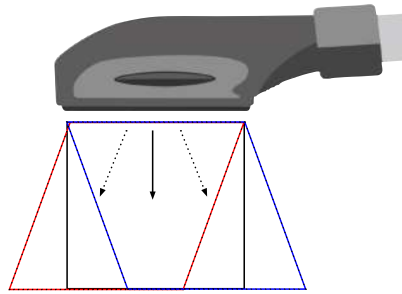


Figure 1: Spatial compounding principle

The images below show transverse and longitudinal views of a radial artery without and with spatial compound. Notice how spatial compound has made image artefacts like wall shadows and enhancements less prominent. In the longitudinal view (image 3 and 4), the small transverse vessel in the bottom right part of the images is much more visible with spatial compounding enabled.

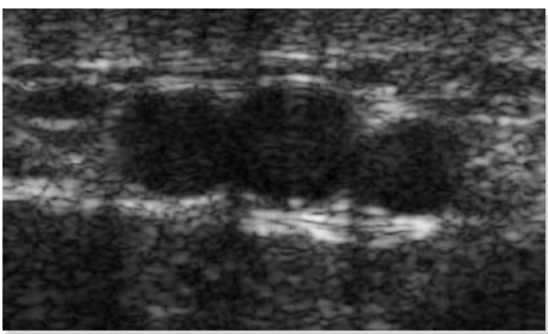


Image 1: Transverse view of radial artery and veins

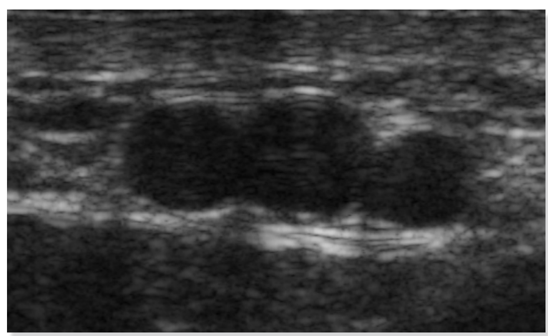


Image 2: Radial artery and veins with spatial compound

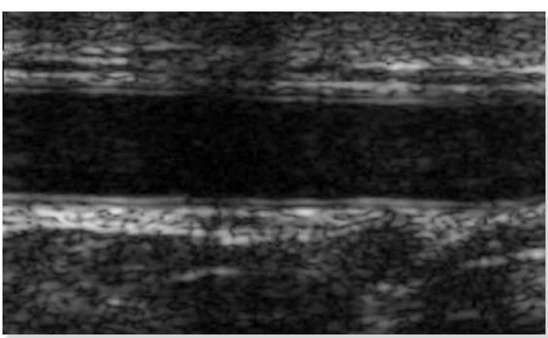


Image 3: Longitudinal view of radial artery

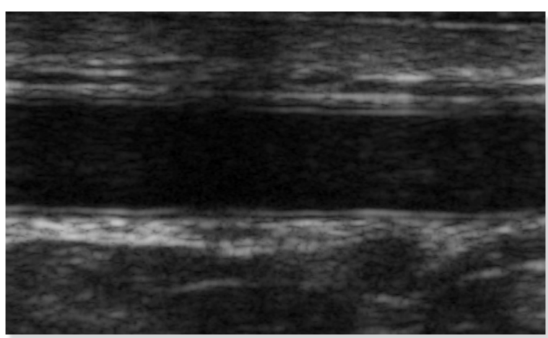


Image 4: Radial artery with spatial compound

Color flow mapping (CFM)

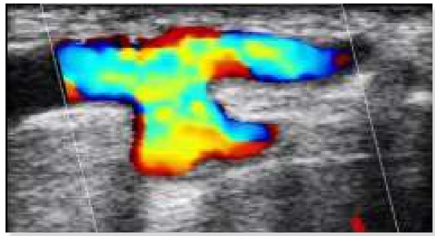
In color mode, the system performs fast time-sharing between B-mode scanning and Doppler operation, which provides a live 2D image for orientation plus color flow. There are two different mapping techniques with color flow:

- **Power mode** uses the power in the returned Doppler signal to detect the presence of flow but gives no information about direction or velocity. This mode is more sensitive to flow movements than velocity mode.

- **Velocity mode** uses the Doppler shift to detect flow and provides information about flow direction relative to the probe and flow velocity.

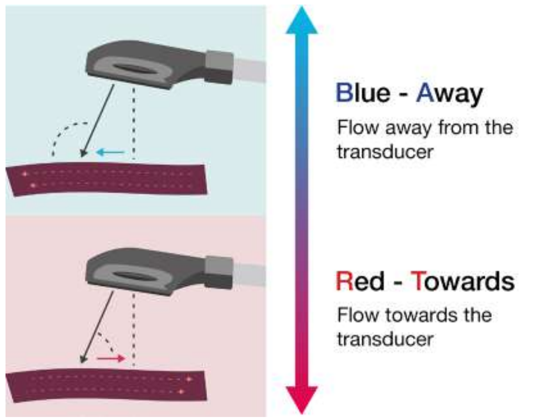
Aliasing may occur when the blood flow velocity is higher than what the system is set to measure. The red or blue color will change through green to the opposite color. This effect makes it difficult to discern flow velocity and flow direction but can be corrected by adjusting the velocity scale.

Region of interest (ROI) is the area of the image that the system is analyzing for blood flow. A wide ROI will often slow the frame rate down. Press and drag the steering icons to adjust the angle, position and size of the ROI.

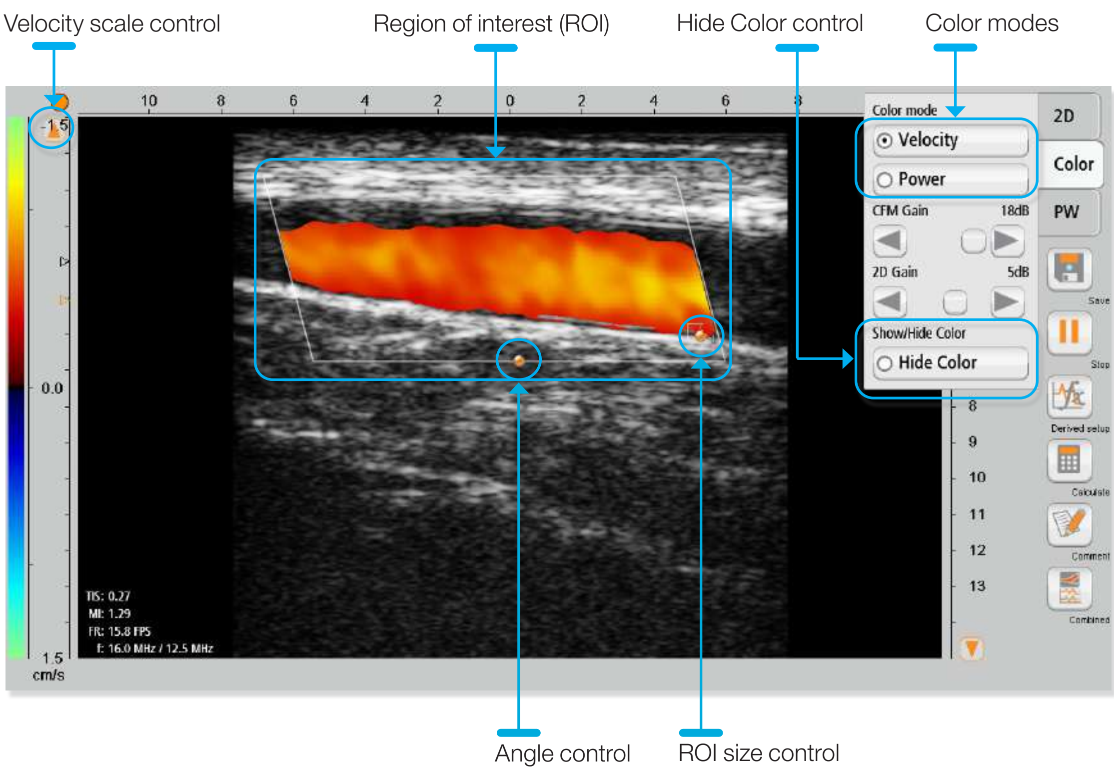


CFM image with suboptimal velocity setting (aliasing).

To evaluate the flow direction, use the “BART color convention” (Blue Away, Red Towards) as shown below.



Screen elements in Color mode



Pulsed Wave Doppler (PW)

Similar to Color flow, pulsed wave Doppler (PW) mode performs fast time-sharing between B-mode scanning and Doppler operation in order to provide a live 2D image for orientation plus measuring flow velocities using Doppler pulses.

Adjust the strength of the Doppler signal by using the gain control. Too low gain will result in a weak signal and too high gain results in mirroring artifacts and noise pollution.

A small angle between the incoming Doppler pulses and the bloodstream will yield the best measurement results. At 90° to the flow, no flow will be detected. The system will always select the optimal steering angle based on the PW-gate placement and velocity correction angle combination.

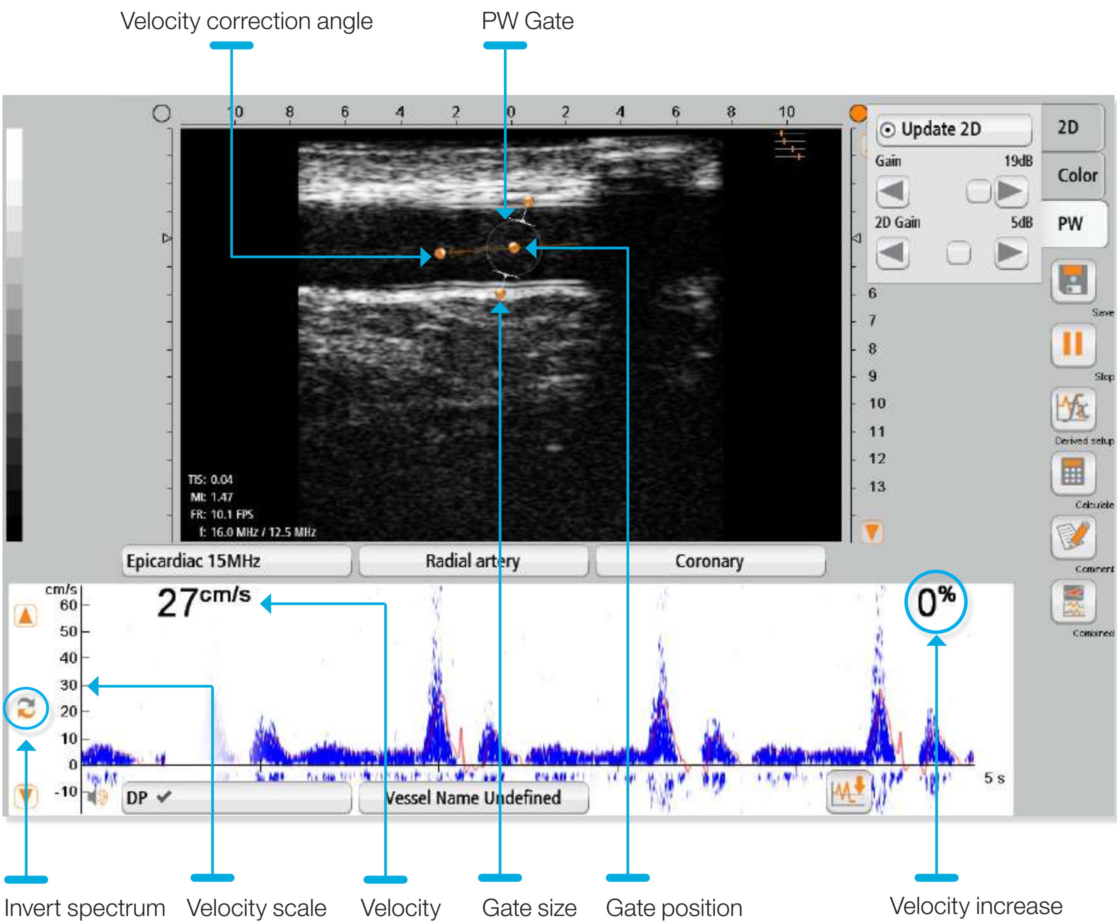
PW Gate adjustment

- Press the Position icon and drag the gate to the desired position.
- Press and drag the Size icons to achieve the desired gate size.
- Press and drag the Velocity correction angle icon to align the line so that it is parallel to the flow.

Pulse Repetition Frequency (PRF) sets the sampling rate of the measurements and is adjusted by the velocity scale. High or low velocities will sometimes not fit within the measurement range. The measurements will then either wrap around and appear as negative velocities at the bottom of the range (aliasing), or not be registered at all.

The size and position of the Doppler gate can easily be adjusted to suit the situation at hand.

Screen elements in Pulsed Wave Doppler



6.4 Imaging artifacts

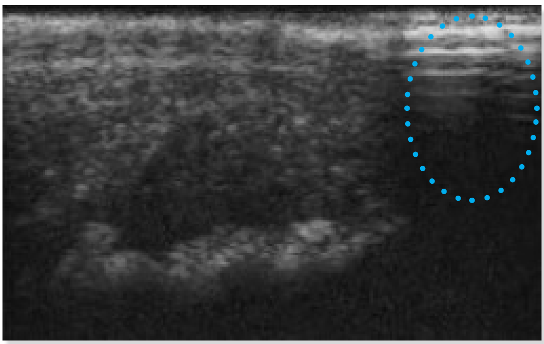
Imaging artifacts are elements in the image that are caused by the ultrasound technology, and are not actual tissue. Typical artifact categories are presented below.

How to identify an artifact?

Try to move the probe to check if a different angle will make the artifact disappear.

Reverberation

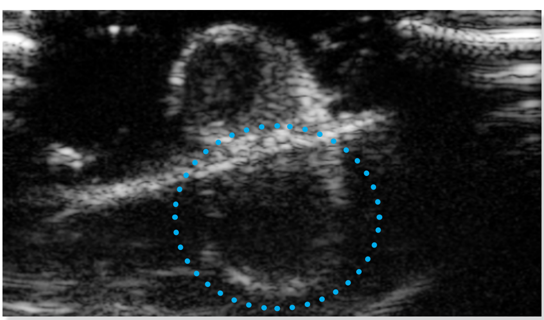
Reverberation artifact occurs when an ultrasound beam encounters two strong parallel reflectors. This can help identify foreign bodies like surgical clips, catheter tips, debris, glass or metal. It is seen by repetitive patterns in the image.



Reverberation at the top right of the image.

Mirroring

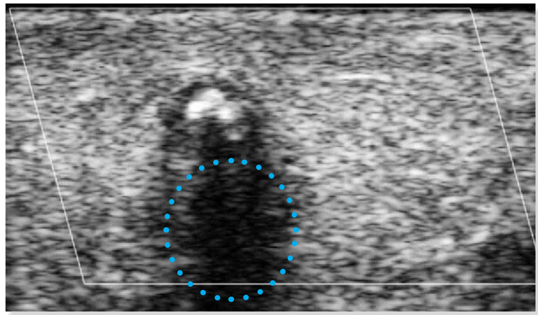
This happens when the ultrasound waves hit a strongly reflective surface. The example below shows mirroring from a glove held under an ITA.



ITA shown over the white line and the mirroring underneath.

Shadowing

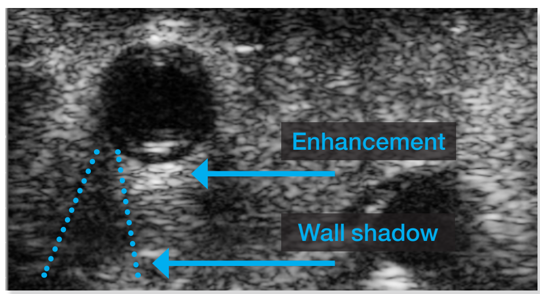
When the ultrasound waves hit hard tissue like calcified plaque, a shadow is formed on the image below this area. In the following image example, a shadow is created below a piece of calcified plaque.



Shadow under a calcified area (white).

Enhancement and wall shadow

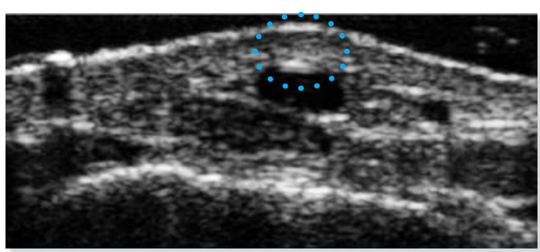
When the sound-waves go through an area with low attenuation and hit tissue, enhancement of the signal may occur. The difference in attenuation between the two media will create a stronger signal (white area). Unlike the case for calcified plaque, there will be no shadow under an enhancement.



Enhancement (white) and dark wall shadow.

Specular reflection

This artifact appears when a smooth surface perpendicular to the ultrasound ray reflects the sound waves. In the example below, the top side of a blood vessel reflects the ultrasound, creating a white area.

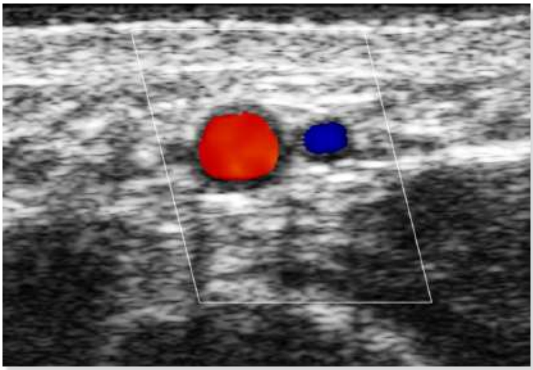


Specular reflection in the upper part of the vessel.

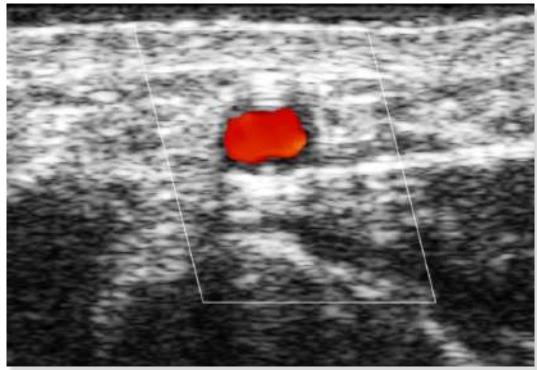
6.5 Mistakes to avoid

Compressing vessels

While it is important to have good contact between tissue and the imaging probe, pressing too hard might hide important information or completely compress veins.



Imaging performed with little pressure showing an artery and a vein.

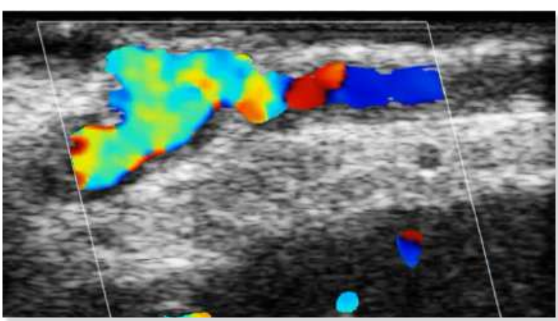


Imaging performed with excessive pressure showing only the artery. The vein is completely compressed.

Aliasing

Aliasing may occur if the blood flow velocity is higher than what the system is configured to measure. The peaks of the velocity spectrum will exceed the highest values of the velocity scale and reappear at the bottom of the scale, now represented as negative values. Aliasing can be corrected by adjusting the velocity scales.

If the CFM image is displaying the color green the velocity scale range should be increased.



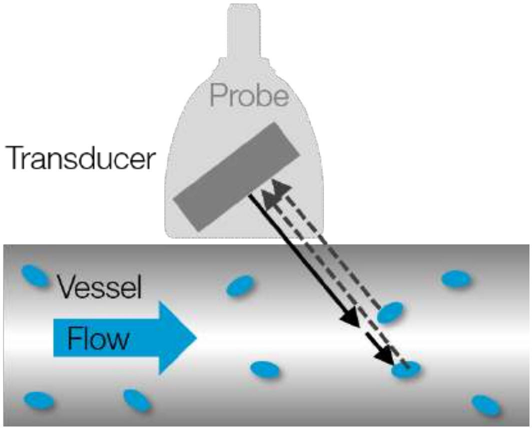
CFM image with aliasing

CFM utilizes the Doppler principle for estimating the blood flow velocities. To correctly estimate the velocities, the functionality must be set up appropriately for the velocity being estimated. If the velocity scale is set to a range that is too large, the measurement will not have the sensitivity required to detect the low flow velocities. If the velocity scale is set to a too low range, the high velocities will not be adequately sampled and the resulting estimation will be incorrect.

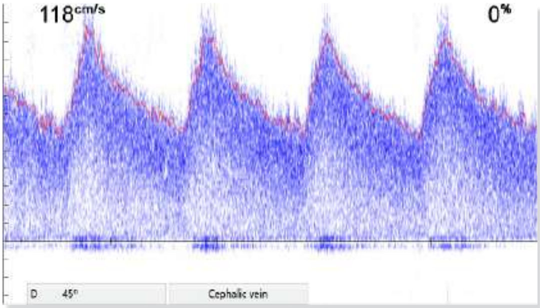
An example: If the velocity scale is set up for measurements in the range +/- 5 cm/s, and the actual velocity is 6 cm/s, the velocity will wrap around the scale and display as -4 cm/s instead. This phenomenon is called aliasing and will, at best, cause the CFM image to be very confusing. More often than not, if aliasing is not corrected it will make the CFM information useless as it is not possible to determine the direction or nature of the flow. Aliasing is often seen as green color, but can also be a mix of all the colors.

7. Doppler

The Medistim Doppler probe estimates the flow velocity and displays it as a spectrogram. It is useful when searching for non-superficial vessels and the flow direction and velocity spectrum help to distinguish between arteries and veins. The velocity spectrum can also help distinguish between turbulent or laminar flow as well as locating and quantifying a stenosis.



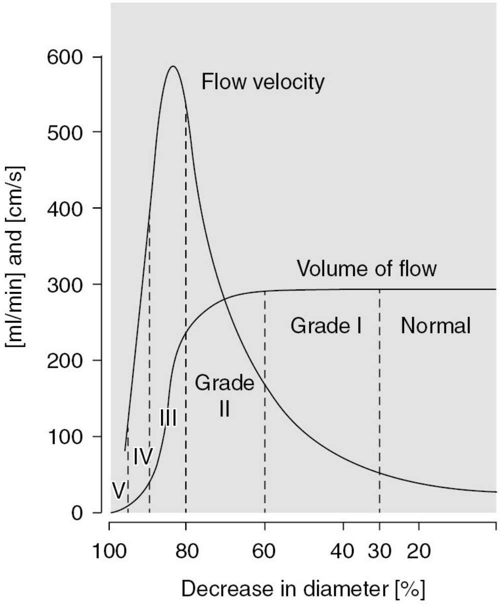
Doppler technology estimates velocities from the Doppler shift of the reflected waves (backscattering) from particles (blood cells) within the vessel. Doppler measurements provide a spectrogram, showing the velocity distribution of the blood within the range gate.



The audible Doppler shift further facilitates the search and explore nature of the Doppler. It allows the surgeon to focus on the probe while searching for vessels and the audible signal will alert them when flow is detected. The pitch of the audio is correlated to the flow velocity, so a high pitched sound indicates a high velocity while a low rumble indicates a steady low velocity flow.

Flow velocity measured by Doppler can be used to estimate flow volume, but such estimations have sources of error that might lead to inaccuracies. TTFM offers the most accurate flow volume measurement.

TTFM can assist in detecting stenoses that obstruct over 70-75% of the vessel lumen. This is the limit for a flow-obstructing stenosis, as shown in the Spencer's curve below:



Spencer's curve. The flow volume stays stable until the narrowing exceeds 70-75%.[22]

The Doppler probe is more sensitive when it comes to detecting low-grade stenoses by measuring increased flow velocity. This detection can be performed with the Medistim Doppler probe or by using the imaging probe that also has a pulsed wave Doppler mode.

The Medistim Doppler probe for use with VeriQ and MiraQ systems.

8. Peripheral Bypass

Secure short and long-term graft patency

HFUS and TTFM are useful as both guidance and completion control during peripheral bypass.[1] SVS/ESVS / WFVS strongly recommend intraoperative imaging on completion of open bypass surgery for critical limb threatening ischemia in order to correct significant technical defects during the operation.[5] The workflow below is followed by a large volume center in Helsinki, Finland. TTFM shows the effect on distal perfusion during peripheral bypass.

Workflow Peripheral Bypass

Ideally, flow should be measured at systolic pressure >100 mmHg.

Pre grafting

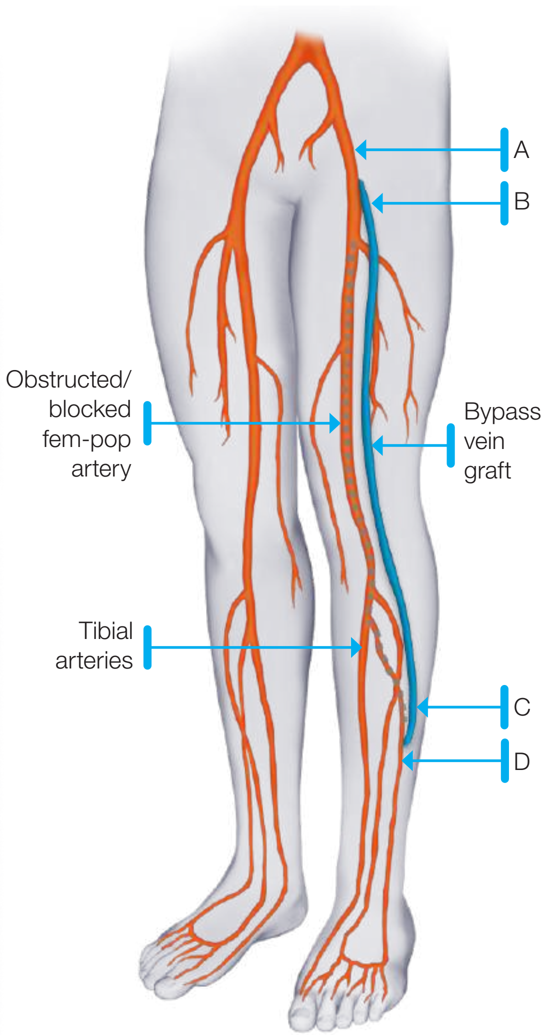
- HFUS to select a good distal anastomotic site to minimize need of exploration and wound complications.

After completion of proximal anastomosis

- HFUS to check clamping sites.
- Perform TTFM of native inflow artery (site A).

After completion of distal anastomosis and declamping

- TTFM to measure graft resting flow at Site B and C.
- Assess max flow capacity
  1. Inject papaverine or similar.
  2. Assess max flow capacity after approximately 1 min. Expect about 50% increase. If less than 20-30% increase, search for explanation (Site B and C).
  3. Measure graft resting flow at steady state (after 5-10 min.), which is usually higher than initial resting flow (Site B and C).
- HFUS to check distal anastomosis and distal clamping site for intima flaps, thrombi and technical errors etc.
- TTFM at distal anastomosis site (D) only if not too fragile and readily available. Shows the effect in bypass for distal perfusion.



Measurement points

A - Proximal to anastomosis (native inflow)
B - Proximal on graft (graft inflow)
C - Distal on graft (graft outflow)
D - Distal to anastomosis (native outflow)

Reference values

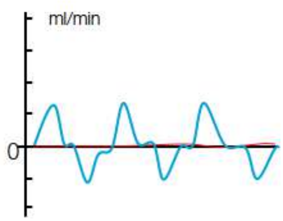
The included table presents estimates of low, normal and high flow for different vessel territories.[1]

Vessel/bypass graft	Low flow (ml/min)	Normal flow (ml/min)	High flow (ml/min)
Iliac arteries	<300	500-2000	>1000
Popliteal bypass	<100	>100	>300
Inframalleolar bypass	<50	>50	>200
Crural bypass	<80	80-200	>200
Common Femoral artery	<200	300-1000	>700

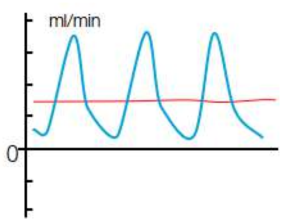
Locating side branches

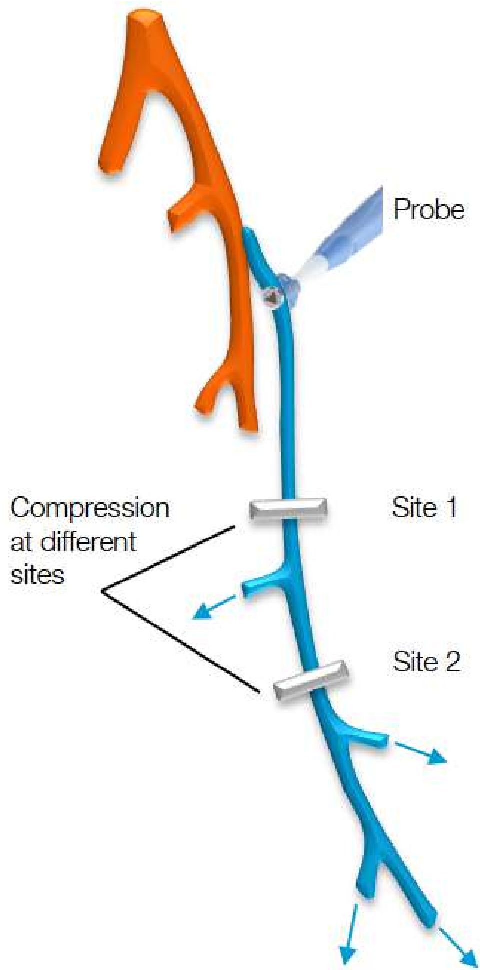
Side branches along an in situ graft can act as arteriovenous fistula and must be located and ligated to ensure that the flow will reach the intended destination. TTFM is useful in locating these. Place the probe just below the proximal anastomosis and occlude the vein successively at different sites along its course – from the probe to the distal anastomosis. Alternatively, use HFUS to locate side branches. [22]

Site 1
No open side branches proximal to compression site. The flow curve will look pulsatile and a pulse is palpable, but there is zero mean flow in the graft.



Site 2
If flow is found – expect to find an open side branch proximal to the compression site.





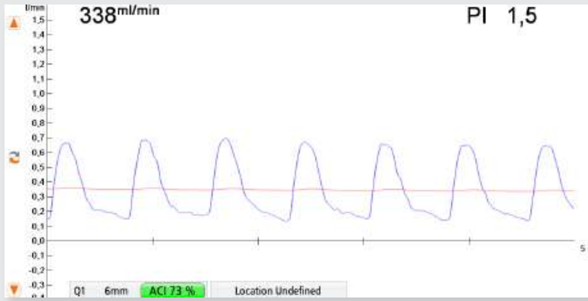
Pressure measurements

Measure pressure at both anastomotic sites (Site B and D) to detect the pressure drop over the graft. Measure pressure at radial and femoral arteries. There is reason for concern if the difference is more than 10 mmHg (risk of inflow disease proximal to the origin of the superior femoral artery). Accept larger differences for high flow than for low flow situations.

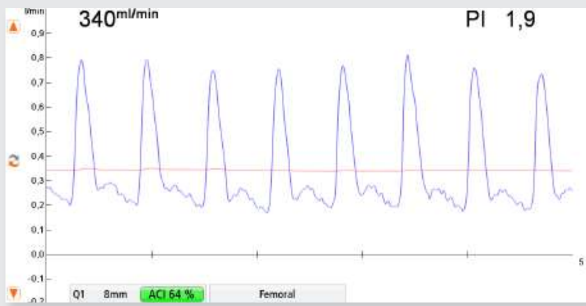
8.1 Normal TTFM in Peripheral Bypass

Normal flow curves are repetitive and show a flow within the expected range.

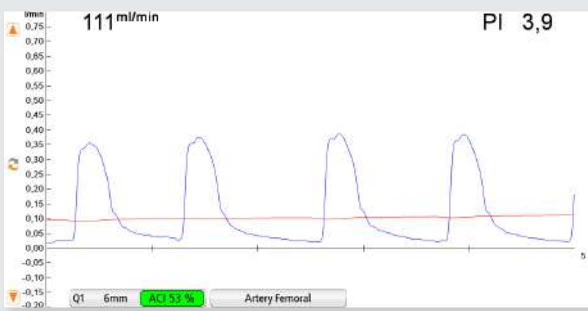
TTFM on near distal anastomosis on a femoral-tibial bypass performed with a hybrid Dacron/bovine graft. The measurement showed high flow with a low PI. The flow curve pattern indicated a good systolic inflow (peaks) and low diastolic resistance (>100ml/min during diastole).



TTFM of Femoral Artery after performing a Fem-pop bypass. This is a typical arterial flow curve.



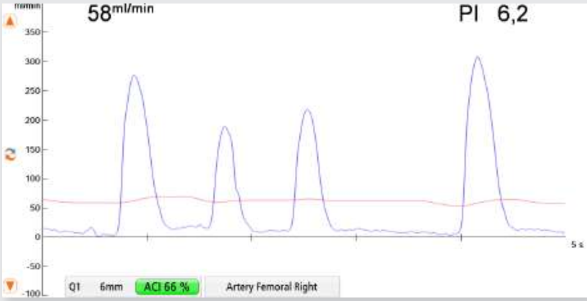
TTFM of Common Femoral Artery showed good flow and nice and repetitive flow curve pattern. This measurement was performed after a revision of the initial repair of a restenosis.



8.2 Suboptimal TTFM in Peripheral Bypass

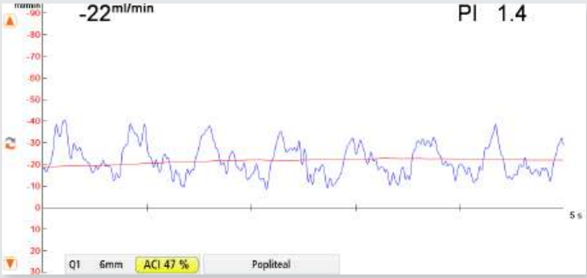
Suboptimal flows may indicate different problems. Poor run-off (resistance) distally to the graft is one major challenge. Issues with the graft itself or technical imperfections in the anastomosis may lead to disorganized TTFM curves that have low flow and often high spikes.

TTFM of a cross-over pedal graft. The flow was acceptable, but the flow curve was not completely repetitive so we recommend to measure again and save when the pattern is repetitive.



TTFM of Popliteal Artery during Fem-pop procedure. Flow evaluation before bypass showed low flow and signs of flow obstruction.

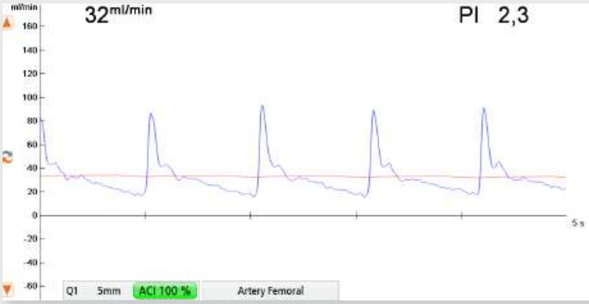
The flow value was negative because of the probe orientation. To get access to the measurement site it sometimes is technically easier to use the opposite orientation of the probe. This will not affect the measurement reading.



TTFM of a femoral artery that was occluded. The high spikes indicate a flow-occluding narrowing in the vessel. There was also negative flow during the diastole. Further investigation with ultrasound would be advisable here.

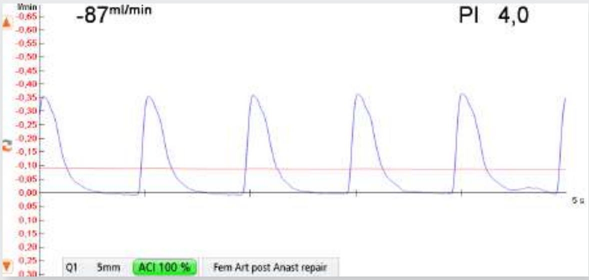
8.3 Femoral-popliteal bypass with revision

Once the anastomosis was complete, flow was 32 ml/min and the flow curve showed slightly compromised run-off after a nice systolic peak.



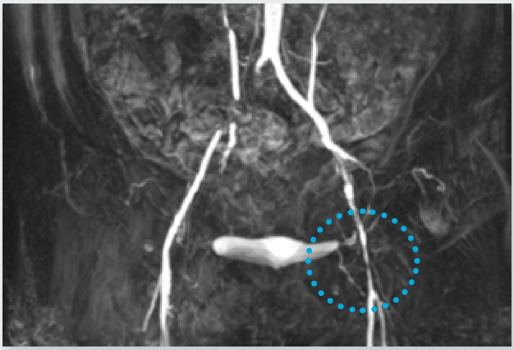
Measured one minute after, the tracing showed a further reduction in diastolic flow. The surgeons noted that the femoral artery was less expanded. The mean flow went down to 18 ml/min and continued decreasing.

A leak was located at the distal anastomosis requiring intraoperative repair. A new measurement showed increased flow with a typical peripheral vascular flow curve.

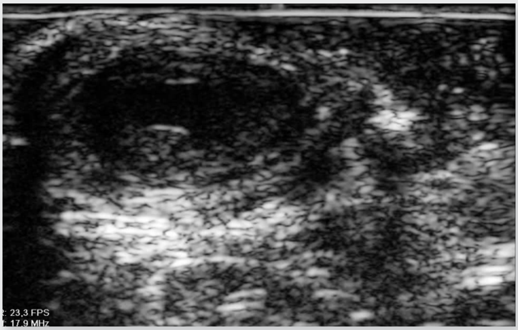


8.4 Femoral-popliteal restenosis

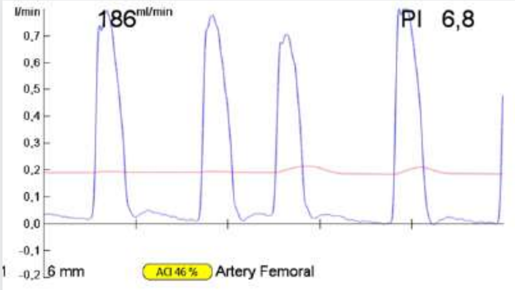
This patient had a thrombendarterectomy perfomed 18 months previous and returned with a new stenosis. The angio showed an occluded common femoral artery.



HFUS performed to confirm the occlusion. The lumen of the vessel is filled with plaque.



The TTFM flow pattern shows high spikes that indicate occluded flow.

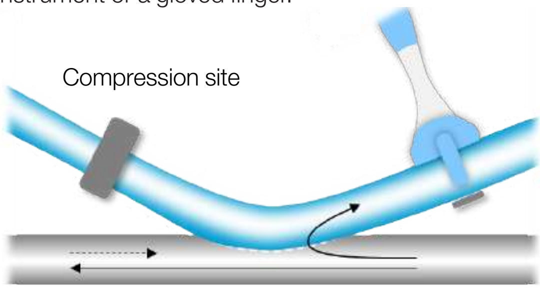


Improve maturation rate

HFUS and TTFM are useful as both guidance and completion control during AV fistula creation. ESVS recommends considering further investigation if there is no thrill or a bruit in the region of the anastomosis after creation of a vascular access.[7]

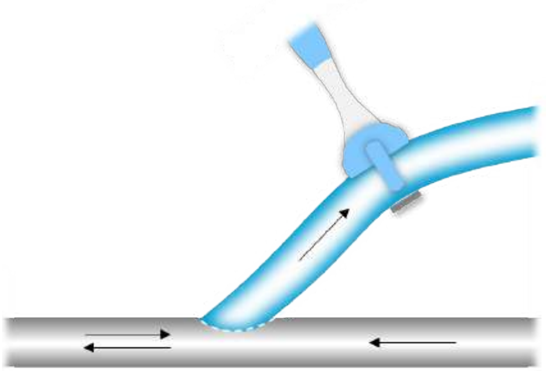
Side-to-side AV fistula

The inflow vein should be compressed with a blunt instrument or a gloved finger.



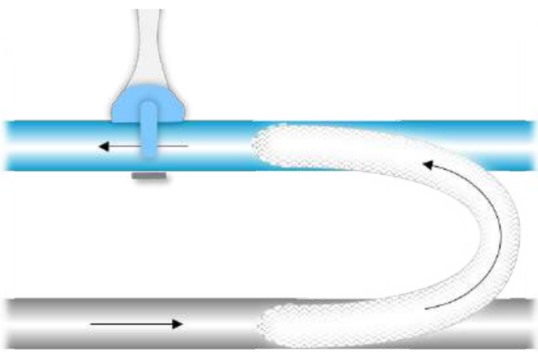
End-to-side AV fistula

Place the probe on the outflow vein. There will usually be some retrograde flow in the artery.



Prosthetic loop AV fistula

Place the probe on the outflow vein. Avoid measuring on the synthetic graft as this might give a poor reading.



Reference values

Flow rate is the single most important determinant of primary and secondary patency for autogenous vascular access. Vikatmaa and Albäck refer to flows over 200 ml/min in a radiocephalic arteriovenous fistula as normal.[1] Other studies also confirm a threshold value for predicting successful fistula maturation:

Reference	Value
Saucy 2010 [16] (n=58)	120 ml/min
Kim 2015 [8] (n=252)	190 ml/min
Vikatmaa 2018 [1]	> 200 ml/min
Meyer 2019 [13] (n=41)	170 ml/min

A. Meyer recommends PI <1 during TTFM on the outflow vein of an AV fistula.

AV Access steal syndrome

The construction of an AV access can compromise the perfusion of the extremity distal to the anastomosis, resulting in symptoms consistent with acute or chronic ischemia. This occurs most commonly after brachial artery–based AV accesses.

In DGG (2010),[6] high flow is defined as >800 ml/min for autogenous accesses and >1200 ml/min for prosthetic accesses. Target flow during flow reduction is 400 ml/min for autogenous and 600 ml/min for prosthetic accesses.

KDOQI Guidelines from 2020 state that the exact threshold to define high-flow access has not been rigorously validated or universally accepted, although an AV access flow rate (Qa) of 1 to 1.5 l/min or Qa of >20% of the cardiac output (Qa/CO) is suggested.[24]

Workflow fistula creation

The workflows suggested should be considered as a guideline that show different steps where the MiraQ systems might assist during surgery. Ideally, flow should be measured at systolic pressure > 100 mmHg.[13]

Before AV fistula creation

- Imaging of the outflow vein can detect hemodynamic relevant side branches, spasms and vein valves.

Functional evaluation

- After creation of the AV fistula, check the anastomosis with HFUS to exclude any morphological problems which could lead to fistula failure.
- Check the flow in the outflow vein with TTFM.
- If there is no thrill or bruit, and the flow is lower than expected, a technical problem should be excluded and further investigation should be performed.[7]

Immediate flow modulation

- At high flow, assess risk for steal syndrome and consider a reduction of blood flow.
- Use TTFM during the management of high-flow arteriovenous access-related symptoms of distal ischemia and cardiac insufficiency.

Workflow flow modulation

TTFM is useful during flow modulation in high flow situations.[15] Workflow for flow modulation when a dialysis patient experience symptomatic ischemia or cardiac insufficiency related to a high-flow access:

During dissection

- HFUS to assist dissection of the vessels near the AV anastomosis where TTFM is to be performed.

Flow modulation

- Place the flow probe at the exposed segment of the fistula vein for autologous grafts.
- Perform narrowing of the fistula vein or graft near the anastomosis. Diameter reduction should be performed during a simultaneous measurement of the access flow until the desired flow is established.

Final evaluation

- Perform a final flow measurement before wound closure.

AV

AV ACCESS TTFM EXAMPLES

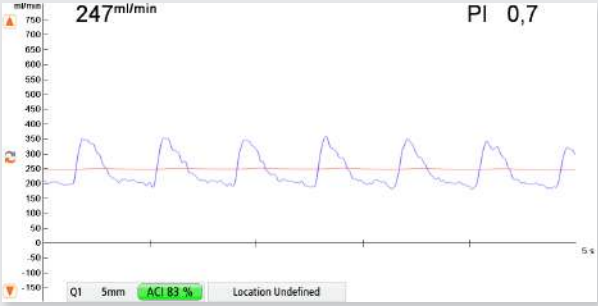
9.1 Normal TTFM in AV Access

Normal flow curves for the outflow vein of an AV fistula shows a repetitive pattern and a mean flow within the recommended values.

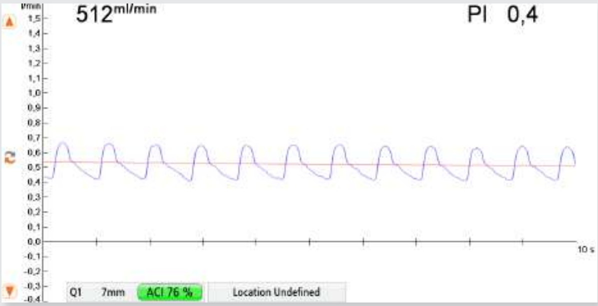
Guidelines from ESVS recommend further examination if there is no thrill/bruit registered after AV fistula creation.

Normal intraoperative flow measurement of an AV-fistula with high flow and a low PI. The measurement was performed on the radio-cephalic vein.

Normal flow during av AV access creation. The measurement was performed on the radio-cephalic vein.



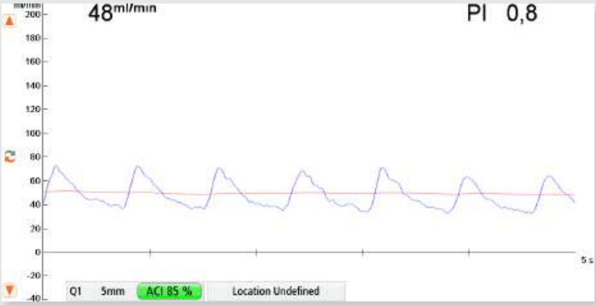
Normal intraoperative flow measurement from a radio-cephalic vein. The flow curve was smooth and repetitive and both flow and PI are within recommended values.



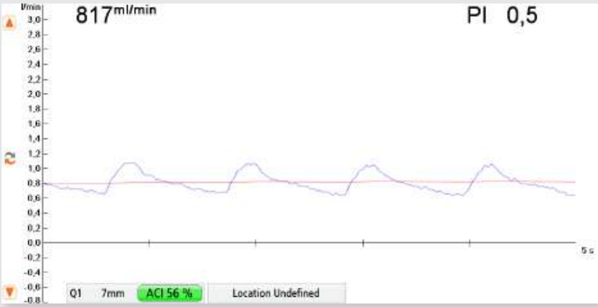
9.2 Suboptimal TTFM in AV Access

Flow values that are too high may indicate steal syndrome in the shunt arm, and mean flow that is too low may lead to maturation failure. Both cases will have to be revised before completing the surgery.

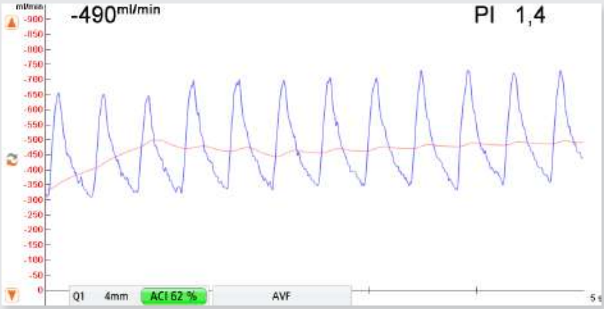
This flow measurement showed flow that is too low compared to suggested reference values. The reason should be further investigated, possibly with HFUS.



In this case the flow was very high and could pose a risk of steal syndrome.



This flow measurement from AV access showed high flow and a PI higher than recommended.

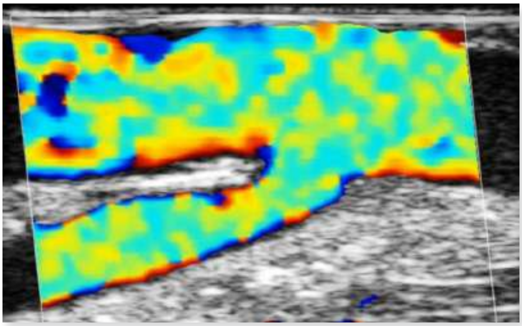


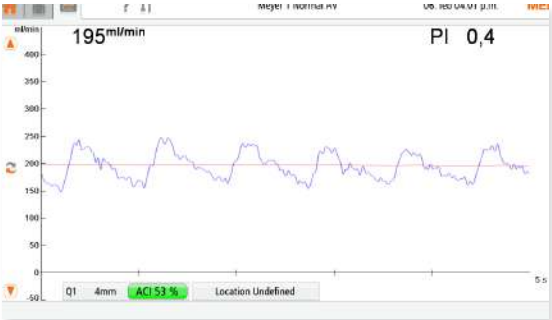
The use of TTFM and HFUS is useful during the creation of AV-fistulas and also during flow modulation after initial fistula creation.

Shown below are some case examples from the use of intraoperative guidance and quality control using Medistim systems.

9.3 Radiocephalic AV fistula creation

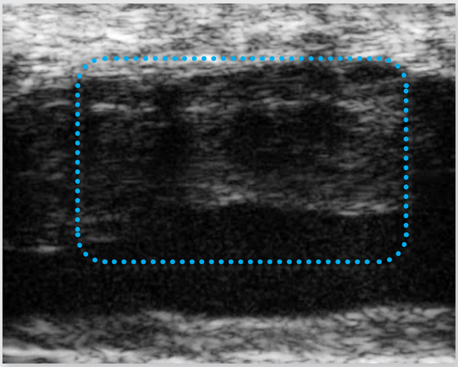
Normal intraoperative situation of an AV-fistula. In this case, high-resolution ultrasound served as first completion control to detect any problem in the anastomosis. The system is set in Color mode and the image shows an open arteriovenous anastomosis. As a tool to predict AV fistula maturation, TTFM was performed. The flow was considered high enough for a successful maturation.





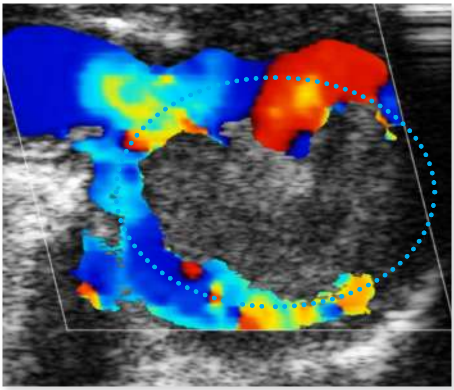
9.4 Radiocephalic AV fistula thrombus

AV-prosthesis graft with a dysfunction. The reason for the dysfunction was an atheromatous thrombus close to the wall of the prosthesis graft in the region of the puncture sites.



9.5 Radiocephalic AV fistula obstruction

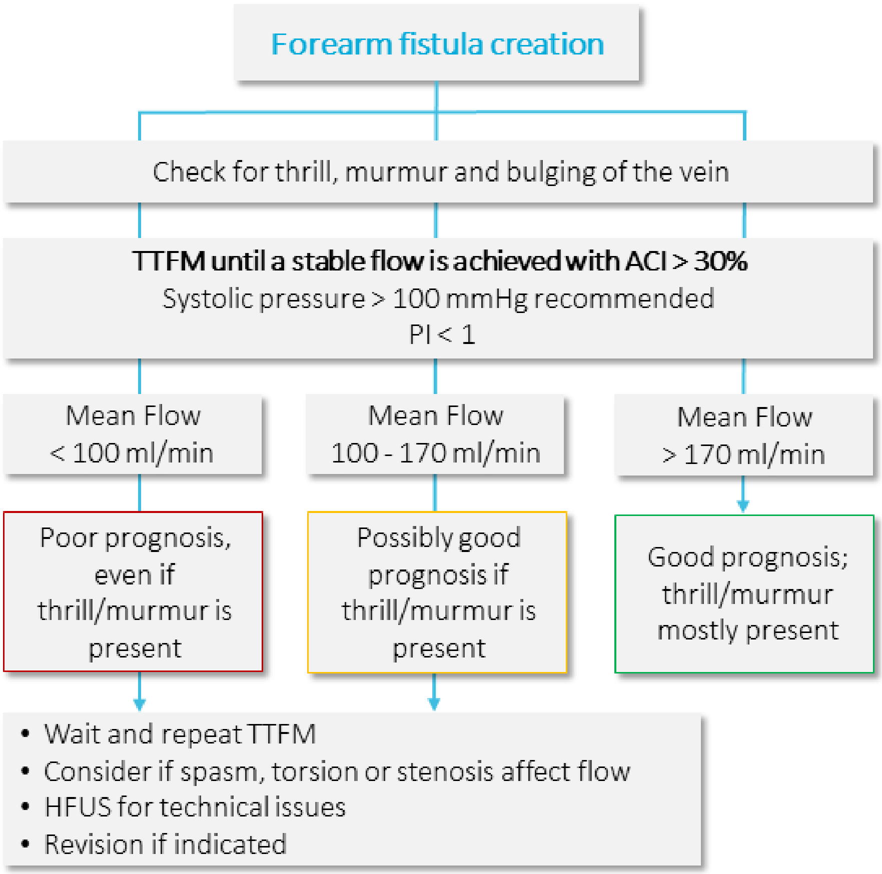
This ultrasound image with CFM shows how a thrombus is occluding a native arteriovenous fistula.



Workflow TTFM in AV Access

Recommended workflow for quality control during forearm fistula creation

Developed in collaboration with Alexander Meyer, 2022*



This workflow is developed for creation of forearm fistulaes, but can in principle also be used for brachiocephalic fistulaes.

Note that the recommended blood flow volume in upper arm fistulaes might be higher than for forearm fistulaes.

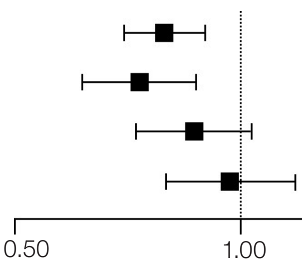
**Alexander Meyer, MD. Head of the Department of Vascular Surgery, Johanniter-Krankenhaus Duisburg Rheinhausen, Germany*

10. Carotid Endarterectomy

Reduced risk of stroke and death

The 2018 ESVS Guidelines state that targeted monitoring and quality control strategies may be considered to reduce the risk of perioperative stroke. In a publication by Eckstein and Knappich in 2017, the statistical material from 138.476 patients in Germany was analyzed, showing that Ultrasound-guided completion control reduced the risk of stroke or death by 26%.[2] (See table below)

Intraoperative completion study	Adj. RR [95% CI]	P-value
Angiography	0.80 [0.71 - 0.90]	<0.001
Ultrasound	0.74 [0.63 - 0.88]	0.001
Flowmetry	0.87 [0.74 - 1.04]	0.121
Other technique	0.97 [0.80 - 1.17]	0.756



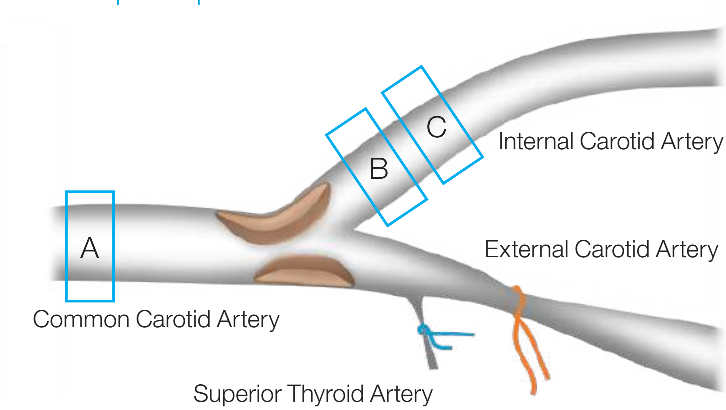
Cerebral Hyperperfusion

Cerebral hyperperfusion syndrome (CHS) is a rare complication that may occur following CEA. This complication may be devastating, especially if it appears after discharge from the hospital.

CHS is most common in patients with more than 100% increase of ICA blood flow compared with pre-endarterectomy measurements and is otherwise rare.[23] Matsumura et al. published a paper in 2020 with the conclusion that an increase of more than 81 ml/min from pre- to post-CEA predicts Cerebral Hyperperfusion (sensitivity 100%, specificity 78%).[21]

Flow was measured on the CCA while clamping both the ECA and the Superior Thyroid Artery. This method enables pre-CEA flow measurements with reduced risk of plaque dislodgement in the ICA. Probe placement during post-CEA TTFM involves less risk of plaque dislodgement.

TTFM probe placement



A. Check flow in CCA or in either of the other carotids during compression of the other.

B. For pre-endarterectomy TTFM, this area is risky if the plaque is soft. Ideal measuring site after endarterectomy.

C. Potentially difficult measurement if it demands extra dissection in a narrow space.

Workflow CEA

Ideally, flow should be measured at systolic pressure >100 mmHg.[4] Keep in mind that HFUS and TTFM on a calcified carotid artery might be affected by high grade of calcification causing a low ACI. Medistim recommends measuring TTFM both before and after CEA. Too low flow might indicate intima remnants in the vessel or technical imperfections during closure. High flow (>500 ml/min) or a flow increase too large from pre CEA flow may indicate a risk of cerebral hyperperfusion. [1]

Before endarterectomy

- Use HFUS to confirm the location of plaque and to avoid manipulation of risky areas.
- Perform TTFM to assess flow in the affected vessel.

Intraoperative HFUS

- Perform HFUS of the inflow artery and proceed downstream.
- Use B-mode in transverse and longitudinal planes to reveal morphological issues like residual plaque, stenosis, dissections, thrombus formation, intimal flaps, kinks and external compression.
- HFUS can be performed both before and after clamp removal.
- Use Pulsed Wave Doppler to look for stenoses or to check the resistance in the bifurcation.

Intraoperative TTFM

- Perform TTFM post CEA to ensure that flow is adequate.

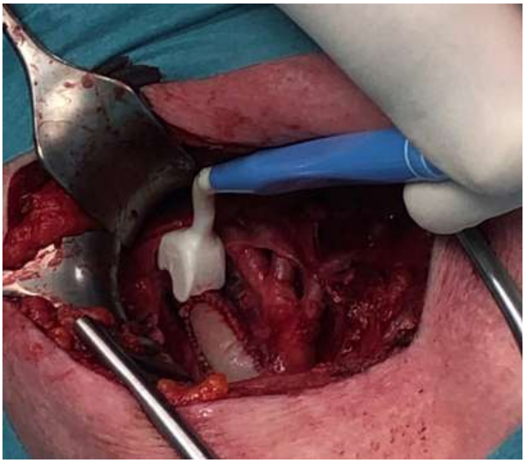
Reference values

There are no established cut-off values for flows in the carotid arteries. There are, however, publications guiding us in what values are seen as normal, too high or too low. The previously mentioned paper by Vikatmaa and Albäck (2018) refers to the values below.

ICA	Reference
Low flow	<100 ml/min
Normal flow	100-300 ml/min
High flow	500 ml/min

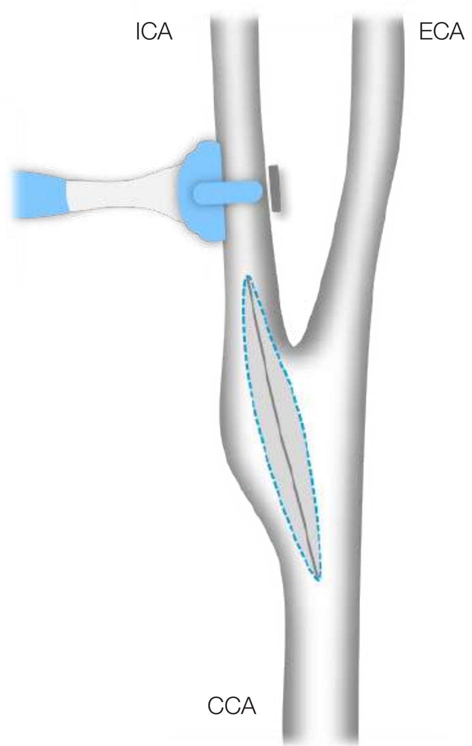
There are several publications available with different suggested reference values for carotid arteries. Aleksic published a paper in 2009 (N=1000) with pre- and post-CEA flow values that may be used to determine reference values for the different carotid artery flows.[4]

Vessel	Pre CEA	Post CEA	Change
CCA	290 ml/min	336 ml/min	+16%
ECA	152 ml/min	150 ml/min	-4%
ICA	160 ml/min	240 ml/min	+46%

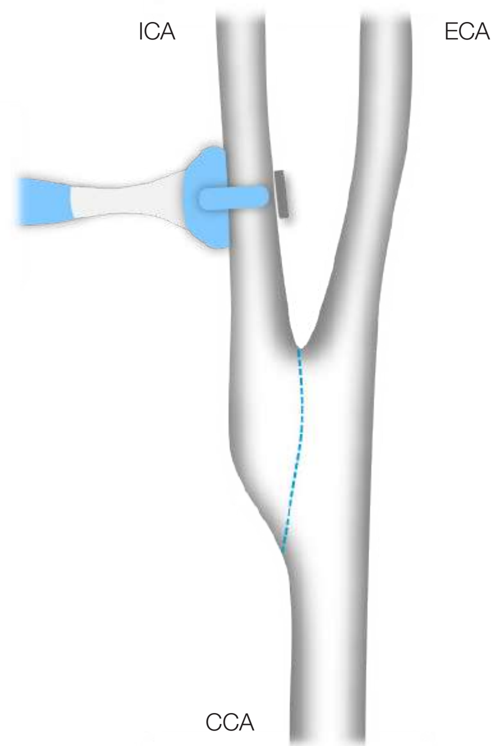


Different techniques for CEA

The most commonly used technique for CEA is the conventional method with or without a patch. For larger, high-volume centers, using the eversion technique may show better outcomes. This is a more challenging procedure and demands more experience by the surgeon.



TTFM after conventional CEA. Closure performed by using a patch to avoid narrowing of the lumen.



TTFM after eversion technique CEA.

TTFM may be used to evaluate flow before and after CEA for both techniques. The probe may be placed on the Internal Carotid Artery (ICA) or on the Common Carotid Artery (CCA) while compressing the External Carotid Artery (ECA).

Show caution not to manipulate the ICA too close to the plaque during pre-CEA measurements.

Revision criteria during CEA

The workflow presented on page 39 is derived from the CIDAC study published by Knappich et al. in 2020. The abstract and results from this study are presented in Chapter [11]. Using a standardized workflow was previously proposed by Ascher et al.[18]

In the CIDAC trial, both HFUS and angio was performed and videos presented to the independent investigator after the surgery. A four-stage rating scale was established with Grade I representing no defect and Grade II representing a minor lesion. Grades III and IV were defined as a major defect and severe lesion, respectively. Grades III or IV were considered relevant defects requiring intraoperative surgical revision and correction of the defect.

This scale is presented here and includes the criteria used for both angio and HFUS.

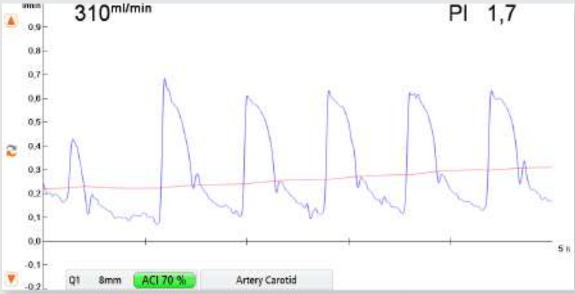
Grade	Definition	Morphological Criteria		Hemodynamic Criteria	
		Angiography	**IDUS**	**Angiography**	**IDUS**
1	no defect	• smooth vessel wall • no narrowing • no angulation • no false lumen	• smooth vessel wall • no narrowing • no angulation • no false lumen	• fast continuous contrast runoff	• no aliasing phenomenon • PSV* <100 cm/sec
2	minor defect	• irregularity of vessel wall • no significant narrowing • small distal intimal step or intimal flap (no significant narrowing, not mobile) • vasospasm of ICA	• irregularity of vessel wall • narrowing <30% • intimal flap in ICA <2 mm • intimal flap in CCA <3 mm	• dynamic but pulsatile runoff	• aliasing phenomenon without morphologic defect • PSV <150 cm/sec
3	major defect	• significant narrowing of CCA or ICA • significant intimal flap (significant narrowing or mobile) • dissection • occlusion of ECA	• narrowing >30% • intimal flap in ICA >2mm • intimal flap in CCA >3 mm • dissection • occlusion of ECA	• delayed and pulsatile runoff	• aliasing phenomenon with morphologic defect • PSV >150 cm/sec
4	severe lesion	• high grade stenosis • intraluminal contrast filling defect • occlusion	• high grade stenosis • valve mechanism • occlusion	• slow and pulsatile runoff • no runoff	• PSV >300 cm/sec • no flow

**Peak systolic velocity*

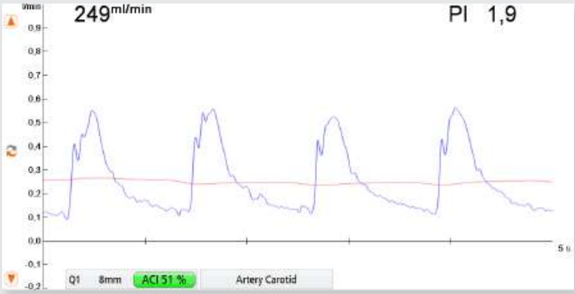
10.1 Normal TTFM in Carotid Endarterectomy

In the carotid arteries, the normal flow curve has a steep systolic spike that plateaus before it sinks again.

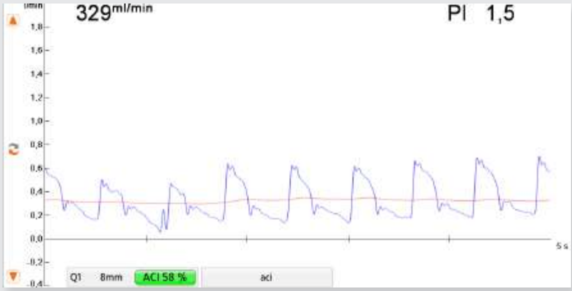
Normal flow curve from Internal Carotid Artery (ICA). The measurement was saved a little prematurely, causing the red line to not be completely horizontal.



Normal flow curve from Internal Carotid Artery (ICA).



Normal flow curve from Internal Carotid Artery (ICA).



10.2 Suboptimal TTFM in Carotid Endarterectomy

Flow before or after CEA might be too low or too high. A large increase in flow post-CEA may predict cerebral hyperperfusion. Low flows might indicate flow obstruction caused by intima flaps, technical issues with the patch, or thombosis.

This example showed a very disrupted flow. The ACI was low and should have been resolved using a smaller probe for a better fit or a coupling agent. Pre-CEA TTFM - expect low ACI due to a high degree of calcification.

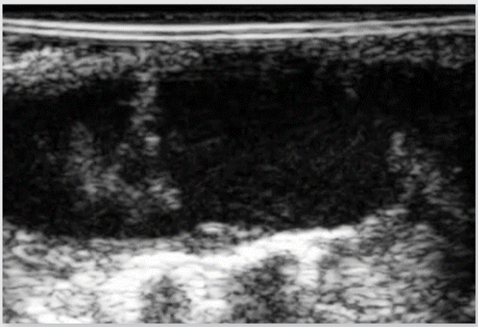
This pre-CEA flow measurement showed a jagged curve that indicated a possible obstruction. The flow was very low.

Flow measurement pre-CEA with almost total occlusion of the ICA.

10.3 Thrombus detected by HFUS

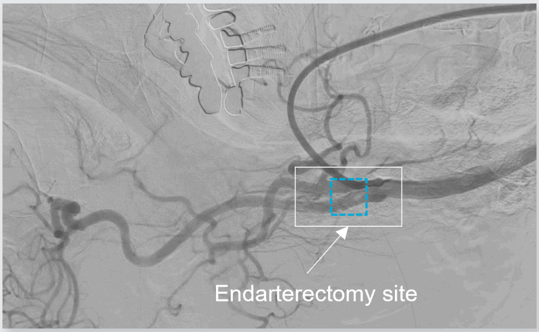
This case illustrates how ultrasound imaging enables more correct detection of higher-grade defects than angiography after CEA. The case is provided by the authors of the CIDAC[2] study. Additional case examples from CIDAC can be found on Medistim's online learning platform, EduQ [(medistim.com/education)](medistim.com/education).

An endarterectomy at the upper part of the internal carotid was performed. HFUS detected a grade 4 defect, in comparison, angiography only showed a grade 2 defect. The ultrasound images clearly show the thrombus in the lumen, visualized both by a cross-sectional and a longitudinal view.

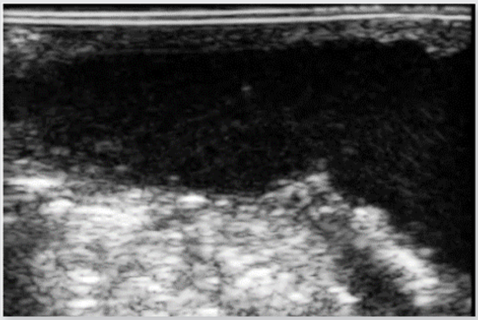


HFUS showed grade 4 defect (intraluminal thrombus) - longitudinal view.

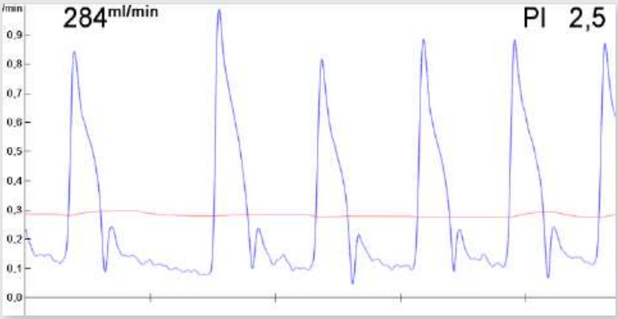
HFUS showed grade 4 defect (intraluminal thrombus) - transverse view.



Angio showed grade 2 defect (minor filling) after CEA



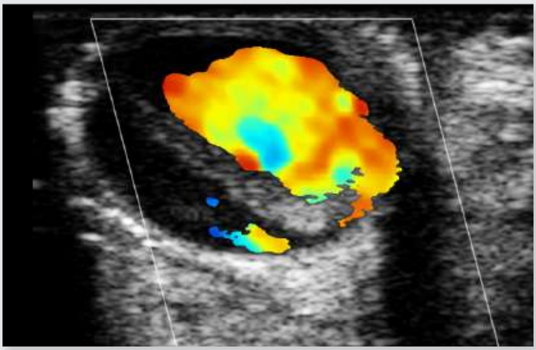
HFUS after revision



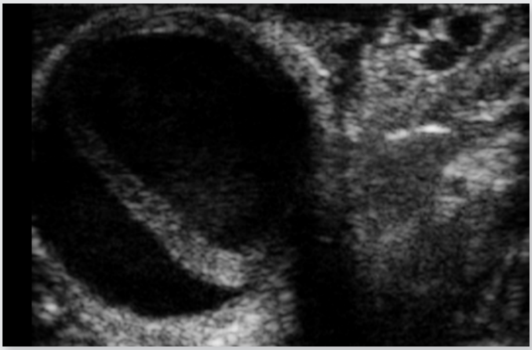
TTFM confirmed good flow post revision.

10.4 Carotid dissection seen by HFUS

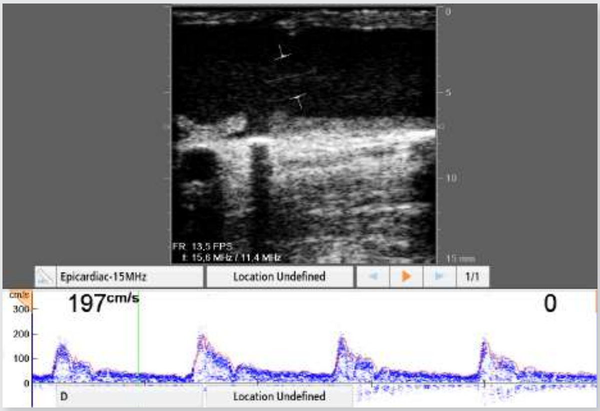
In this CEA case, a dissection was discovered in the common carotid artery by using HFUS.



2D imaging with Doppler on the Common Carotid Artery (CCA). Dissection in carotid seen with CFM.

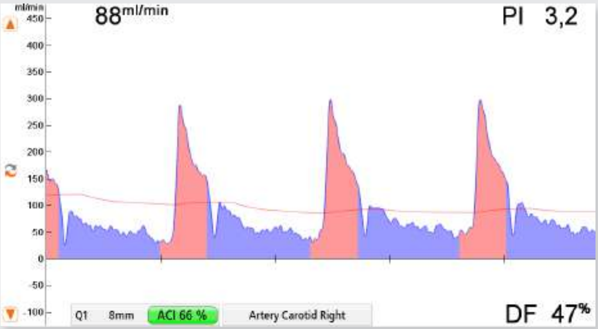


2D view of dissection in Carotid artery.



Common Carotid Artery (CCA)

After the procedure, completion control showed low grade stenosis by using PW Doppler. The flowmeter used in this case was the MiraQ Cardiac, which includes an ECG connection. This helps differentiate between the systolic and diastolic flow.



Common Carotid Artery (CCA)

The flow measurement showed a lower flow than is usually accepted for carotid arteries.

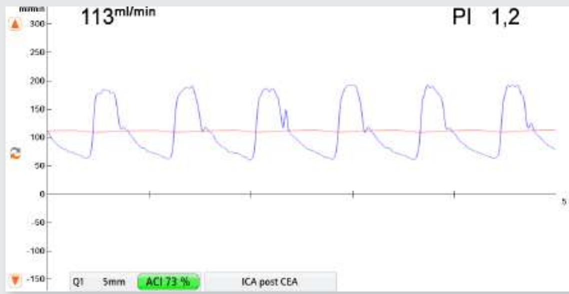
10.5 Intimal flap found after Carotid Endarterectomy

In this case, TTFM and HFUS were used during each step of the surgery.

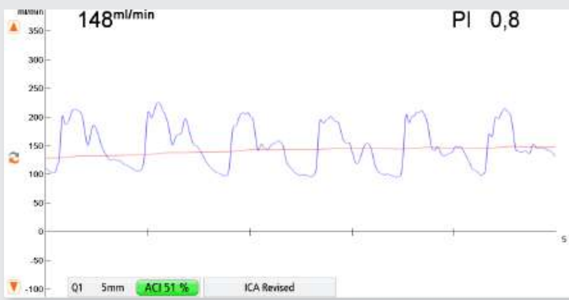
A female patient, 59 y/o was presented for conventional CEA with Bovine Patch and with the use of a shunt. The internal carotid artery had a stenosis close to 90%.

TTFM performed before the endarterectomy showed a very low flow. After the CEA, the flow was borderline, but since HFUS was also performed, an obstructing flap was discovered. Post revision, the flow and the HFUS showed a much better result.

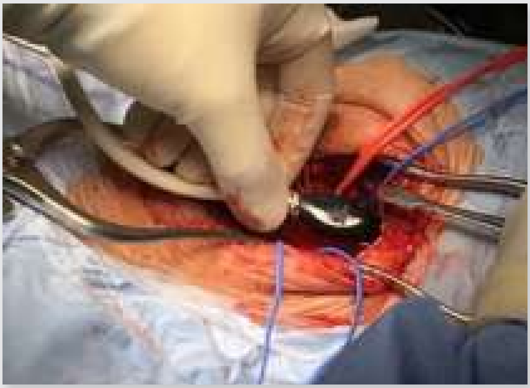
TTFM of ICA before CEA showed very low flow.



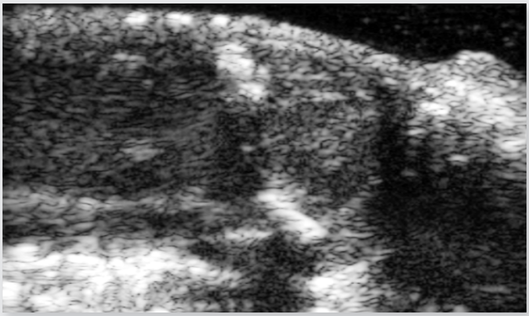
TTFM after CEA showed borderline flow. The surgeon suspected that something might be obstructing the flow.



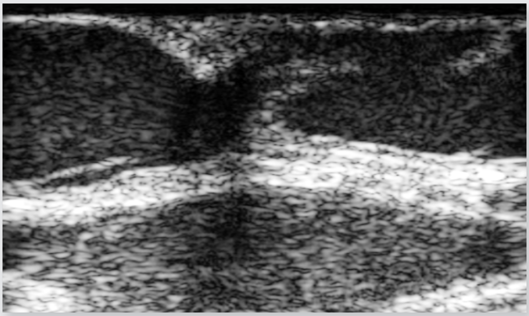
Final TTFM showed improved flow.



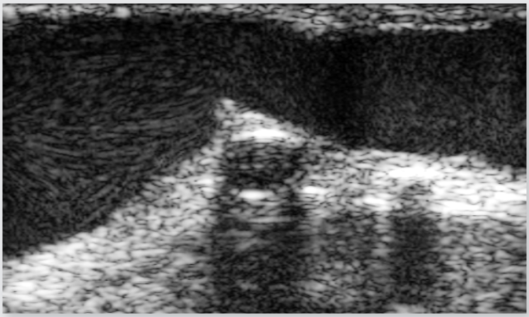
HFUS was performed during each step of the surgery. This helped discover an intimal flap that was obstructing the flow. Removing this defect increased the flow significantly.



HFUS performed before the CEA showed the plaque.



A large flap was discovered, confirming that the flow was obstructed. A revision was performed to remove the flap.



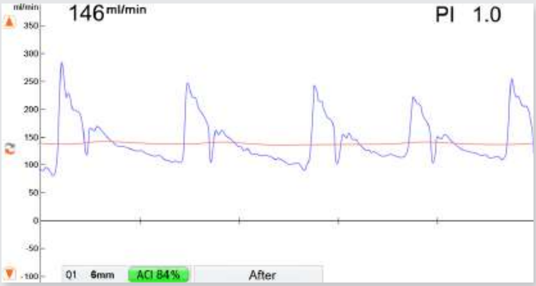
Final HFUS showed a minor residual flap that was deemed acceptable.

10.6 Kinked Internal Carotid Artery (ICA)

In this case, revision was avoided due to TTFM and HFUS.

This case shows the benefit of using TTFM in addition to HFUS after CEA when dealing with a kinked ICA. Finding kinks like these before performing CEA are not uncommon in elderly people. The surgeon decided not to repair the kink since it could result in more kinks upstream causing further problems. Nor did he shorten the artery since it might increase the risk of creating an unwanted flap. When he measured the flow with TTFM after CEA, he found it satisfactory hence avoiding further revision.

The kink on the ICA has a sharp angle and is clearly visible above the bovine patch. An HFUS probe was used as part of the completion control after CEA to visualize a clean intima with no flow obstructions.



The flow probe was placed on the ICA distally to the patch and TTFM indicated adequate flow volume with a low PI and a steady, repetitive flow curve. Hence, the kinked ICA was left untouched since both HFUS and TTFM assured the surgeon that there were no flow issues.

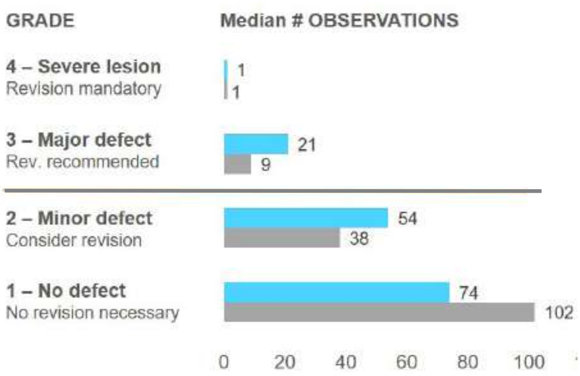
11. CIDAC Protocol and Results

Intraoperative duplex ultrasound (IDUS) using a Medistim system was compared to angiography during intraoperative diagnostics after carotid endarterectomy (CEA) in 150 patients. This is a prospective, clinical trial where a comparison of the findings of defects was performed by 3 independent and blinded investigators.

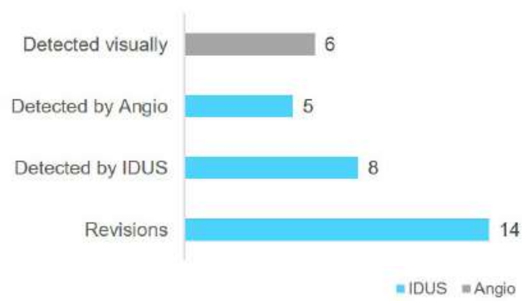
The investigators analyzed intraoperatively obtained videos and used a 4-stage rating scale for defects detected. This is a prospective, clinical trial where a comparison of the findings of defects was performed by 3 independent and blinded investigators. The investigators analyzed intraoperatively obtained videos and used a 4-stage rating scale for defects detected.

The main finding from this study is that IDUS detects more defects qualifying for revision than angiography. It is easier to see movement of structures with IDUS compared to angio. It shows more defects, leads more frequently to intraoperative revision and shows a higher interobserver reproducibility. With support from this study, Medistim can recommend IDUS instead of angiography for intraoperative completion control after CEA.

RESULTS



More defects were rated more severe with IDUS than with angio (p<0.001).



Significantly more defects requiring intraoperative revision were detected by IDUS compared to angio (p=0.040).

RATING SCALE

Grade	Definition	Implication
1	No defect	No operative revision
2	Minor defect	Consider operative revision
3	Major defect	Revision recommended
4	Severe lesion	Revision mandatory

CONCLUSIONS

- IDUS enables more correct detection of higher grade defects than angiography (P < 0.001)
- IDUS leads to intraoperative revision more frequently than angiography
- Inter-observer reliability of IDUS is higher than of angiography

CIDAC - Comparison of Intraoperative Duplex Ultrasound and Angiography after Carotid Endarterectomy

Christoph Knappich, Sofie Schmid, Pavlos Tsantilas, Michael Kallmayer, Michael Salvermoser, Alexander Zimmermann & Hans-Henning Eckstein
European Journal of Vascular and Endovascular Surgery 2020

Abstract

Background
The application of intraoperative completion studies might have contributed to the ongoing improvement of perioperative outcomes in carotid surgery.

Methods
The aim of this prospective study was to compare two methods of intraoperative completion studies, angiography and intraoperative duplex ultrasound (IDUS), after carotid endarterectomy (CEA) with respect to differences in ratings of vessel wall defects and inter-rater reliabilities. Patients, who underwent CEA for symptomatic or asymptomatic carotid stenosis were included. After CEA, angiography and IDUS were applied subsequently. Intraoperatively obtained video footage was evaluated at a later date by three independent and blinded raters with different levels of clinical experience. Rating occurred according to a four-stage rating scale with higher stages representing more severe defects. Statistical standard methods (Pearson's chi-Squared test, permutation test, Wilcoxon signed rank test, Kendall's coefficient of concordance W) were applied.

Results
In total, 150 patients (mean age 72±7 years, 68.7% male, 33.3% symptomatic) were enrolled between March 2016 and September 2017. Significantly more defects requiring intraoperative revision (Grades III and IV on rating scale) were detected by IDUS [22 (14.7%) vs. 10 (6.7%); $p=0.040$], which in part remained undetected by angiography. Defects were judged to be more severe with IDUS compared to angiography [median rating; Grade I: 74 (49.3%) vs. 102 (68.0%); Grade II: 54 (36.0%) vs. 38 (25.3%); Grade III: 21 (14.0%) vs. 9 (6.0%); Grade IV: 1 (0.7%) vs. 1 (0.7%); $p<0.001$]. Furthermore, W was significantly higher for IDUS compared to angiography (0.701 vs. 0.568; $p=0.003$).

Conclusions
IDUS revealed more defects after CEA compared to angiography. With a higher inter-rater reliability, IDUS is less dependent on the surgeon's subjectivity compared to angiography. Taking into account the absence of procedure associated risks (i.e. adverse effects of iodinated contrast media and X-ray), IDUS could be considered an alternative intraoperative morphologic assessment tool in carotid surgery.

12. Guiding publications

12.1 Vikatmaa et al.[1]

Intraoperative quality control with transit time flow measurement

Pirkka Vikatmaa & Anders Albäck
Gefässchirurgie 2018 · 23:580–585

Abstract

Vascular reconstructions carry a high risk of early and late failure, leading potentially to major problems. Therefore, it is crucial to ensure the quality of reconstructions at the end of every operation. No method has been shown to be superior to others and it is beneficial for the vascular surgeons to master many techniques. Transit time flow measurement (TTFM) is a fast and easy way to directly evaluate the desired end result; blood flow to the end organ. It is not problem free nor totally reliable. In addition to TTFM different quality control methods including their pros and cons are discussed.

Medistim comments

Vikatmaa and Albäck have extensive experience using Medistim TTFM and imaging systems and have performed several workshops to train fellow surgeons in using our technology. This paper discusses the pros and cons of intraoperative digital subtraction angiography (DSA), high quality intraoperative ultrasound (IUS) and TTFM. Some interesting statements from this paper are:

"IUS should be readily available in all operating theaters performing vascular surgery. With a high frequency (>15MHz) superficial transducer the visibility of anastomoses, dissection flaps and other anatomical structures is excellent."

"TTFM completion control can and should be utilized at the end of virtually every open or hybrid vascular surgical operation. It is the only method that easily and relatively reliably measures the desired endpoint with reconstructions and flow to the end organ."

They recommend considering further imaging after all "low flow" values. After CEA the routine use of IUS is recommended and routine DSA after extreme and high-risk bypass surgery. TTFM is considered sufficient after femoral endarterectomy or routine bypass surgery.

For peripheral bypass, the increase in flow is more important than specific cut-off values. When it comes to carotid endarterectomy, problems seem more likely when the flow volume is less than 100ml/min.

The included tables present estimates of low, normal and high flow for different vessels and compare the usability of the three discussed quality control methods.

Table 1 Rough estimates of low, normal and high flow values in different arteries and reconstructions (ml/min). There is no high-quality scientific evidence to support these values. These figures should be seen as a suggestion developed in clinical practice after routine use of TTFM at the end of nearly all open arterial operations in this unit since the early 1990s.

	Low flow (ml/min)	Normal (ml/min)	High (ml/min)
ICA	<100	100–300	500
Axillary artery	<100	100–500	>500
Radiocephalic FAV	<200	>300	>1000
A. hepatica/lienalis	<100	>150	>500
SMA	<200	>400	1000
A. renalis	<150	200–400	>500
Iliac arteries	<300	500–2000	>1000
CFA	<200	300–1000	>700
Popliteal bypass	<100	>100	>300
Crural bypass	<80	80–200	>200
Inframalleolar bypass	<50	>50	>200

ICA internal carotid artery, SMA superior mesenteric artery, CFA common femoral artery, FAV arteriovenous Fistula.

Table 2 Different reasons for early graft failure and an estimation of the capacity of three different completion control methods.+ =moderate, ++ = good, +++ = excellent in diagnosing the problem.

	Anastomotic error or thrombus	Embolus	Flap remnant	Kinking / Twist
Ultrasound	+++	+	+++	++
Angiography	++	+++	++	+++
TTFM	+	++	++	+++

12.2 Miyake et al.[25]

Graft flow predictive equation in distal bypass grafting for critical limb ischemia

Miyake K, Kikuchi S, Okuda H, Koya A, Yoshiki Sawa Y & Azuma N
J Vasc Surg 2019;-:1-12

Abstract

Objective

Graft flow (GF) seems to be an important prognostic predictor in distal bypass for critical limb ischemia, but previous studies have failed to clarify the association between GF and the graft prognosis. GF differs significantly among grafts, and each graft seems to have an optimal GF depending on various factors. We hypothesized that comparison between the measured GF (mGF) and optimal estimated GF (eGF) would be important in predicting graft prognosis. Herein, we aimed to develop a GF predictive equation by assessing GF determinants and to validate the equation against a clinical dataset.

Methods

A total of 198 distal bypasses with vein grafts for critical limb ischemia from 2011 to 2016 were enrolled. Of these grafts, 135 normal grafts without any abnormalities on early postoperative ultrasound examination were used to develop and validate the equation. Various anatomic and patient-related factors were analyzed to detect GF determinants with stepwise selection, and the GF predictive equation was developed with multiple linear regression analysis. After developing the equation, all 198 grafts were categorized into two groups according to the equation developed based on data from the 135 normal grafts as follows: optimal flow grafts (OFGs), in which mGF > eGF - 14.6, and suboptimal flow grafts (SFGs), in which mGF < eGF - 14.6. The cutoff value of 14.6 was determined using receiver operating characteristic curves to detect graft abnormalities. By comparing OFGs and SFGs, the efficacy of the equation in predicting bypass abnormalities and graft prognosis was assessed.

Results

The GF determinants were runoff, hemodialysis (HD), diabetes mellitus (DM), and graft quality (GQ). The predictive equation was estimated as follows:

$$GF(ml/min)=(32.9\times run\text{-}off)+(9.9\times GQ)-(13.0\times DM)-(35.1\times HD)+12.1$$

(R^2 = 0.71, coefficient: runoff and GQ, 3 [good], 2 [fair], 1 [poor]; DM and HD, 1 [yes], 0 [no]).

In the efficacy assessment of the equation, SFGs showed a significantly higher rate of bypass abnormalities (64.0% vs 12.2%; $P < .0001$), graft intermediate stenosis (10.7% vs 1.6%; $P = .0071$), graft critical stenosis (28.0% vs 3.2%; $P < .0001$), and early graft occlusion (17.3% vs 4.3%; $P = .0037$) than OFGs and were associated with a higher rate of revision surgery within 2 years after surgery (50.7% vs 34.2%; $P = .026$). SFGs also showed significantly lower primary patency rates ($P < .0001$) and secondary patency rates ($P = .0005$).

Conclusion

GF was well-estimated with runoff, GQ, and the presence of DM and HD. A comparison between mGF and eGF, calculated with the equation, will help to detect bypass abnormalities and determine the necessity of additional intraoperative procedures and, thus, achieve optimal outcomes.

Calculation examples

eGF(ml/min) =(32.9 x Run-off) + (9.9 x Graft Quality) - (13.0 x DM) - (35.1 x HD) + 12.1

Run-off:	Poor = 1	Fair = 2	Good = 3
Graft Quality (GQ):	Poor = 1	Fair = 2	Good = 3
Diabetes (DM):	Yes = 1	No = 0	
Hemodialysis (HD):	Yes = 1	No = 0	

Example patient 1:

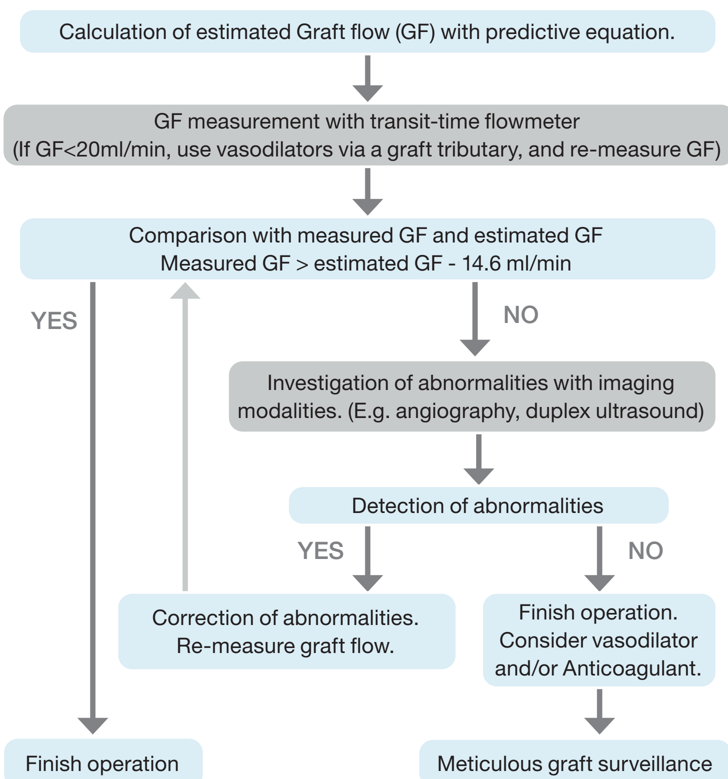
Fair Run-off	eGF = 32.9 x	2	
Fair Graft Quality	+ 9.9 x	2	
Diabetes	- 13.0 x	1	
Hemodialysis	- 35.1 x	1	+ 12.1
	= 49.6 ml/min		

Example patient 2:

Good Run-off	eGF = 32.9 x	3	
Good Graft Quality	+ 9.9 x	3	
No Diabetes	- 13.0 x	0	
No Hemodialysis	- 35.1 x	0	+ 12.1
	= 140.5 ml/min		

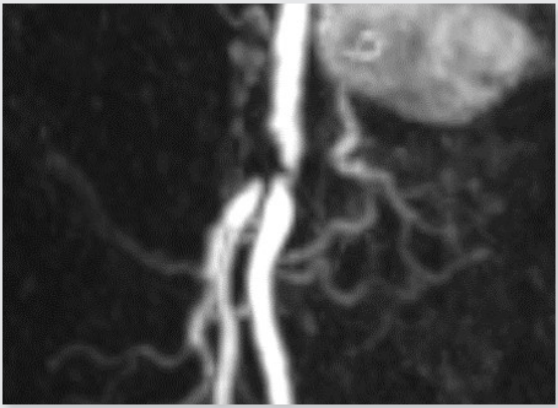
Suggested flowchart for application of predicted graft flow

The publication includes a suggested flowchart for the application of the graft flow predictive equation.



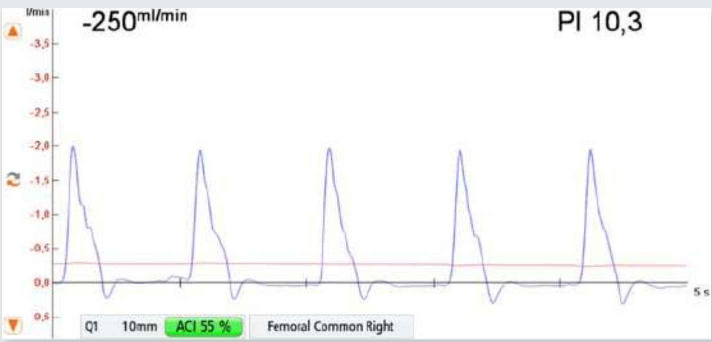
13.1 Femoral thrombendarterectomy

This is a case that involved a 72-year old man with severe claudication. Femoral endarterectomy with a venous patch was performed and TTFM showed great improvement in flow after the endarterectomy.

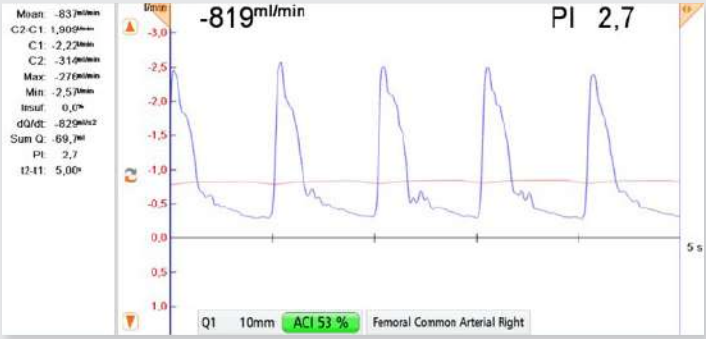


Angio pre-endarterectomy showed that the flow was obstructed.

HFUS pre-endarterectomy showed that the lumen was obstructed by calcified plaque.

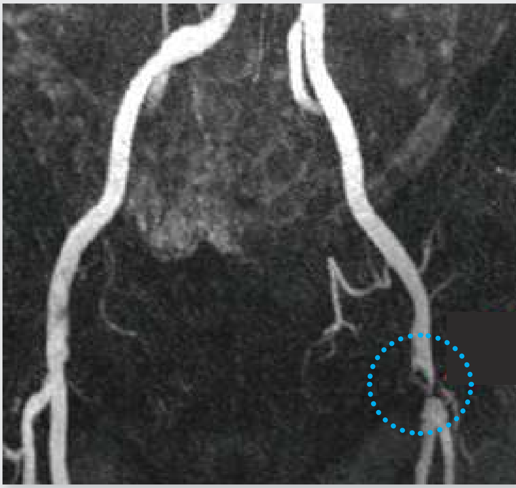


TTFM pre-endarterectomy. Flow was low and PI high, indicating obstruction.



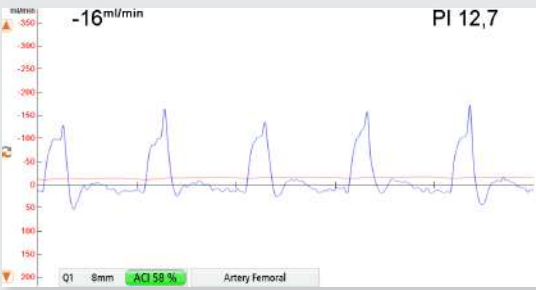
TTFM post-endarterectomy. The flow was clearly improved with lower PI and zero backflow.

13.2 Femoral thrombendarterectomy with revision*

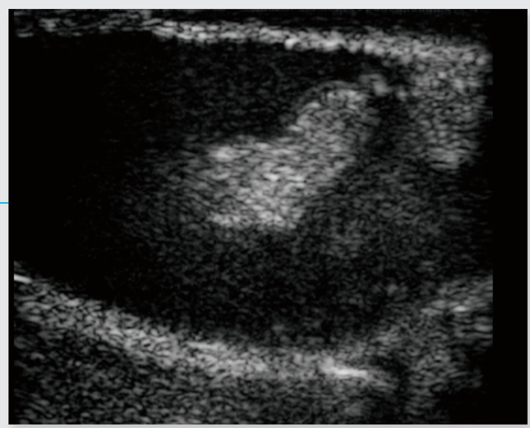


Both MRI and ultrasound indicated high-grade stenosis of the left common femoral artery, while the other vessels were patent. A local thromboendarterectomy of the common, superficial and deep femoral arteries was performed. Before closure, inflow and backflow were tested. There was a good pulse palpable on all femoral vessels.

The course after the operation was uneventful. The peripheral pulses were distally palpable. The patient was dismissed on the 7th postoperative day.



Transit Time Flow Measurement (TTFM) served as first quality control. The results indicated poor flow and high PI in the superficial femoral artery (SFA).



HFUS was performed to detect the cause of the poor flow. The scan revealed a flap with partial occlusion of the reconstruction, despite the good pulse in the SFA.

After revision, TTFM and ultrasound scanning indicated good flow and PI was reduced significantly. The flow curve is triphasic and typical for a peripheral artery.

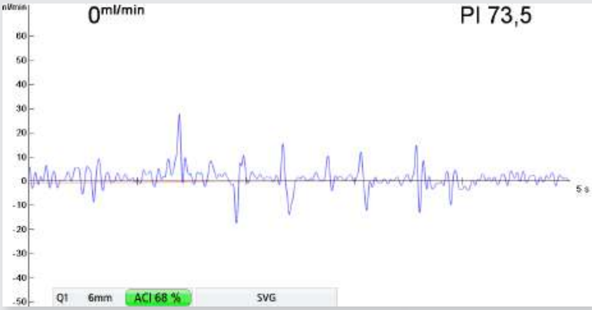
*Courtesy of Prof. Dr. E.S. Debus | Dep. of Vascular Medicine | University of Hamburg-Eppendorf, Germany

13.3 Meso-Rex shunt: Thrombus detected with TTFM and HFUS

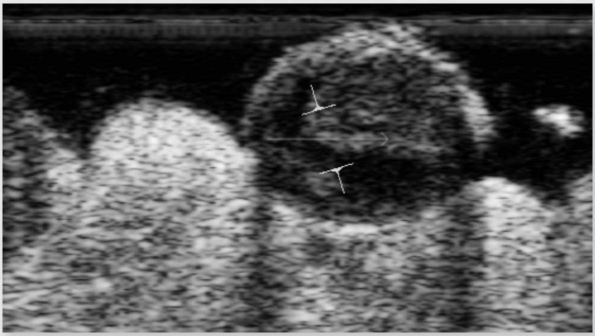
This case demonstrates how Transit Time Flow Measurement (TTFM) and High-Frequency Ultrasound (HFUS) were instrumental in avoiding a catastrophic incident. A thrombus in the saphenous vein graft (SVG) was detected during surgery.

Meso-Rex shunt is a surgical procedure that restores physiological portal venous blood flow to the liver by using a graft to connect the superior mesenteric vein and the left portal vein within the Rex recess.

During the procedure, the SVG was accidentally sewn in the wrong direction. When performing TTFM on the graft it showed no flow and a very high PI.



The surgeon used Doppler, which revealed some sound but was inconclusive. Palpation of the graft indicated that it was pulsative. The surgeon further assessed the graft by using HFUS which revealed a thrombus that occluded the SVG.



The SVG was exchanged with part of the internal jugular vein. Post revision, TTFM showed an increased flow and a much lower PI, which was acceptable.

14. Checklists

TTFM checklist

1. Insert the TTFM probe holding the widest part of the connector.*
2. Enter patient information
3. Perform functionality test
4. Choose the vessel to be measured
5. Annotate if relevant
6. ACI should be green or yellow
7. Mean flow red line should be flat
8. Press SAVE

**Never disconnect a probe by pulling on the cable*

HFUS checklist

1. Insert the imaging probe with the cable to the right and the locking lever in the unlocked position.*
2. Make sure connective medium is available
3. Select vessel to be imaged
4. Choose appropriate preset
5. If necessary, optimize settings
6. Label the measurement for future reference
7. Press SAVE once the desired object is in frame

15. Extracting images and video clips

Extracting images and video clips from the system

This can be done by connecting a USB memory stick to one of the USB ports located on the media panel of the device.

Screen capture and video export functionality is accessible through the **Screen Capture** button available on the right hand side menu when viewing a measurement in **Stopped** or **Edit** mode.

Depending on the device software version, ensure the functionality is made available by:

- Setting the device software to **Advanced Mode** under **System Settings** *(device software older than version 4.2.3)*
- Selecting **Enable Screen Capture** under **System Settings** > **Software Customization** *(device software version 4.2.3 or later)*

Go to the **Patient** screen and select **Search** to search for the patient with the relevant measurements. Select a patient from the list and choose **Select Patient**.

Open the **Archive and Reporting** tab and choose the desired measurement. Select **Edit** to open the selected measurement. Now select **Screen Capture** from the menu.

For non-imaging data, a screen shot of the current screen will be exported as a PNG file.

If the selected measurement contains imaging data, either a **Video** or a **Screen Shot** can be exported. When **Video** is selected, the current position of the cursors in the measurement defines the start frame and the end frame of the generated video. The currently selected playback speed will be used in the generated video.

The screen **Specify Filename and Folder** will appear. Choose the USB memory stick and which folder to export the file to. Specify a filname and press **OK**. Once the file has been generated, the option for safe removal of the USB device will appear automatically.

MiraQ system media panel

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Additional references can be provided upon request.

"The CIDAC trial showed that post hoc analysis of intraoperative ultrasound revealed more defects after CEA than angiography, which in practice, would have implied a higher rate of intra-operative revisions." [2]

Knappich et al., 2020

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