

Reduce Early Graft Failure Following CABG Surgery

Accurate Flow Measurements Help You
Identify and Repair Flow Restrictions to
Assure Graft Patency Prior to Closure



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Coronary Flowprobes take the guesswork out of knowing bypass flow

Transonic® Cardiovascular Flowprobes work with the Transonic® Flowmeters to measure volume flow in vessels or grafts from 1.5 - 36 mm diameter. The non-constrictive perivascular Flowprobes use transit-time ultrasound technology to measure volume blood flow directly, quickly and easily, even in the low-flow range.

The surgeon now has a quantitative tool with which to objectively assess the quality of the anastomosis. Unseen blood flow obstructions can be detected intraoperatively and repaired before closing the patient. This ability to correct otherwise undetectable flow restrictions gives the surgeon with a unique opportunity to improve patient outcomes.

European Revascularization Guidelines

"Graft flow measurement, related to graft type, vessel size, degree of stenosis, quality of anastomosis, and outflow area, is useful at the end of surgery. Flow <20 mL/min and pulsatility index >5 predict technically inadequate grafts, mandating graft revision before leaving the operating theatre."¹

¹ The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) "Guidelines on Myocardial Revascularization," Eur J CardiothoracSurg 2010; 38, S1 S52

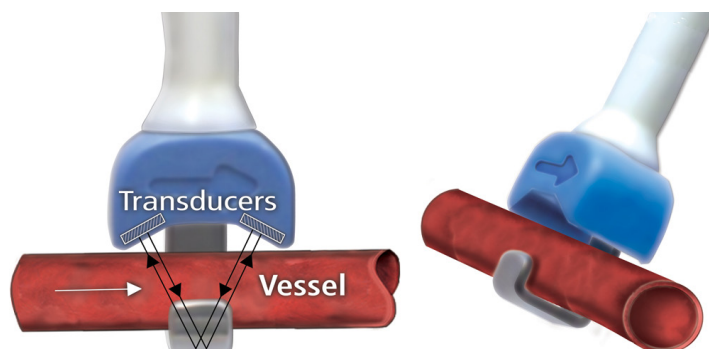
"...TTFM predicts graft failure within six months after CABG."
Jokinen et al, "Clinical value of intra-operative transit-time flow measurement for coronary artery bypass grafting: a prospective angiography-controlled study", Eur J Cardiothorac Surg 2011;39(6):918-23.

"TTFM is a reliable method to verify intraoperative graft patency."
Di Giammarco et al, "Can transit-time flow measurement improve graft patency and clinical outcome in patients undergoing coronary artery bypass grafting?" Interact Cardiovasc Thorac Surg 2010; 11(5): 635-40.

"Routinely, the use of TTFD significantly reduced the incidence of post operative VFib, post-operative CKICK-MB fraction and angiographically detected bypass malfunction." Bauer SF et al, "Intraoperative bypass flow measurement reduces the incidence of postoperative ventricular fibrillation and myocardial markers after coronary revascularisation," Thorac Cardiovasc Surg 2005; 53(4): 217-22.

"The intraoperative use of flow measurements provide invaluable information in a timely, accurate, cost-effective manner allowing for the surgical correction of a surgical problem. This has significantly reduced the complication related to early technically induced graft failure."
Mindich B, MD

TRANSIT-TIME ULTRASOUND TECHNOLOGY MEASURES VOLUME FLOW, NOT VELOCITY



Two transducers pass ultrasonic signals, alternately intersecting the vessel in upstream and downstream directions. The difference between the two transit times yields a measure of volume flow.



Transonic Systems Inc. is a global manufacturer of innovative biomedical flow measurement equipment. Founded in 1983, Transonic sells state-of-the-art, transit-time ultrasound devices for surgical, hemodialysis, perfusion, ECMO, and medical device testing applications, and for incorporation into leading edge medical devices.

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Flow-based Patency Assurance: Illustrative CABG Case Reports

“The intraoperative use of flow measurements provides invaluable information in a timely, accurate, cost-effective manner allowing for the surgical correction of a surgical problem. This has significantly reduced the complications related to early technically induced graft failure ... and provides documentation of the *sine qua non* of the operation: patency.”

Mindich BP et al, “Reduction of Technical Graft Problems Utilizing Ultrasonic Flow Measurements,”
NY Thoracic Society, 2001.



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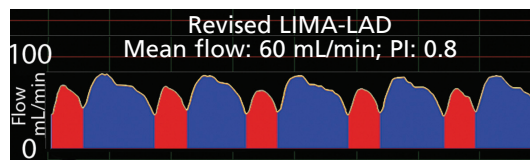
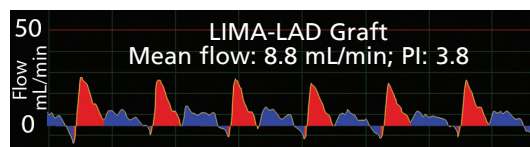
Flow-Based Patency Assurance

Two LIMA-LAD Cases Demonstrate that PIs <5 Can Be Misleading; Acceptable Mean Flow Is Key



A 76-year-old male patient underwent coronary artery bypass grafting (CABG) surgery to bypass a lesion in the left anterior descending (LAD) artery utilizing a left internal mammary artery (LIMA) graft. Initial LIMA-LAD mean flow measured 8.8 mL/min (PI: 3.8) (top waveform).

The graft was revised. Following revision, LIMA-LAD mean flow improved to 60 mL/min (PI: 0.8) and was accompanied by a classic, diastolic dominant waveform profile (bottom waveform).

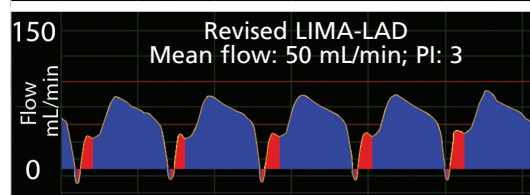
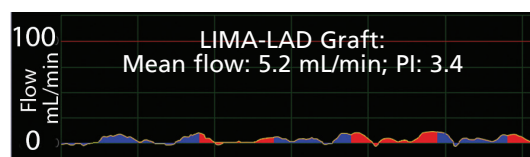


The top LIMA-LAD graft waveform with a spiky systolic profile shows an initial graft flow of 8.8 mL/min (PI: 3.8). Following revision of the graft, flow increased to 60 mL/min (PI: 0.8) and was accompanied by a diastolic dominant waveform profile (bottom waveform).

These two cases demonstrate that a PI < 5 doesn't always mean that the graft has good flow. Acceptable mean flow is critical for graft patency assurance and decision making.

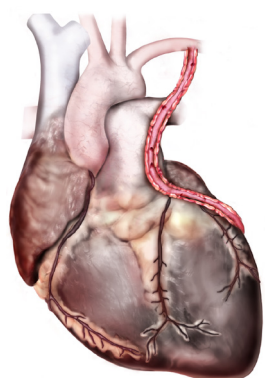
In the second case, a 67-year-old male patient with single-vessel coronary artery disease underwent off-pump CABG. LIMA-LAD graft flow first measured 5.2 mL/min (PI: 3.4). The patient's pulse and pressure appeared normal and the graft appeared functional, but the waveform exhibited a damped profile and atypical diastolization (top waveform). The surgeon decided to revise the graft.

After revision, LIMA-LAD graft flow improved to 50 mL/min (PI: 3). The flow waveform (bottom) exhibited a classic LIMA-LAD profile. Note that the first PI was 3.4, the revised PI was 3.



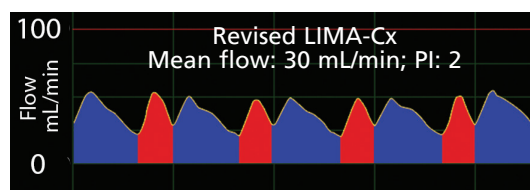
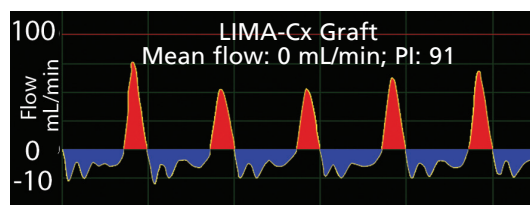
The top waveform demonstrated a damped profile and an atypical diastolization, and was accompanied by the 5.2 mL/min flow. This supported the surgeon's decision to revise the LIMA-LAD graft. Flow improved dramatically after revision and the waveform exhibited a classic LIMA-LAD profile (bottom waveform).

Zero Mean Flow Demands Revision of LIMA-Cx Graft



A 78-year-old female patient underwent single coronary bypass grafting to bypass a blocked circumflex (Cx) coronary artery with the LIMA. Flow first measured 0 mL/min (PI: 91) following anastomosis of the LIMA to the Cx. The flow waveform had a spiky systolic profile (top waveform). Revision was demanded.

Following revision of the graft, mean graft flow improved to 30 mL/min (PI: 2), and the waveform exhibited a balanced systolic/diastolic profile (bottom waveform). Zero mean flow was the determining factor in the decision to revise the graft.

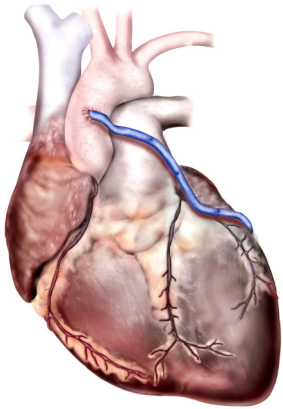


The top waveform exhibited a spiky systolic profile, which, accompanied by zero mean flow, called for the surgeon to revise the LIMA-Cx graft without hesitation. Flow improved to 30 mL/min after revision and the waveform exhibited a balanced LIMA-Cx profile (bottom waveform).

Case demonstrates serious problem with a graft when flow measures 0 mL/min.

Flow-Based Patency Assurance

Zero Flow in SVG-Cx Graft Reveals Clot

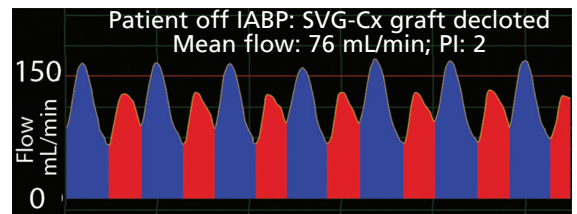
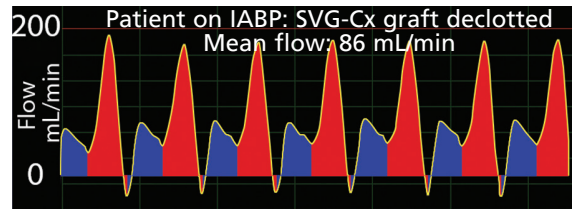
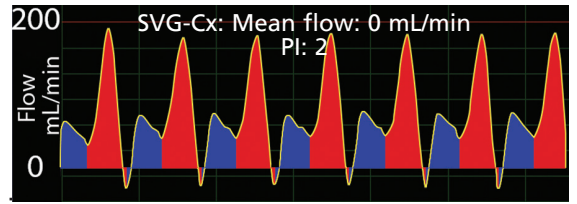


Case demonstrates that IABP support does not significantly influence flow.

An 81-year-old male patient underwent CABG surgery to bypass a blocked circumflex (Cx) coronary artery. A harvested saphenous vein graft (SVG) was used to connect the aorta to the Cx distal to the lesion (top waveform).

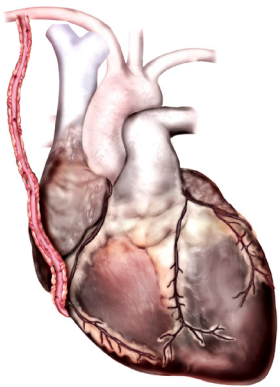
Following anastomosis of the SVG to the Cx, graft flow measured 0 mL/min, clearly indicating that there was a problem. Investigation revealed a clot in the graft. The patient was placed on IABP support. The graft was declotted and flow was remeasured with the patient still on IABP support. Flow measured 86 mL/min (middle waveform).

When the IABP support was removed, graft flow measured 76 mL/min (PI: 2) indicating that the presence of an IABP did not significantly affect graft flow (bottom waveform).



Three waveforms above show a progression from a clotted graft with zero mean flow (top waveform) to a declotted graft on IABP (mean flow, 86 mL/min) to the declotted graft with IABP removed (mean flow, 76 mL/min, bottom waveform).

RIMA-RCA Graft Flow Suppressed by Competitive RCA Flow



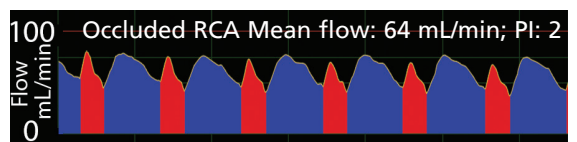
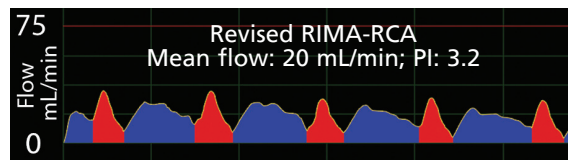
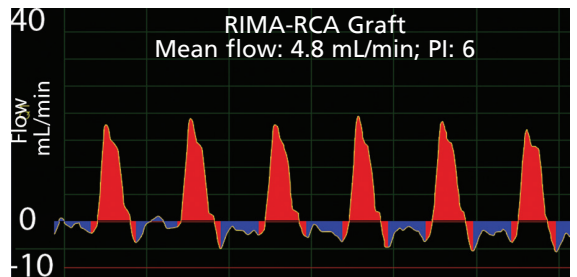
Case demonstrates that competitive flow from a native coronary can suppress graft flow.

A 60-year-old male underwent CABG to bypass a blockage in his right coronary artery (RCA) with a right internal mammary artery graft (RIMA).

Following the RIMA-RCA anastomosis distal to the blockage, flow measured 4.8 mL/min (PI: 6). Low mean flow, a high PI and a systolic dominant waveform profile indicated the need for graft revision.

After revision, flow improved to 20 mL/min (PI: 3.2), but this flow was not as high as the surgeon expected given the size of the patient. Suspecting the presence of competitive flow from the native RCA, the surgeon occluded the native RCA proximal to the anastomosis of the graft. Mean graft flow increased to 64 mL/min (PI: 2). Another graft was added, placed more distally on the RCA. Runoff improved, competitive flow decreased and graft flow was > 40 mL/min

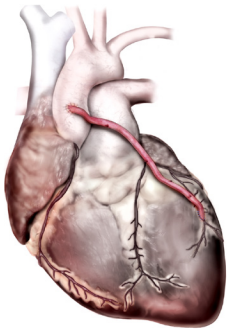
The significant increase in mean graft flow supported the surgeon's suspicion that competitive flow was suppressing graft flow.



The three waveforms show the systolic dominant profile of the RIMA-RCA graft before revision (top), the systolic/diastolic flow waveform profile following revision of the graft (middle), and the similar graft waveform with the proximal RCA occluded (bottom).

Flow-Based Patency Assurance

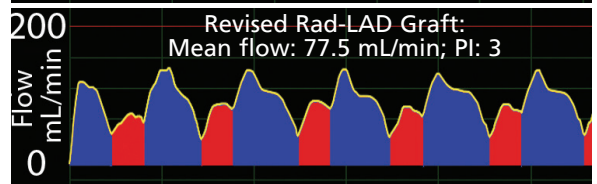
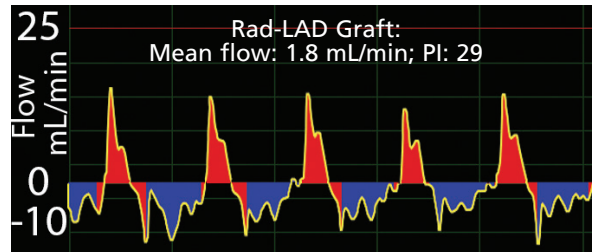
Poor Rad-LAD Graft Flow Triggers Graft Revision



Case demonstrates that poor flow signals need for graft revision.

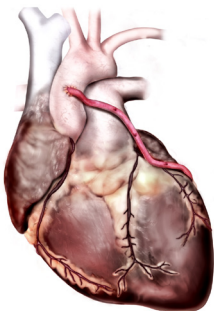
A 71-year-old male with single-vessel coronary artery disease underwent CABG surgery. A segment of the radial artery (Rad) was harvested and grafted proximally to the aorta and distally to the LAD. Initial Rad-LAD mean flow measured 1.8 mL/min (PI: 29) indicating that revision of the graft was warranted (top waveform).

After revision, graft flow improved to 77.5 mL/min (PI: 3). The flow was accompanied by a repetitive systolic/diastolic waveform profile (bottom waveform).



The top Rad-LAD waveform exhibits a spiky systolic profile and is coupled with an initial graft flow of 1.8 mL/min. Following revision of the graft, flow increased to 77.5 mL/min and was accompanied by a diastolic dominant waveform (bottom).

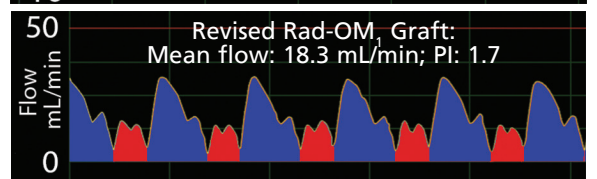
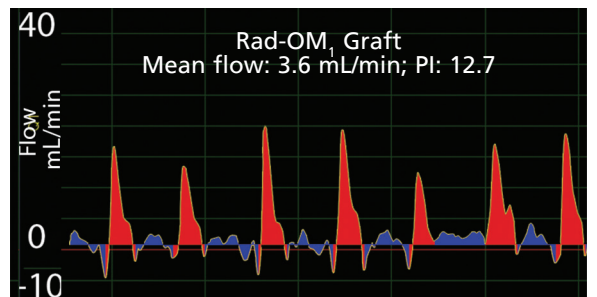
Low Mean Flow Spurs Rad-OM₁ Graft Revision



Case demonstrates that poor flow in one out of four grafts signals need for need for graft revision in that one graft.

A 48-year old male patient with multi-vessel coronary artery disease underwent quadruple CABG. Four grafts including a LIMA-LAD, SVG-OM, SVG-Dx and Rad-OM₁ were constructed to deliver flow to the distal myocardium. Mean flows in the LIMA-LAD, SVG-OM and SVG-Dx grafts were acceptable.

However, mean Rad-OM₁ graft flow measured 3.6 mL/min (PI: 12.7) signaling the need for revision of the graft. Following Rad-OM₁ graft revision, mean graft flow improved to 18.3 mL/min (PI, 1.7) and was accompanied by a systolic/diastolic waveform.



The top waveform with a spiky systolic profile shows initial Rad-OM₁ graft flow of 3.6 mL/min. Following revision of the graft, flow increased to 18.3 mL/min and was accompanied by a diastolic dominant waveform profile (bottom waveform).



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FAST - Flow-assisted Surgical Techniques during Coronary Artery Bypass Grafting

Why Measure Coronary Bypass Blood Flow?

During coronary artery bypass grafting (CABG) surgery, coronary Flowprobes may be used as a quantitative tool to measure blood flow through a bypass graft and to provide objective intraoperative flow information. This information may assist the surgeon in evaluating graft flow characteristics while the patient remains in the operating room.

Measuring CABG Blood Flow

The following techniques reflect reported user practices intended to support flow measurement consistency. Flow-assisted graft assessments are typically performed once the patient is off-pump.

- If using an internal mammary artery graft, skeletonize a 1.0cm segment of its distal end before performing the anastomosis. For flow measurement purposes, unlike IMA grafts, no additional local dissection/skeletonization is typically needed for saphenous vein grafts before placing the Flowprobe.
- Select a Flowprobe size such that the graft fills at least approximately 75% of the Flowprobe sensing window. Avoid selecting a probe that is unnecessarily small for the graft, as the vessel should fit comfortably within the sensing window to support proper placement and measurement performance.
- Inspect each flowprobe prior to use. Do not use in any of the following cases:
 - Sharp edges or burrs on the device
 - Cracks or chips on the Probe head, reflector, handle, or connector
 - Nicks in the Probe cable
 - Damage to the silicone seal (if integrity of the silicone is compromised).
 - Damage to the sterile packaging:
 - For reusable Flowprobes, return the Flowprobe to central processing to be cleaned and sterilized following the appropriate instructions for use in your country supplied with your Flowprobes
 - For single use Flowprobes discard Flowprobe after use.
- Prior to use verify Flowprobe connection and signal strength. Plug in the Flowprobe then immerse (couple) the Flowprobe in still, sterile saline or use sterile acoustic gel couplant in the probe's window to establish a zero-flow condition.
 - Once coupling is achieved, the Signal Strength Indicator icon will fill with the appropriate number of bars to indicate the quality of coupling. Confirm that signal strength is adequate ($\geq 15\%$). If the probe is properly coupled, a moderate signal strength does not have any impact on flow accuracy.
 - Confirm that the waveform in the meter's display window is stable, offset is within specification and no environmental interference is evident.
- Apply sterile ultrasonic couplant in the Flowprobe's sensing window and turn on FlowSound. A low-pitched hum generally indicates that the Flowprobe is properly connected and that adequate ultrasound couplant is present within the sensing window.
- Place the Flowprobe on the graft so that it is positioned perpendicular to the graft. Avoid stretching, compressing, or kinking the graft. Do not place the Flowprobe over surgical clips or sutures. The ultrasound's signal quality is indicated on the meter's display.
- Observe the contraction of the heart while listening to FlowSound. In CABG grafts, a lower pitch generally corresponds to lower-flow systolic phases and a higher pitch to higher-flow diastolic phases. Listen to the relative systolic and diastolic FlowSound characteristics to help assess graft flow balance.
 - FlowSound in Diastolic-dominant Left Heart Grafts: Because myocardial contraction can



Pictured, from left to right, are 1.5 mm, 2 mm, 3 mm and 4 mm Coronary Flowprobes showing their blue Probe bodies, J-style reflectors and ultrasonic sensing windows.

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FAST during CABG

reduce inflow during systole, grafts supplying the left heart often demonstrate a stronger diastolic flow component. This may be heard as a lower pitch during systole, and relatively greater diastolic flow, which may be heard as a higher pitch during diastole.

- FlowSound in Systolic/Diastolic Balanced Right Heart Grafts: Because the right side of the heart generally contracts less forcefully than the left heart, graft flow to a right heart coronary graft may be less impeded during systole and thus may demonstrate more balanced systolic and diastolic flow components. In these grafts, the FlowSound pitch during systole and diastole may be more similar and balanced.
8. The average (mean) flow will display on the Flowmeter screen or the front panel of the Flowmeter.
 9. Assess for competitive flow if graft flow appears lower than expected or when waveform findings are uncertain. Temporarily occlude the native coronary artery proximal to the anastomosis, in accordance with surgical judgment, and observe any changes in FlowSound, mean flow, or waveform pattern. An increase in mean flow, corresponding rise in FlowSound pitch, and a more favorable waveform profile during occlusion may be consistent with competitive native coronary flow. Competitive flow may also be associated with brief reversed or negative flow components. Measurements obtained with temporarily reduced competitive native flow may provide additional insight into graft flow capacity. However, waveform findings should be interpreted together with mean flow and overall clinical context.
 10. When flow waveform and mean flow have stabilized, press Snapshot, Print, or Export to the USB v2.0 Type A on the Flowmeter.

Mean Flow as a Primary Clinical Indicator

Transonic's FAST Assessment for CABG places primary emphasis on mean graft flow interpreted together with waveform characteristics and overall clinical context. Mean flow is generally the primary parameter used to support a surgeon's assessment of graft flow adequacy and to identify findings that may warrant further clinical evaluation.

Mean Flow assessment includes the following range guidance:

1. **Mean Flow \geq 25 mL/min** (small patients, >20 mL/min) is often consistent with favorable graft flow when interpreted in clinical context. If mean flow is lower than expected, first assess for the presence of competitive flow by temporarily occluding the native coronary artery proximal to the anastomosis to assess the graft flow's capacity.
2. **Mean Flow $<$ 5 mL/min** may indicate the need for evaluation of technical, physiologic, or graft-related factors

If competitive flow is reasonably excluded as a contributor to lower flow, consider that mean graft flow can vary over a wide range and should be interpreted with consideration of:

- patient size, weight, and overall condition;
- graft size and quality;
- target vessel size and quality;
- Mean Arterial Pressure (MAP);
- myocardial runoff and distal vascular bed condition.

FlowSound may provide supplemental information when evaluating lower flow. With the probe on the graft, activate FlowSound and listen for pitch changes as the graft or surrounding tissue is gently manipulated and assessed. Evaluate for potential kinks or twists in the graft, low MAP, or diminished pulsatility on the displayed waveform. If technical concerns remain after evaluation, further surgical assessment or revision may be considered.

FAST during CABG

Derived Parameters

1. If mean graft flow is lower than expected and competitive flow has already been assessed, the next step is assessment of the systolic/diastolic waveform characteristics. Waveforms should first be evaluated for a repetitive flow pattern generally expected for the ventricle supplied (left ventricle grafts are typically diastolic dominant; while right ventricle grafts typically display a more balanced systolic/diastolic distribution).
2. If the Flowmeter is connected to the patient's ECG for systolic-diastolic phase detection, D/S Ratio (or DF%) may be calculated to further characterize the flow waveform through the bypass graft. D/S Ratio compares diastolic flow to systolic flow. DF% compares diastolic flow to total flow. Either derived parameter can be selected in the Settings screen.
3. If ECG-based systolic-diastolic detection is unavailable, Pulsatility Index (PI) may be reviewed. If competitive flow is not present, analysis of diastolic/systolic waveform properties can shed light on a possible problem. Waveforms should be examined first to see if they exhibit a repetitive flow pattern characteristic for the ventricle it is supplying (left ventricle: diastolic dominant pattern; right ventricle: systolic/diastolic balanced waveform).

The derived parameters depend on the quality of the waveform and no flow-derived parameter is intended to be relied on as a sole diagnostic indicator. All flow-related assessments should be performed within the clinical context of the patient. If waveform appearance is unstable or inconsistent with expected physiology, refer to Appendix G of the FlowXL Operator's Manual before relying on derived parameters.

DIASTOLIC SYSTOLIC RATIO (D/S)

D/S ratio compares the diastolic flow to systolic flow. Expressed mathematically:

$$D/S \text{ Ratio} = \frac{\text{Total Diastolic Flow}}{\text{Total Systolic Flow}}$$

- D/S Ratio >2 is generally more consistent with a diastolic-dominant profile;
- D/S Ratio between 1 and 2 is generally more consistent with a balanced systolic/diastolic profile, often seen in right-heart grafts;
- D/S Ratio <1 may indicate a relatively systolic-

dominant profile and may warrant further evaluation.

DIASTOLIC FRACTION (DF%)

Diastolic Fraction compares diastolic flow to flow occurring during both systole and diastole as a percentage. Expressed mathematically:

$$DF\% = \frac{\text{Average Diastolic Flow}}{\text{Total (Diastolic + Systolic) Flow}} \times 100$$

- DF% greater than 50% is generally more consistent with a diastolic-dominant flow profile;
- DF% approximating 50% is generally more consistent with a balanced systolic/diastolic profile;
- DF% less than 50% is generally more consistent with a systolic-dominant flow profile.

NOTE: D/S Ratio and DF% are two methods of evaluating similar waveform characteristics.

In general:

- D/S of greater than 2 corresponds to DF% greater than 67%;
- D/S between 1 and 2 corresponds to DF% between 50% and 67%;
- D/S less than 1 corresponds to DF% less than 50%.

PULSATILITY INDEX (PI)

Pulsatility Index (PI) is a derived parameter that reflects the relationship between waveform amplitude and mean flow. Expressed mathematically:

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

While PI may provide useful supplemental information, it should not be used alone to determine graft patency or graft quality. In some clinical practices, a PI >5 has been used as a potential indicator of technical concern; however, **Transonic has long recommended that PI be used only as a supplementary parameter with an understanding of its limitations.**

Publications such as Jelenc M, et al. in Understanding Coronary Artery Bypass Transit-Time Flow Curves: Role of Bypass Graft Compliance, have noted important limitations of PI when used in isolation. These authors

FAST during CABG

reported that PI may be significantly influenced by factors such as graft compliance, measurement location, pulse pressure, and mean flow, which may reduce specificity when used for graft patency assessment.

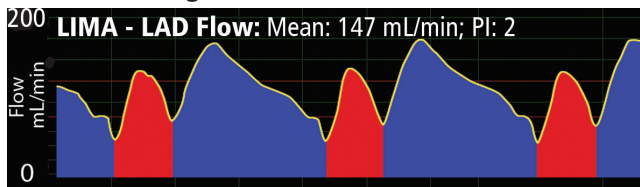
PI can also be influenced by factors other than graft obstruction, including competitive native coronary flow, heart rate, arterial pressure, distal coronary runoff quality, downstream vascular resistance, and other hemodynamic conditions. As a result, an elevated PI may occur in a technically satisfactory graft, while an unfavorable graft condition may at times present with a PI within commonly accepted ranges.

Published literature has also reported that mean flow and diastolic flow metrics (such as D/S Ratio) may provide greater sensitivity than PI alone for indicating certain graft abnormalities, particularly less severe or subcritical stenoses.

For these reasons, PI is best interpreted together with mean flow, waveform appearance, D/S Ratio or DF% (when available), and the overall clinical context. Mean flow and direct waveform assessment should remain the primary considerations.

In general clinical use:

- PI >5 has been associated with certain low-flow, restrictive, or competitive flow conditions and may warrant further clinical assessment.
- PI between 1 and 5 may be acceptable when interpreted together with mean flow, waveform appearance, and other clinical findings.



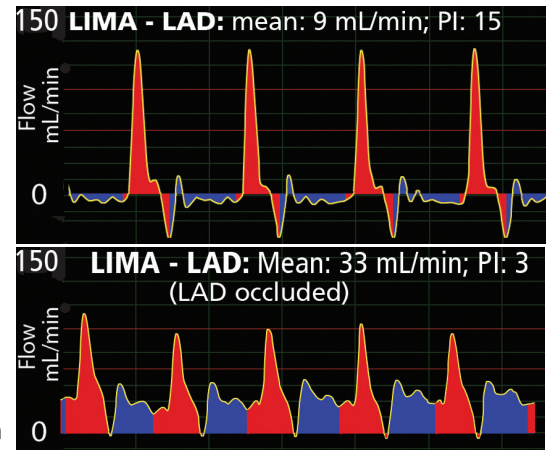
Diastolic Dominant Pattern (Left-Heart Grafts)

For grafts to the left ventricle, the shorter waveform peak is often systolic and the broader higher peak is often diastolic, except in conditions such as marked tachycardia where diastole may be shortened. A typical left-heart graft waveform is diastolic dominant, where delivered diastolic blood volume exceeds systolic blood volume.



Balanced Systolic Diastolic Pattern (Right-Heart Grafts)

In grafts to the right ventricle, flow may be more evenly distributed between systolic and diastolic phases. This may produce a waveform in which the systolic peak is prominent and is followed by a proportionally strong diastolic component.



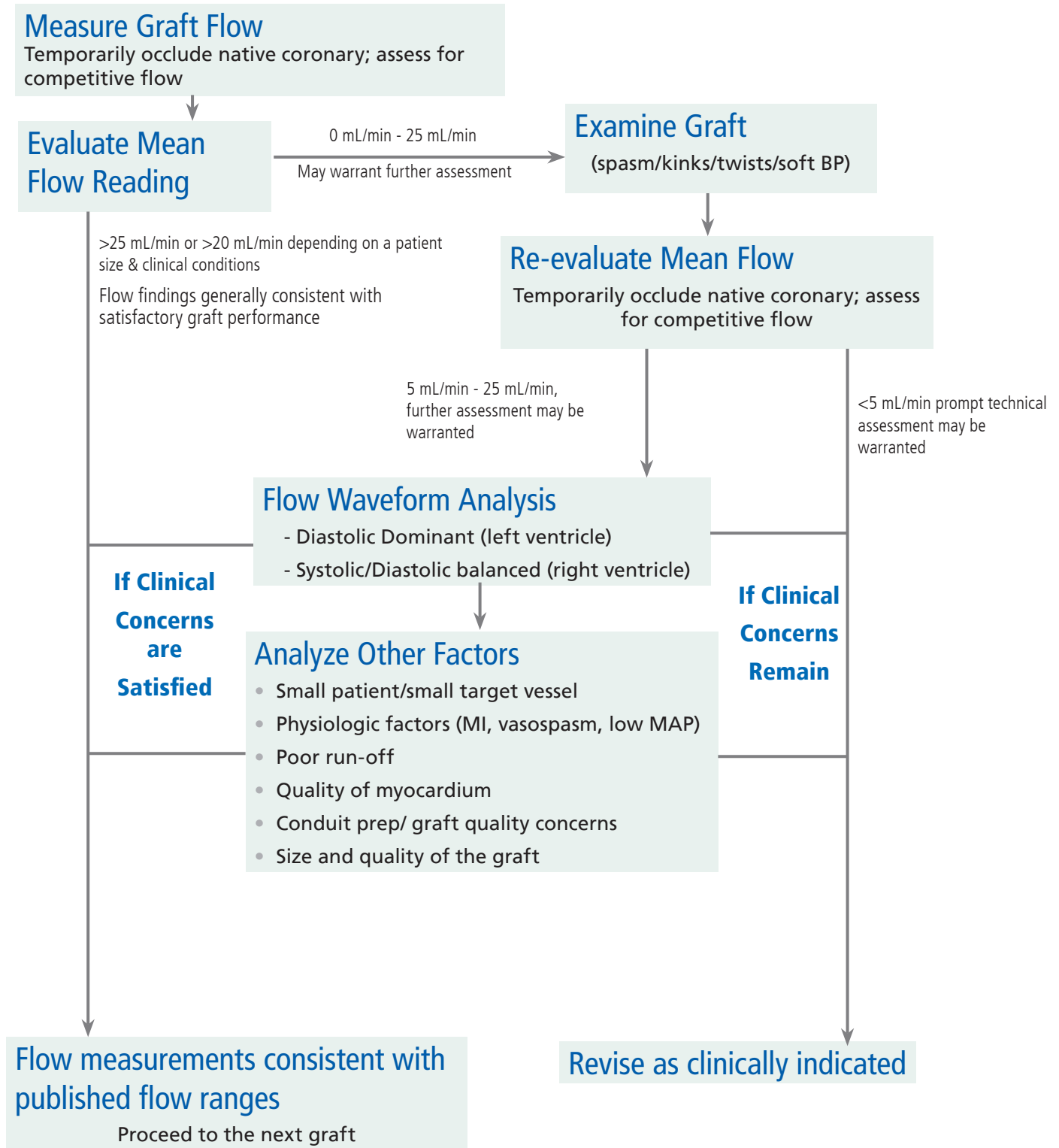
Competitive Flow in LIMA-LAD Graft

Flow increased from 9 mL/min to 33 mL/min when the LAD was temporarily occluded. The presence of competitive flow (top waveform) was associated with a spiky systolic profile and PI of 15. When the LAD was occluded (bottom waveform), the waveform shifted toward a more diastolic-dominant profile with PI of 3.

References:

- 1 Mindich BP *et al*, "Reduction of Technical Graft Problems Utilizing Ultrasonic Flow Measurements," NY Thoracic Society, 2001.
- 2 Di Giammarco G, Rabozzi R, "Can transit-time flow measurement improve graft patency and clinical outcome in patients undergoing coronary artery bypass grafting?" *Interact Cardiovasc Thorac Surg*. 2010 Nov; 11(5): 635-40.
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FAST during CABG



Signature Transit-time Ultrasound CABG References

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Signature Transit-time Ultrasound CABG References cont.

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Validations

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