

Flow-Assisted Surgical Technique F•A•S•T during Cardiac Surgery



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Intraoperative Graft Patency Assessment during Coronary Artery Bypass Grafting (CABG) Surgery

"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 complications related to early technically induced graft failure. In an era of rapidly changing surgical techniques this provides documentation of the sine-quo-non of the operation: patency."

Bruce Mindich, MD

Introduction

The first Transit-time Ultrasound Flowmeter was cleared to market for human clinical use in 1988. Shortly thereafter, a series of handle probes were developed so that surgeons could easily slip a probe around a vessel or graft and get a quick, on-the-spot measurement. Dr. Eugene Grossi demonstrated this intraoperative measurement technique in a 1992 video of coronary artery bypass grafting (CABG) surgery filmed at NYU. Dr. Charles Canver and Norman Dame at New Hampshire's Dartmouth University then published a landmark validation study showing that transit-time technology could accurately measure internal thoracic artery (ITA) flow, which earlier electromagnetic flowmeters had not been able to do.

Off-pump CABG Wave Drives Acceptance

During the mid 1990s, the interest in OPCAB (Off Pump Coronary Artery Bypass Grafting) and MIDCAB (Minimally Invasive Coronary Artery Bypass Grafting), pioneered by Transonic collaborator Dr. James Fonger, sparked market acceptance of measurements of coronary bypass grafts as a quick intraoperative assessment tool. In response to customer feedback, a curved long-handle Coronary Flowprobe (shown below) was developed which allows a surgeon to more easily reach the bypass grafts at the back of the heart.

"What do these flows mean?"

Surgeons asked questions. "What is a 'good' flow?" Or "What does a certain flow mean?" In 2001, Dr. Mindich from Valley Hospital in Ridgewood, NJ, culled through hundreds of his CABG cases and gave Transonic 90 representative cases to analyze. From this treasure trove of raw data the *Flow-based Intraoperative Coronary Graft Patency Assessment* handbook was generated and published in 2002. It became a "Bible" for many surgeons worldwide, and has been translated into Chinese and Japanese. It also outlined clear "Rules of Thumb" for determining the patency of the graft. Look at mean flow first. If flow is five milliliters per minute or under, there is a problem with the graft. If flow is between five and twenty to thirty milliliters per minute, examine the flow waveform. Check Pulsatility Index (PI) and Diastolic to Systolic Ratio last to corroborate other indicators, because one can get a false positive by relying on PI alone. Transonic's Rules of Thumb for intraoperative flow assessment during CABG surgery have stood the test of time. With the release of the AureFlo® system with its digital waveform display, they remain as valuable and important as ever in determining the patency of a coronary artery bypass graft (see following pages for CABG Protocol).



FMC-Series Coronary Handle Flowprobes are available in sizes 1.5 mm to 4 mm. They feature a J-style reflector, designed for spot flow checks of coronary artery bypass grafts and an extended neck with a flexible end to reach coronary grafts even behind the heart.

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.

Flow Protocol: CABG Surgery

Intraoperative Graft Patency Assessment during CABG Surgery

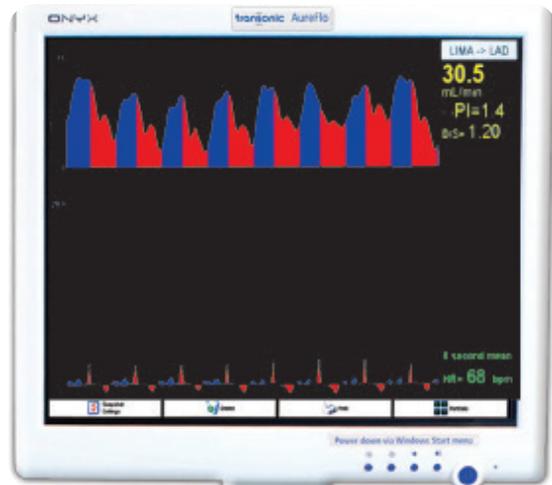
Mean Flow Assessment Is Primary

Transonic's CABG Flow Assessment Protocol is based, first and foremost, on mean graft flow. It is the primary consideration to confirm graft patency or to alert the surgeon to an undesirable condition.

Mean Flow Assessment Rules of Thumb are:

1. Mean Flow ≥ 30 mL/min (small patients, >20 mL/min) = Patent Graft: If mean flow is less than expected, first consider the presence of competitive flow.
2. Mean Flow < 5 mL/min = Graft in Trouble
3. Medium Range Mean Flows (5 mL/min - 30 (20 mL/min): Analyze Graft Flow Waveforms, D/S Ratio or DF% and PI.

(Detailed protocol steps follow.)



AureFlo® single-channel display of recorded LIMA-LAD volume flow waveform (systolic flow volume in red; diastolic in blue). Also displayed are mean flow in mL/min, pulsatility index (PI), D/S Ratio and ECG tracing.

Measuring Graft Flow

Accurate measurements are technique dependent (see sidebar on last page)

- Select a Flowprobe sized so that the graft will fill at least 75% of the window of the Probe without compressing the graft.
- Fill Probe window with ultrasound gel.
- Position Probe on graft (not over metal clips or fascia).
- Occlude native coronary artery in order to assess graft at maximum graft flow.
- On AureFlo®, take snapshot or record when flow reading is stable (10-15 seconds).
- On Optima Flowmeter, press Print when flow reading is stable (10-15 seconds).

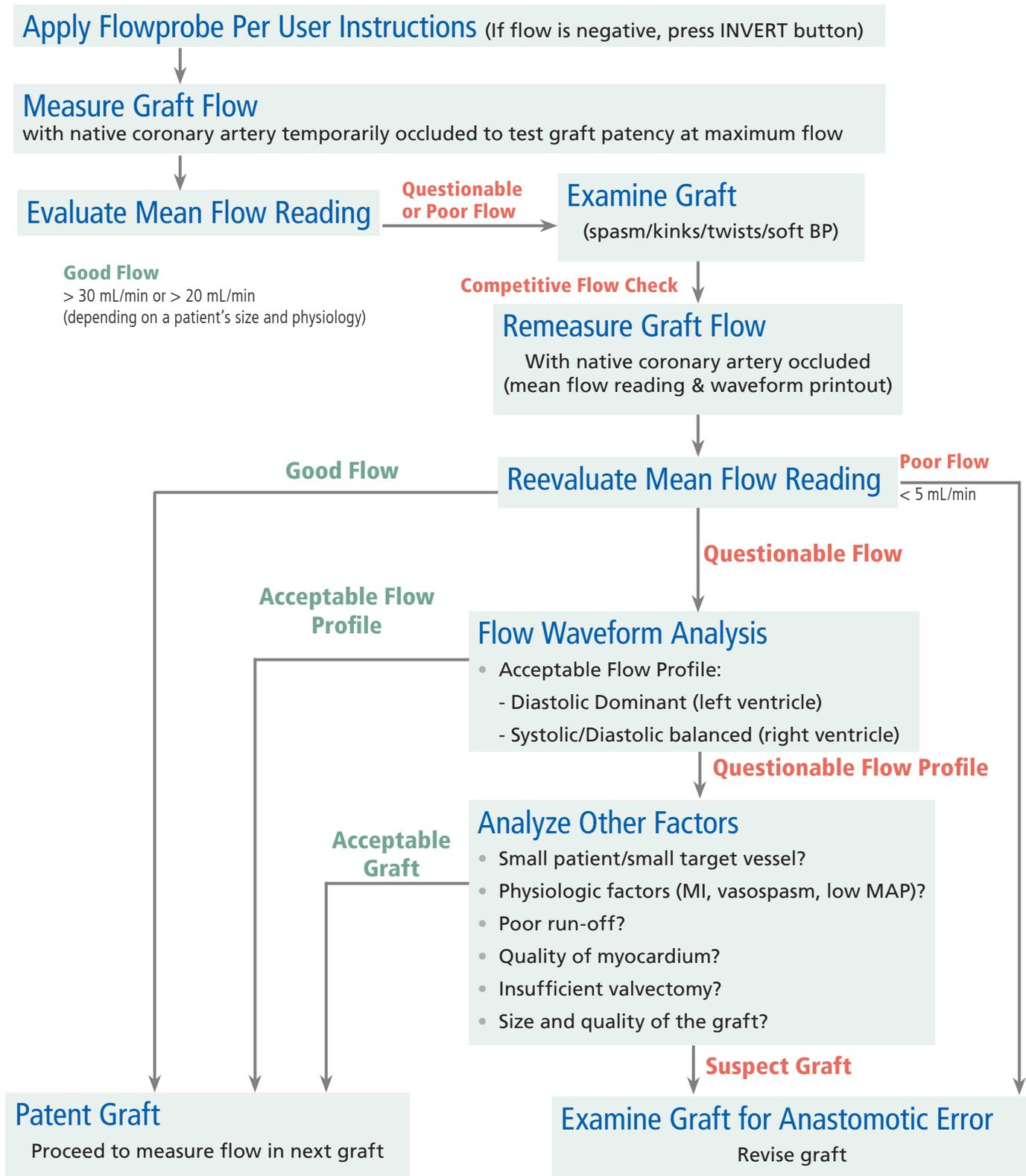
When Does Mean Flow Confirm Graft Patency?

Flows greater than 20 mL/min for a small patient and 30 mL/min for a normal sized patient indicate a good graft. However, mean graft flow can vary over a wide range. It is influenced by, and should be evaluated with respect to:

- The size and quality of the graft;
- The size and quality of the target vessel;
- Mean arterial pressure (MAP);
- State of disease in the myocardial run-off.

If mean flow is lower than expected, the presence of competitive flow must be considered first.

Protocol: CABG Graft Patency Assessment cont.



This protocol and evaluation is intended only to assist in surgical decision-making and is not a diagnostic device. Surgical interpretation is required.

Protocol: CABG Graft Patency Assessment cont.

When Do Mean Flows Not Confirm Graft Patency?

Flows below 5 mL/min indicate a problem graft that demands further investigation. When flows are questionable (between 5 mL/min and 20 mL/min to 30 mL/min depending on a patient's size, examine waveforms).

1. Flows < 5 mL/min, Suspect Graft Patency

- With Probe on the graft, turn on FlowSound® and listen for the change in pitch (flow) as the vessel around the anastomosis is manipulated.
- Look for kinks/twists in the graft, low MAP, flow with diminished pulsatility (dampened waveform).
- Redo anastomosis if technical error is indicated.

2. Questionable Flows: Analyze Waveforms

If flow values fall in the medium range (more than 5 mL/min but less than 20-30 mL/min), flow waveform analysis of systolic/diastolic waveform properties can shed light on a possible problem. Waveforms should be first examined 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).

When Mean Flow Is Inadequate Consider

Other Factors: PI, D/S (or DF%)

D/S Ratio and DF%

Transonic Surgical Flowmeters can use ECG or pressure signals to analyze and display D/S Ratio (or DF%) to represent the amount of blood flow passing through a bypass graft. A D/S Ratio (or DF%) compares diastolic flow to systolic flow

- D/S Ratio >2 (or DF%, 67%): acceptable diastolic-dominant profile;
- D/S Ratio between 1 and 2 (or DF between 50% and 67%): indicates a diastolic-systolic balanced profile (acceptable for a right heart bypass).
- D/S Ratio <1 (or DF%, <50%): a systolic dominant flow profile which signals the need for further examination of the graft.

Is Pulsatility Index (PI) between 1 & 5?

A PI greater than 5 has been associated with low mean flow and systolic-dominant flow pattern indicating that the graft should be reexamined.

Diastolic-Dominant Pattern (L-Heart Grafts)

For grafts to the left ventricle, the shorter waveform peak is usually systolic, and the higher, broader peak is diastolic (Fig. 1) except in the presence of severe tachycardia where diastole is shortened. An acceptable left ventricular waveform is "diastolic dominant" where the delivered diastolic blood volume (i.e., area under diastolic curve) exceeds delivered systolic blood volume.



Fig. 1: LIMA-LAD: mean = 147 mL/min; diastolic dominant; PI=2.

Balanced Systolic/Diastolic Pattern (R-Heart Grafts)

In grafts to the right ventricle, flow is more equally distributed between the systolic and diastolic phases. This produces a flow waveform where the systolic peak may dominate but is followed by a proportionally strong diastolic flow producing a systolic/diastolic balanced waveform (Fig. 2).

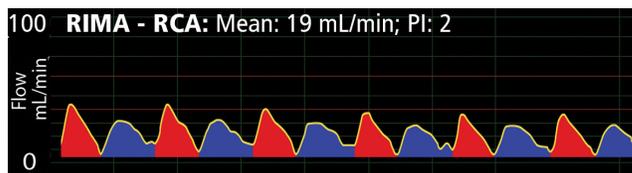


Fig. 2: RIMA - RCA: mean is 19 mL/min. systolic/diastolic balanced; PI=2

Stenotic Pattern

In stenotic grafts, the systolic phase dominates the flow profile and is associated with low or zero mean flow. Often, systolic charge flow runs backwards as a negative flow during diastole.



Fig. 3: The RIMA - RCA graft illustrates a graft with a stenotic flow profile. The flow waveform dips below zero which indicates the presence of competitive flow.

Protocol: CABG Graft Patency Assessment cont.

Technique Is Critical

Measurement results are technique dependent.

The following step-by-step procedure ensures accurate, reliable measurements.

1. If using an internal mammary artery graft, skeletonize a 1.5 cm segment of its distal end before performing the anastomosis. Vein grafts require no additional preparation.
2. Select a Flowprobe sized so that the graft will fill at least 75% of the window of the Flowprobe. Take care not to undersize the probe for the graft.
4. Apply ultrasound couplant (Aquasonic 100, Surgi-Lube or similar) into the window of the Flowprobe.
5. Turn on FlowSound®. A low-pitch zero flow sound (“hum”) indicates that the Probe is properly connected to the Flowmeter, and that there is adequate ultrasound signal coupling for a measurement.
6. Place the Flowprobe on the graft, bending its flexible neck as needed for perpendicular placement. 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 AureFlo® Monitor or the Flowmeter’s front panel display.
7. Observe the contraction of the heart while listening to FlowSound. Listen for a strong diastolic flow component.
8. Note, after 10 seconds, the average (mean) flow is displayed on the AureFlo screen or the front panel of the Flowmeter.
9. Occlude the native coronary artery and note any changes in the pitch and pattern of FlowSound. An increase in FlowSound pitch (i.e. mean flow) indicates the presence of competitive flow. If no competitive flow is observed, the occlusion may be released.
10. When flow has stabilized in 10 to 15 seconds, press PRINT on the Flowmeter to record the next 10 seconds of flow, or tap SNAPSHOT or RECORD on AureFlo to document the previous 8 seconds of flow. Hold the probe steady on the graft until the printer stops.

Case Report

Courtesy of Bruce Mindich, MD

Reversed Bypass Flow during Systole, Detected by Intraoperative Transit-time Flow Measurements, Leads to Discovery of Left Subclavian Artery Occlusion

Extracted from: Jelenc M, Knezevic I, Stankovic M, Gersak B, *Interact Cardiovasc Thorac Surg.* 2012 Oct;15(4):772-3; Dept. of Cardiovascular Surgery, Univ. Medical Centre Ljubljana, Ljubljana, Slovenia. jelenc@gmail.com

PRESENTATION

- A 62-year-old male patient with a history of hypertension and hypercholesterolemia was experiencing worsening chest pain.
- Preoperative angiography showed left coronary artery dominance and narrowing in the left main coronary (LCA) and left anterior descending (LAD) arteries.
- His right coronary artery (RCA) showed an 80% stenosis.
- Echocardiography indicated a normal ejection fraction and no valvular pathology.
- His right carotid artery had been stented.

PERI-OPERATIVE

1. Off-pump coronary artery revascularization was performed.
 - The left internal thoracic artery (LITA) was anastomosed to the left anterior descending artery (LIMA-LAD);
 - Saphenous vein grafts were anastomosed to the intermediate artery and the first and second obtuse marginals, respectively from the right internal thoracic artery (RITA) because the aorta was found to be heavily calcified.
2. During construction of the distal anastomoses to the obtuse marginals, radial arterial pressure suddenly dropped to 39/25 (31) mmHg.
3. The left hand turned pale and was pulseless.
4. A femoral artery catheter was placed for pressure monitoring and comparison with radial arterial pressure. Left femoral artery pressure was 110/35 (52 mmHg)
5. The anastomoses to the obtuse marginals were completed as planned.
6. Intraoperative transit-time graft flow measurement showed reversal of LITA flow during systole and lower than expected flow during diastole.
7. The surgery was completed and the patient was closed.

POST-OP

- There were no signs of myocardial ischemia, but the left hand was cold and pulseless.
- On the third day postop, an angiogram showed a subtotal stenosis of the proximal left subclavian artery.
- The proximal left subclavian artery was dilated and stented with two Protégé stents
- The further postoperative course was uneventful and the patient was discharged on the 12th postoperative day.

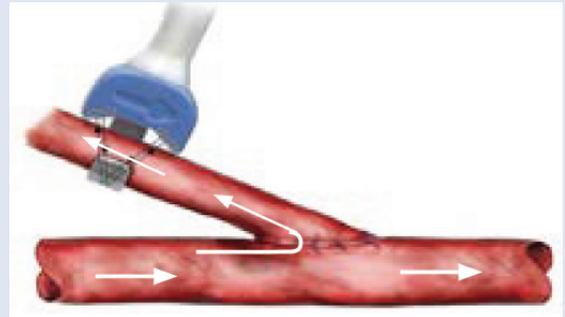


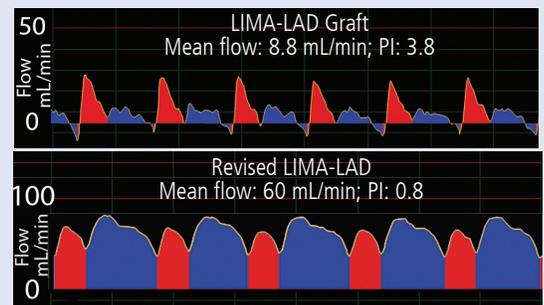
Fig. 1: A subclavian blockage reduced mammary arterial pressure to the extent that flow did not move forward down the graft during systole, but was flowing backward through the graft as shown in the diagram. The Flowmeter detected the backward movement by registering negative flow. During diastole, there was lower than expected forward flow.

Case Reports

Courtesy of Bruce Mindich, MD

LIMA-LAD Case Demonstrates that a PI <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).

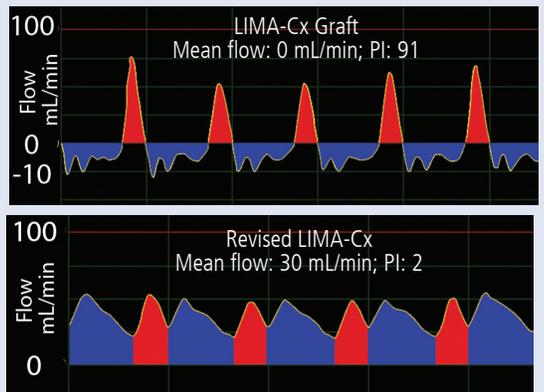


The top LIMA-LAD graft waveform with a spiky systolic profile shows an initial graft flow of 8.8 mL/min (PI: 3.8). Following revision of the graft, flow increased to 60 mL/min (PI: 0.8) and was accompanied by a diastolic dominant waveform profile (bottom waveform).

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.

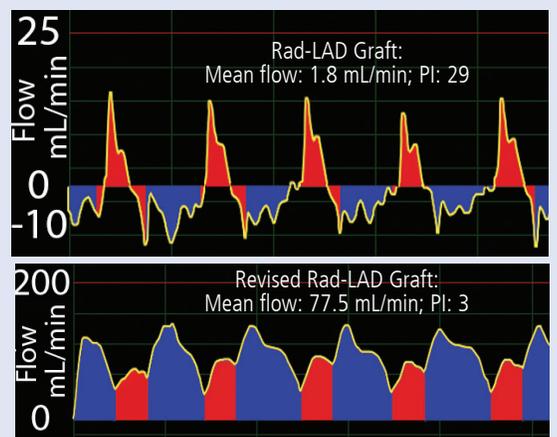


The top waveform exhibited a spiky systolic profile, which, accompanied by zero mean flow, called for the surgeon to revise the LIMA-Cx graft without hesitation. Flow improved to 30 mL/min after revision and the waveform exhibited a balanced systolic-diastolic profile (bottom waveform).

Poor Rad-LAD Graft Flow Triggers 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 waveform exhibits a spiky systolic profile, which, accompanied by 1.8 mL/min mean flow and PI of 29, caused the surgeon to revise the Rad-LAD graft. After revision, flow was 77.5 mL/min and the waveform exhibited a classic 1/3 systolic, 2/3 diastolic profile. The PI was 3.

Case Reports

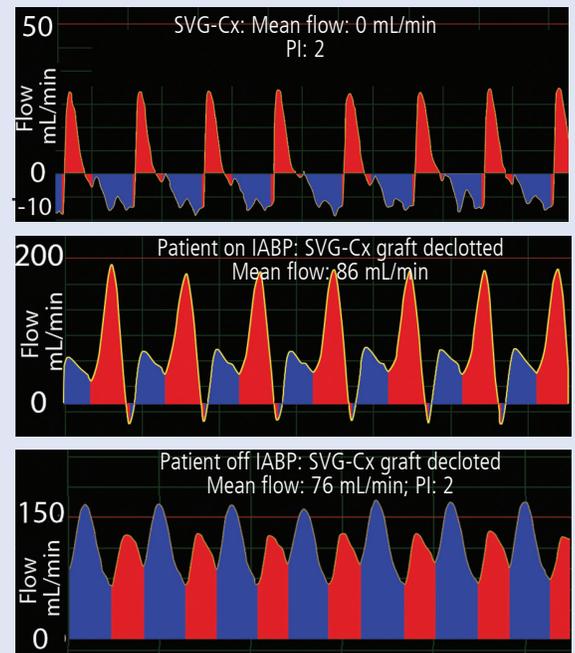
Courtesy of Bruce Mindich, MD

Zero Flow in SVG-Cx Graft Reveals Clot

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).

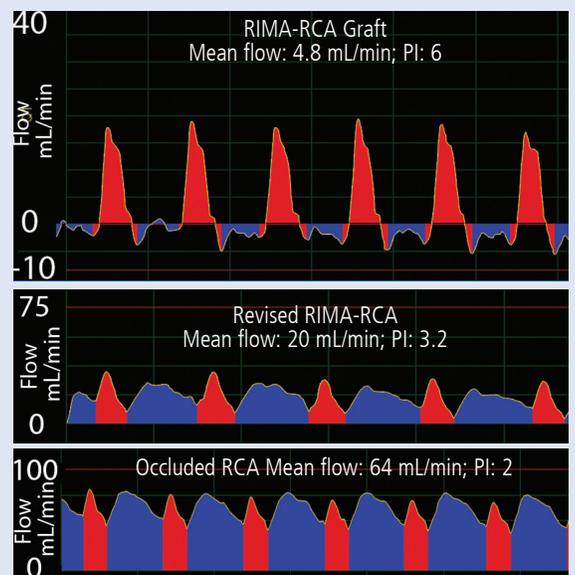
RIMA-RCA Graft Flow Suppressed by Competitive RCA Flow

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 waveforms show a systolic dominant RIMA-RCA graft profile 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).

Annotated CABG References

- 1 Di Giammarco A, Rabozzi R, "Best Evidence – Coronary: 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. (Transonic Reference # CV-9685AH). *Ten CABG publications out of 102 publications identified, were analyzed with regards to three major topics: intraoperative graft verification with the aim of improving immediate graft patency; predictive power of early- and mid-term graft patency, and clinical outcome. The studies demonstrated the usefulness of intraoperative TTFM as a method to improve intraoperative graft patency. TTFM is a reliable method to verify intraoperative graft patency.*
- 2 Canver CC, Dame N, "Ultrasonic Assessment of Internal Thoracic Artery Graft Flow in the Revascularized Heart *Ann Thorac Surg* 1994; 58: 135-8. (Transonic reference # 51V) *"We investigated the clinical applicability of the transit-time ultrasound technique for quantitation of internal thoracic artery (ITA) graft flow in coronary artery bypass grafting... We conclude that ITA graft flow can be quantitated intraoperatively by the transit-time ultrasound technique. Ultrasonic assessment of ITA graft flow in the revascularized heart may be a useful means of detecting immediate coronary graft failure caused by technical errors."*
- 3 Kim KB Kang CH, Lim C, "Prediction of graft flow impairment by intraoperative transit time flow measurement in off-pump coronary artery bypass using arterial grafts," *Ann Thorac Surg.* 2005; 80(2): 594-8. (Transonic Reference # 6918AHM) *Five variables (flow pattern, mean flow, pulsatility index, insufficiency ratio, and fast Fourier transformation ratio) were measured and compared between 103 normal and 14 abnormal (occluded or competitive) grafts in 58 patients who underwent total arterial off-pump coronary artery bypass. "Our data suggest that TTFM is a reliable intraoperative tool to predict graft flow impairment."*
- 4 Leong DK, Ashok V, Nishkantha A, Shan YH, Sim EK, "Transit-time flow measurement is essential in coronary artery bypass grafting, *Ann Thorac Surg.* 2005; 79(3): 854-7. *"Transit-time flow measurement enables technical problems to be diagnosed accurately, allowing prompt revision of grafts. It should be mandatory in coronary artery bypass grafting to improve surgical outcomes."*
- 5 Bauer SF, Bauer K, Ennker IC, Rosendahl U, Ennker J, "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. (Transonic Reference # 6997AH) *"Routinely the use of TTFD significantly reduced the incidence of postoperative VF, postoperative CK/CK-MB fraction, and angiographically detected bypass malfunction. A simultaneously implemented algorithm reduced the mortality with VF after CABG. The consequent use of TTFD intraoperatively reduced the incidence of postoperative anastomosis and technically related complications of bypass surgery and led to a significant reduction of postoperative mortality in CABG procedures."*
- 6 Tokuda Y, Song MH, Oshima H, Usui A, Ueda Y, "Predicting midterm coronary artery bypass graft failure by intraoperative transit time flow measurement," *Ann Thorac Surg.* 2008; 86(2): 532-6. (Transonic Reference # 7673AHM) *"Transit time flow measurement provides a good prognostic index, not only for the immediate term but also for the midterm follow-up. A graft with intraoperative lower mean flow, and especially with a higher percentage of backward flow, should be carefully monitored, even if it was initially anatomically patent."*
- 7 Becit N, Erkut B, Ceviz M, Unlu Y, Colak A, Kocak H, "The impact of intraoperative transit time flow measurement on the results of on-pump coronary surgery," *Eur J Cardiothorac Surg.* 2007; 32(2): 313-8. (Transonic Reference # 7577AHM) *"We believe that TTFM seems to be a crucial tool for deciding if a graft is well-functioning or not, and it allows for improvement of graft failure during an operation. Our results suggest that detection of graft dysfunction intraoperatively by TTFM improves the surgical outcome."*
- 8 Herman CR, Sullivan JA, Buth KJ, Legare JF, "Intraoperative graft flow measurements during coronary artery bypass surgery predict in-hospital outcomes," *Interact Cardiovasc Thorac Surg* 2008; 8. (Transonic Reference # 7626AHM) *"Our findings suggest that abnormal flows measured intraoperatively are independently associated with short-term in-hospital adverse outcome."*
- 9 Onorati F, Olivito S, Mastroroberto P, di Virgilio A, Esposito A, Perrotti A, Renzulli A, "Perioperative patency of coronary artery bypass grafting is not influenced by off-pump technique," *Ann Thorac Surg.* 2005 Dec;80(6):2132-40. (Transonic Reference # 7205AH) *"Off-pump coronary artery bypass grafting and cardiopulmonary bypass coronary artery bypass grafting demonstrated similar clinical, biochemical, and transit-time flowmetric results, as well as comparable graft flow reserve. These data exclude a lower anastomotic quality in off-pump coronary artery bypass grafting."*
- 10 Beldi, G. Bosshard A, Hess OM, Athaus U, Walpoth BH, "Transit time flow measurement: experimental validation and comparison of three different systems," *Ann Thorac Surg* 2000; 70(1): 212-217. (Transonic Reference # 1705AH) *"Transit time flow measurements are exact and reproducible. Second-order correction yields good accuracy and high precision, with minimal differences among the three systems evaluated."*
- 10 Windecker S, Kolh P, Alfonso F, Collet JP, Cremer J, Falk V, Filippatos G, Hamm C, Head SJ, Juni P, Kappetein AP, Kastrati A, Knuuti J, Landmesser U, Laufer G, Neumann FJ, Richter DJ, Schauerte P, Sousa Uva M, Stefanini GG, Taggart DP, Torracca L, Valgimigli M, Wijns W, Witkowski "2014 ESC/EACTS Guidelines on myocardial revascularization" *Eur Heart J.* 2014; 35(37): 2541-61. (Transonic Reference # 8114AHR) *"Graft flow measurement may be useful in confirming or excluding a technical graft problem indicated by haemodynamic instability or inability to wean the patient from cardiopulmonary bypass, new regional wall motion abnormalities on transoesophageal echocardiography, or ventricular arrhythmias. It has also been shown to reduce the rate of adverse events and graft failure, although interpretation can be challenging in sequential grafts and T-grafts."*

Flow-assisted Graft Patency Assessment during Robotic CABG Surgery

Introduction

With the introduction of the da Vinci robot surgical system, some cardiac surgeons have turned to more minimally invasive heart surgery or robotically-assisted coronary artery bypass (CABG) surgery so that the chest does not need to be opened through a large chest incision in the traditional manner (sternotomy). Rather, the procedure to correct problems with one or more of the coronary arteries is performed partially or totally endoscopically.

Robotically-Assisted CABG

Traditional, open-chest bypass surgery requires an 8-inch incision through the sternum. The surgeon spreads the sternum to view the heart and then sews the bypass graft to the coronary arteries under direct vision. The incisions used in robotically-assisted CABG surgery are even smaller than those used in traditional minimally invasive surgery. There are three ways the robot can be used to perform bypass surgery:

Totally Endoscopic Coronary Artery Bypass (TECAB)

With this surgery, the surgeon does not need to open the chest. Instead, the procedure is done completely endoscopically. The surgeon makes four or five tiny incisions (port holes). The incisions are used to insert the camera and instruments, and to stabilize the heart. There is also an assistant port. The internal mammary artery (IMA), which runs along the chest wall, is the blood vessel used for the bypass. It is robotically connected to the coronary artery distal to the blockage.

Robot-assisted Minimally Invasive Direct Coronary Artery Bypass (MIDCAB) Surgery

In this surgery, the robot is used to “take down” the internal mammary artery to be used for the

bypass. The surgeon then sews the bypass graft to the recipient coronary artery through small incision between the ribs on the left chest. (See case report from Dr. Francis Sutter on page 19.)

Hybrid Procedure:

Robotic TECAB, robotically-assisted MIDCAB and non-robotic MIDCAB can also be combined with coronary artery stenting to create a hybrid coronary artery bypass grafting procedure. After publication of the 2004 study cited on the next page, Philadelphia’s Lankenau Hospital’s heart team decided to embrace the minimally invasive approach and to explore use of the da Vinci Robot to harvest the internal mammary artery for use as a bypass graft. The most experienced surgeon using this approach is Lankenau’s Dr. Francis Sutter who has performed well over 1,000 cases in this manner. He continues to use a combination of robotic surgery to harvest the LIMA. Part of his operative routine is to measure bypass flow with a Transonic Flowprobe after he has sewn the bypass graft to the coronary artery in order to ensure its patency before he closes the patient (see case study on page 19).

Port Access Flowprobes

Robotic surgery requires longer instruments, including a thoracoscope (long thin tube) which has a light and tiny camera at the end. Images from the camera are sent to a video monitor to guide doctors as they operate. Transonic has developed a long handle, Port Access Flowprobe for laparoscopic use as well as for use with the da Vinci system. The Port Access Flowprobe, available in 2, 3 and 4 mm sizes is now being refined to enable injection of couplant into the sensing window along the side of the Flowprobe.

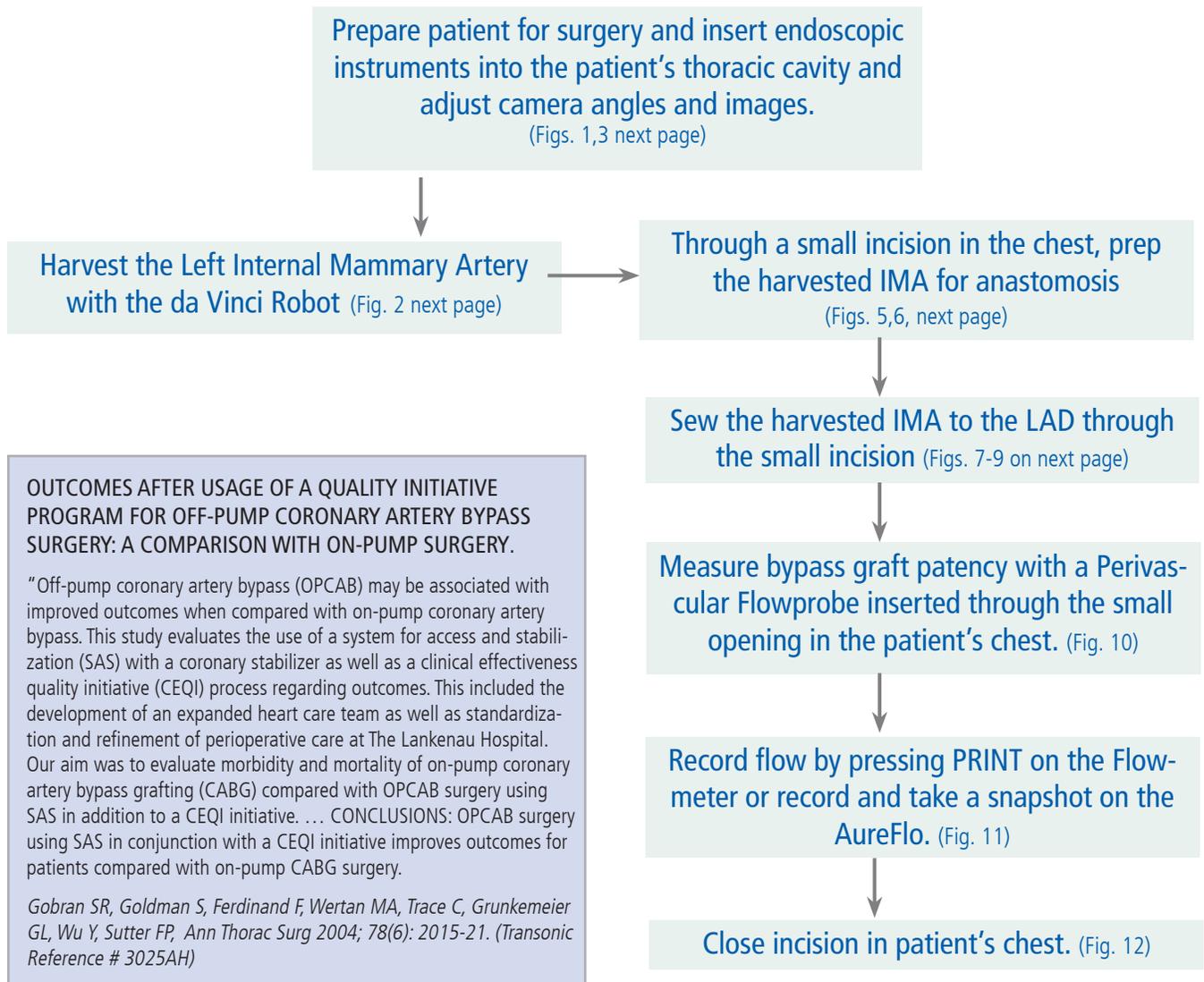


A Port Access Flowprobe features the Flowprobe’s blue body with J-style reflector, ultrasonic sensing windows, malleable probe neck and long stainless steel handle.

Flow Protocol

Flow-assisted Graft Patency Assessment during Robotic CABG Surgery

Coronary Artery Bypass Grafting with Robotic IMA Harvest



OUTCOMES AFTER USAGE OF A QUALITY INITIATIVE PROGRAM FOR OFF-PUMP CORONARY ARTERY BYPASS SURGERY: A COMPARISON WITH ON-PUMP SURGERY.

"Off-pump coronary artery bypass (OPCAB) may be associated with improved outcomes when compared with on-pump coronary artery bypass. This study evaluates the use of a system for access and stabilization (SAS) with a coronary stabilizer as well as a clinical effectiveness quality initiative (CEQI) process regarding outcomes. This included the development of an expanded heart care team as well as standardization and refinement of perioperative care at The Lankenau Hospital. Our aim was to evaluate morbidity and mortality of on-pump coronary artery bypass grafting (CABG) compared with OPCAB surgery using SAS in addition to a CEQI initiative. ... CONCLUSIONS: OPCAB surgery using SAS in conjunction with a CEQI initiative improves outcomes for patients compared with on-pump CABG surgery.

Gobran SR, Goldman S, Ferdinand F, Wertan MA, Trace C, Grunkemeier GL, Wu Y, Sutter FP, Ann Thorac Surg 2004; 78(6): 2015-21. (Transonic Reference # 3025AH)

Intraoperative Graft Patency Assessment during Robotic IMA Harvesting CABG Surgery

Photo Case Study: Courtesy of Francis Sutter O.D., Chief, Department of Cardiothoracic Surgery, Lankenau Hospital, Philadelphia, PA



Fig. 1: Endoscopic instruments inserted in ports in patient's thoracic cavity.



Fig. 2: Dr. Francis Sutter at a da Vinci console harvesting the Internal Mammary Artery (IMA) robotically.



Fig. 3: Assistant at operating table adjusting endoscopic video camera.



Fig. 4: Video screen close-up.



Fig. 5: Back at the operating table, prepping the harvested IMA.

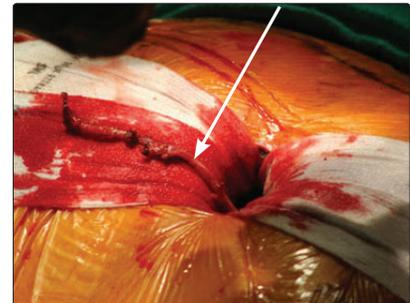


Fig. 6: Exposing the IMA graft.



Fig. 7: Team concentration as the surgeons sew the harvested IMA to the LAD.

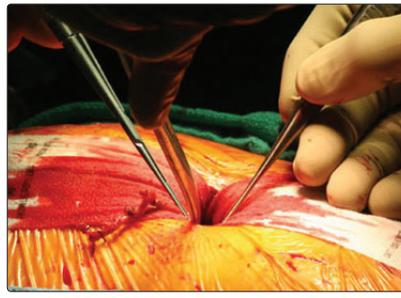


Fig. 8: Anastomosing IMA to the LAD coronary through the camera port.



Fig. 9: View of IMA - LAD anastomosis.

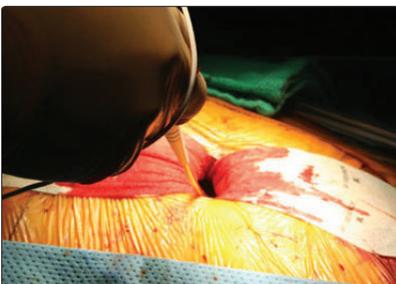


Fig. 10: Measuring IMA flow with flowprobe inserted through port.



Fig. 11: Good IMA graft flow: 63 mL/min.



Fig. 12: Measuring 1 1/2 inch incision in 85-year-old patient.

Annotated Robotic CABG References

- Ishikawa N, Watanabe G, Tomita S, Yamaguchi S, Nishida Y, Iino K, "Robot-assisted minimally invasive direct coronary artery bypass grafting. ThoraCAB," *Circ J*. 2014; 78(2): 399-402. (Transonic Reference # 10555AH) *"Robot-assisted ITA harvesting is safe and feasible. ThoraCAB is a relatively simple procedure and allows multivessel bypass grafting after a small thoracotomy. Therefore, it is expected that ThoraCAB will become the standard procedure for minimally invasive coronary revascularization and will be used in totally endoscopic CABG in the future."*
- Boehm DH, Reichenspurner H, Gulbins H, Detter C, Neiser B, Brenner P, Habaztll H, Reichart B, "Early experience with robotic technology for coronary artery surgery," *Ann Thorac Surg* 1999; 68(4): 1542-6. (Transonic Reference # 2025AHM) *"Using telemetric technology, a completely endoscopic anastomosis of LIMA to LAD is possible on the arrested heart, as well as on the beating heart."*
- Damiano RJ, Tabaie HA, Mack MJ, Edgerton JR, Mullangi C, Graper P, Prasad SM, "Initial prospective multicenter clinical trial of robotically-assisted coronary artery bypass grafting," *Ann Thorac Surg* 2001; 72(4): 1263-8. (Transonic Reference # 2128AH) *"Graft flow was measured (n= 32) in the operating room and averaged 37 +/- 19 mL/min. Mean anastomosis time was 24 +/- 9 minutes. There were three intraoperative revisions (9%). Two were for inadequate flow and one for an inadvertent injury. Each of these grafts was successfully revised by hand. ... This initial prospective multicenter trial documents the feasibility of robotically-assisted coronary bypass grafting."*
- Damiano RJ, Ehrman WJ, Ducko CT, Tabaie HA, Stephenson ER, Kingsley C P, Chambers C E, "Initial United States Clinical Trial of Robotically Assisted Endoscopic Coronary Artery Bypass Grafting," *J Thorac Cardiovasc Surg* 2000;119: 77-82. (Transonic Reference # 1675AH) *"Blood flow through the left internal thoracic artery graft was measured in the operating room and was adequate in 8 of 10 patients. The 2 inadequate grafts were revised successfully by hand. ...This pilot study demonstrates the feasibility of robotically assisted endoscopic coronary artery bypass grafting."*
- Falk V, Diegeler A, Walther T, Banusch J, Brucerius J, Raumanns J, Autschbach R, Mohr FW, "Total endoscopic computer enhanced coronary artery bypass grafting," *Eur J Cardiothorac Surg* 2000; 7(1): 38-45. (Transonic Reference # 2026AHM) *"By July 1999 the da Vinci telemanipulation system (Intuitive Surgical, Mountain View, CA) was used in 66 patients with coronary artery disease. In 12 patients undergoing routine coronary artery bypass grafting (CABG) (group 1) the internal thoracic artery (ITA) to left anterior descending artery (LAD) anastomosis was performed remotely using the system. In 32 patients (group 2) endoscopic dissection of the ITA was performed followed by a conventional minimally invasive direct coronary artery bypass (MIDCAB) operation. In 22 patients (group 3) the complete operation was performed endoscopically through 4 ports (total endoscopic coronary artery bypass, TECAB). Port-Access cardiopulmonary bypass with cardioplegic arrest was used for TECAB.."*
- Prasad SM, Ducko CT, Stephenson ER, Chambers CE, Damiano RJ Jr, "Prospective clinical trial of robotically assisted endoscopic coronary grafting with 1-year follow-up," *Ann Surg* 2001; 233(6): 725-32. (Transonic Reference # 2529AH) *"The results from the first prospective clinical trial of robotically assisted endoscopic coronary bypass surgery in the United States showed favorable short-term outcomes with no adverse events. Robotic assistance is an enabling technology allowing the performance of endoscopic coronary anastomoses."*
- Reichenspurner H, Damiano RJ, Mack M, Boehm DH, Gulbins H, Detter C, Meiser B, Ellgass R, Reichart B, "Use of Voice-Controlled and Computer-Assisted Surgical System Zeus for Endoscopic Coronary Artery Bypass Grafting," *J Thorac Cardiovasc Surg* 1999; 118:11-16. (Transonic Reference # 1728AHM) *"With sophisticated robotic technology, a completely endoscopic anastomosis of the LITA to the LAD is possible, allowing technically precise operations within acceptable time limits."*
- Tang LW, D'Ancona G, Bergsland J, Kawaguchi A, Karamanoukian HL, "Robotically assisted video-enhanced-endoscopic coronary artery bypass graft surgery," *Angiology* 2001; 52(2) 99-102. (Transonic Reference # 2027AHM) *"Robotically assisted video enhanced-endoscopic coronary artery bypass surgery (RAVE-CABG) will most likely follow suit ...for symptomatic coronary artery disease. Since 1998, there are currently two surgical robotic systems that have been used in a clinical setting for endoscopic coronary artery bypass (ECABG): the da Vinci and the ZEUS system. Although each has separate learning curves to overcome, as with any new technology, both offer the promise to contribute in the interests of reduced hospital days, earlier return to normal activity, less pain, better cosmesis, and the rethinking of surgical dogma such as wide exposure."*
- Tabaie HA, Graper WP, Reinbolt JA, "Clinical investigation: endoscopic coronary artery bypass grafting with robotic assistance," *Heart Surg Forum*, 2002; 5(4): 328-33. (Transonic Reference # 2965AH) *"Although E-CABG is an exhaustive and technically demanding procedure, it is feasible for a computer-enhanced robotic telemanipulation system to safely and effectively provide substantial assistance to the surgeon completing a thoracoscopic coronary anastomosis."*

Flow-assisted Pediatric Cardiac Surgery

Congenital Heart Surgery

The American Heart Association estimates that eight out of every 1,000 infants are born with a heart defect. Defects in the fetal heart are discovered within the first 33 days of life. Many of these congenital defects are minor and some do not cause problems until adulthood. Others are serious and require correction either surgically or through less invasive procedures.

Dr. Mavroudis — Flow Pioneer

Shortly after the Transonic flowmeter was approved for human use in 1988, Dr. Constantine Mavroudis, then at Children's Hospital in Chicago, used a Transonic Flowprobe on the aorta to measure cardiac output during pediatric heart surgery.^{1,2} He routinely measured ascending aorta flow before and after the corrective surgery, usually using a 20 mm Flowprobe, but sometimes a 14 or 16 mm Flowprobe. Patients ranged from 18 months to 12 years of age, with the usual age between 3-4 years.

Dr. Mavroudis performed a Fontan procedure to correct congenital conditions called tricuspid atresia (an opening between the right atria and right ventricle), or univentricular heart (one ventricle instead of two). In both conditions, the right ventricle cannot pump sufficient blood into the pulmonary artery to oxygenate the blood in the lungs. The Fontan procedure corrects this by connecting the vena cava directly to the pulmonary artery. Although the Fontan procedure compensates for the original defect, it can create high pressures in the pulmonary artery which, in turn, can cause the repair to break down in several years. A reoperation is then required.

In the late 1980's, Dr. Mavroudis and some of his colleagues introduced a modified version of the surgery called the fenestrated Fontan procedure. A small hole (fenestra) is made in the atrial septum to lower postoperative pulmonary arterial pressure. This allows the heart to reach equilibrium under its new hemodynamic conditions. The hole is then closed using cardiac catheterization several months after the surgery. Dr. Mavroudis was a scheduled podium speaker at the 1989 convention of Experimental Biology.



Fig. 1: Representative human aortic trace.

Courtesy of G. Pantalos, PhD

More Flow Pioneers

George Pantalos, PhD, a longtime Transonic collaborator, and his team at the University of Utah were some of the other early pioneers in using the aortic flowprobes to measure pediatric aortic flows with A-probes.^{4,5} At a Vienna symposium in 2003, Dr. Cabo from Madrid, Spain, reported on his use of AX-Series probes on a variety of his congenital heart surgical repairs where he found the measurements to be valuable. In recent years, Dr. Glenn Van Arsdell and his pediatric cardiac surgery team at the Hospital for Sick Children, in Toronto, have been using aortic Flowprobes to measure flow during their corrective surgeries.⁶

Four-Transducer Aortic Flowprobes

To accommodate the turbulent flows and improve accuracy, Transonic pioneered the development of a four-crystal aortic Flowprobe. The first A-probes were validated by Drs. David Dean and Henry Spotnitz, *et al* at the College of Physicians and Surgeons, Columbia University.³ Now, the Flowprobes have been further modified. These new CONfidence Flowprobes® are ideally suited to monitor cardiac output during cardiac surgical repair. Applied to the aorta or the pulmonary artery, they can continually register blood flow in mL/min through the course of the surgery. The Flowprobe's slim, ergonomic profile creates a minimal footprint that fits in tight anatomical sites. The soft, pliable liner cushions and protects the vessel.

Flow Protocol

Intraoperative Blood Flow Measurements during Pediatric Cardiac Surgery

Introduction

The size and fragile nature of patients make pediatric surgeries undoubtedly among the most challenging to perform. Topping that list is pediatric heart surgery to repair congenital heart defects with which the children are born. Depending on the severity of the condition, surgical repair takes place during the first few years of an infant's life. One of the most common, a complex combination of four defects called the Tetralogy of Fallot, accounts for ten percent of all congenital heart defects in infants. Other congenital heart defects, including atrial/ventricular septal anomalies; patent ductus arteriosus; valve stenosis or atresia, and coarctation or transposition reversal of the aorta and pulmonary artery all demand immediate attention.

Blood Flow — the Heart of the Matter

Whatever the nature of the defect, a surgeon's primary goal is to create or restore blood flow to its natural pathway through the heart into the systemic circulation so that the child can grow and thrive.

In their drive to perform the best possible operation tailored to the specific conditions of a patient, surgeons value technologies that provide an assessment of their intraoperative progress that will inform their surgical decision making. Transonic Flow-QC intraoperative blood flow measurement is such a measurement. The measurements may either confirm the surgeon's clinical impressions during the course of the surgery or they can alert the surgeon to a potential problem at a time when it can be most easily addressed.

Applying the COncidence Flowprobe® and Ultrafit Liner to A Vessel.



4 and 6 mm COncidence Flowprobes® next to a nickel: Flowprobes consist of a Flowprobe shell and a single-use soft, flexible Ultrafit liner. This novel concept for ultrasonic signal coupling enables immediate, accurate, beat-to-beat flow measurements with a minimum of ultrasonic coupling gel. The form-fitting Ultrafit Liner slips into the transducer shell to encircle the vessel and keep the vessel in place. The liner cushions and protects the vessel during a flow measurement. Liners are incrementally sized for optimal fit on the target vessel.

COncidence Flowprobes are now available in the following sizes: 4 mm, 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 20 mm, 24 mm, 28 mm, 32 mm and 36 mm.

- Important:** Measure the diameter of the vessel to determine the appropriate size COncidence Flowprobe® (A) to be used and its associated Ultrafit Liner (B). The Ultrafit Liner should closely match the vessel diameter without constriction.
- Remove the Ultrafit Liner assembly from the sterile packet. Identify the parts of the Liner assembly (Fig. 1): Liner (1), wire (2), and ring (3).
- Position the Ultrafit Liner around the vessel (Fig. 2) making sure that the vessel is completely inside the Liner. It is good practice to pre-soak the Flowprobe (shell but not connector) and Ultrafit Liner in sterile saline to enable quicker and stronger ultrasonic coupling with the vessel.
- Apply a small amount of Aquasonic gel on the inside of the Flowprobe and slide the Probe all the way over the Liner so that the opening of the Flowprobe coincides with the opening of the Liner (see Fig. 3).
- Secure the Liner to the Flowprobe by twisting the Liner wire around the Flowprobe as shown in Fig. 3. Position the Liner ring outside of the surgical field.

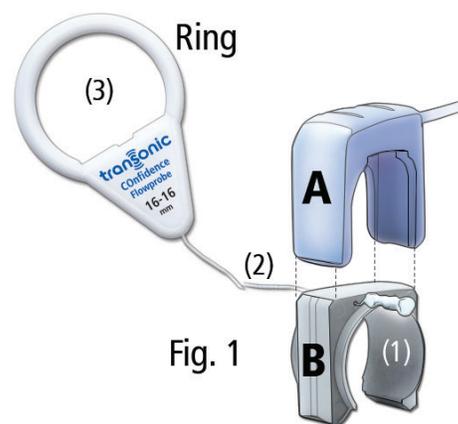


Fig. 1

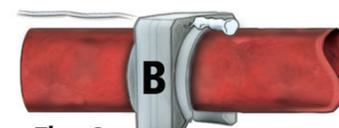


Fig. 2

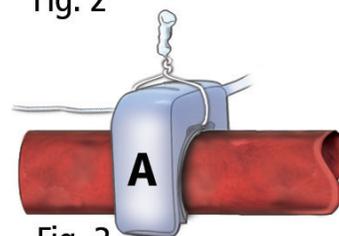
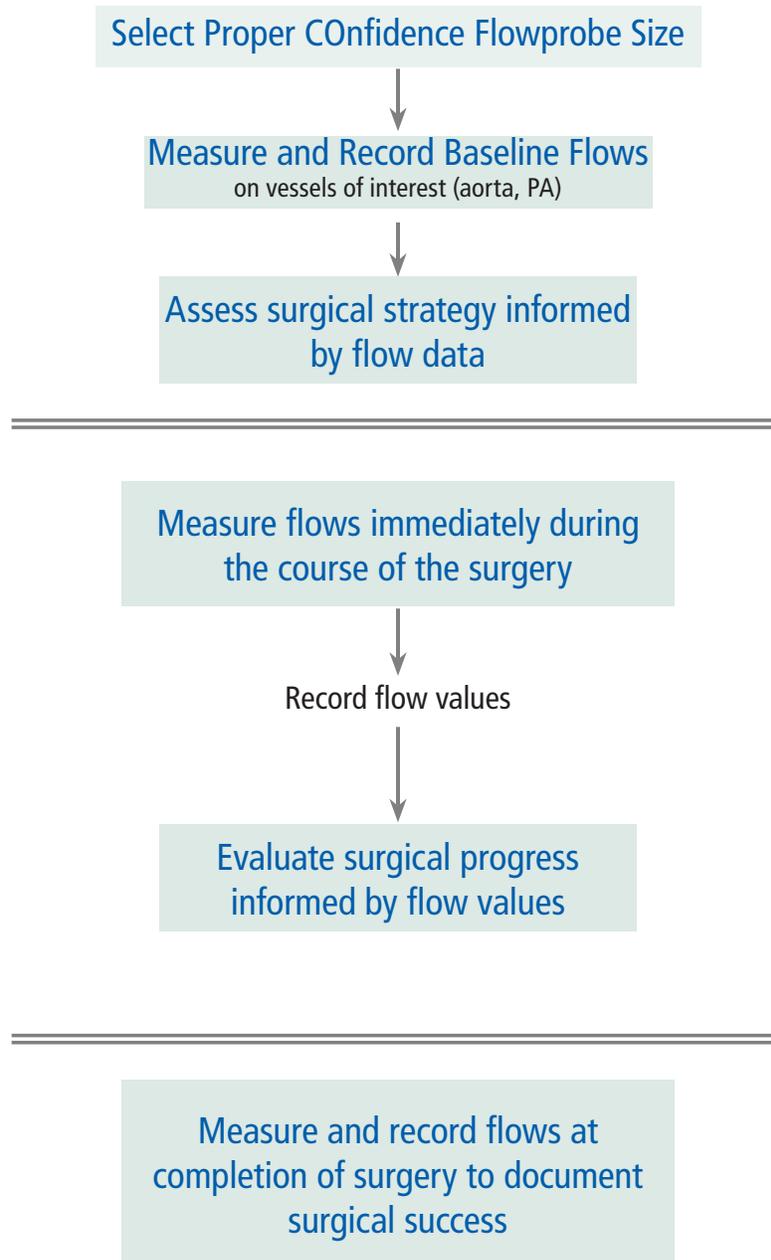


Fig. 3

Intraoperative Blood Flow Measurements during Pediatric Cardiac Surgery cont.

Multi-stage Flow Measurement Protocol



Annotated Pediatric Cardiac References

- 1 Mavroudis C, Zales VR, Backer CL, Muster AJ, Latson LA, "Fenestrated Fontan with Delayed Catheter Closure, Effects of Volume Loading and Baffle Fenestration on Cardiac Index and Oxygen Delivery," *Circulation* 1992; 86 II: 85-92. (Transonic Reference # 261A) *To determine the hemodynamic factors responsible for these improved fenestrated Fontan results for fenestrated Fontan operations 17 high-risk patients with univentricular hearts underwent fenestrated Fontan operations. Cardiac index was determined in eight patients by assessment with an aortic flowprobe. "The fenestrated Fontan operation improves survival in high-risk patients by increasing cardiac index and maintaining oxygen delivery, despite mild arterial O2 desaturation. Subsequent transcatheter fenestration closure can be performed after hemodynamic assessment."*
- 2 Mavroudis C, Backer CL, Kohr L., Deal BJ, Stinios J, Muster AJ, Wax DF, "Bidirectional Glenn Shunt in Association with Congenital Heart Repairs: The 1-1/2 Hour Ventricular Repair," *Ann Thoracic Surg* 1999; 68: 976-982. (Transonic Reference # 1305AH) *"The bidirectional Glenn shunt has been used to incorporate a smaller tripartite ventricle into the circulation and create pulsatile pulmonary artery flow. We reviewed our operative experience and assessed hemodynamics of the bidirectional Glenn shunt in 1(1/2) ventricular repair or in conjunction with other repairs of congenital heart defects. Intraoperative hemodynamic assessment was performed in 2 patients in group A by selective use of inflow occlusion and flow probes. Superior and inferior vena caval flow averaged 36% and 64% of cardiac output, respectively. Postoperative superior vena caval pressure (n = 13) was 13.7+/-4.0 mm Hg with pulmonary arterial flow pattern contributed by the ventricle in systole (pulsatile) and the superior vena cava in diastole (laminar).*
- 3 Dean DA et al, "Validation Study of a New Transit Time Ultrasonic FlowProbe for Continuous Great Vessel Measurements," *ASAIO Journal* 1996; 42: M671-676. (Transonic Reference # 29V) *Continuous measurement of cardiac output is important during experimental and clinical cardiac surgery as an indicator of ventricular function. The new A-series probe (ASP) by Transonic Systems, Inc., uses a new X method of ultrasonic illumination insensitive to perturbations in flow. The probes were found to be accurate during in vitro studies. Six anesthetized pigs were instrumented for right atrium to left atrium bypass, and the Flowprobes were placed on the ascending aorta and pulmonary artery. Baseline measurements included aortic (Ao) and pulmonic flow (P), and thermodilution (Td) cardiac output. Animals then were placed on right heart bypass, and flow was randomly varied from 1 to 6 L/min, and Ao flow was recorded. During laminar flow states, ASPs are accurate and insensitive to position on the great vessels.*
- 4 Sharp MK, Pantalos GM, Minich L, Tani LY, McGough EC, Hawkins JA, "Aortic Input Impedance in Infants and Children," *J Appl Physiol.* 2000: Jun; 88(6):2227-39. (2590AH) (asc. Aorta- A probe) (Transonic Reference # 2769AH) *Flow and pressure measurements were performed in the ascending aortas of six pediatric patients ranging in age from 1 to 4 yr and in weight from 7.2 to 16.4 kg to calculate input impedance.*
- 5 Pantalos GM, Minich L, Tani LY, McGough EC, Hawkins JA, "Estimation of Timing Errors for Intraaortic Balloon Pump Use in Pediatric Patients," *ASAIO Journal*, Vol. 45, No. 3, p. 166-171, 1999. (aortic, pediatric, A probes) (Transonic Reference # 1073AH) *To investigate timing errors when using the traditional IABP inflation and deflation markers in pediatric patients, six patients (age, 2.2+/-1.4 years; weight, 11.5+/-3.9 kg) were studied intraoperatively. For each patient, a sequence of five recorded aortic root waveforms was analyzed.*
- 6 Kotani Y, Honjo O, Shani K, Merklinger SL, Caldarone C, Van Arsdell G, "Is Indexed Preoperative Superior Vena Cava Blood Flow a Risk Factor in Patients Undergoing Bidirectional Cavopulmonary Shunt?," *Ann Thorac Surg.* 2012. (Transonic Reference # 9735AH) *This study evaluated the effect of a new measurement-superior vena cava (SVC) flow-and anatomic factors on postoperative arterial oxygen saturation and clinical outcome in 19 patients who underwent bidirectional cavopulmonary shunt (BCPS). SVC flow was measured at the time of BCPS by a Transonic flow probe (Transonic Systems Inc, Ithaca, NY). SVC flow, preoperative hemodynamics, pulmonary artery size, and clinical outcome were analyzed to determine risk for morbidity and death. A new indicator-low SVC flow, may be a marker for BCPS failure or death, suggesting that the SVC flow vs size is more important in predicting successful BCPS.*
- 7 Kotani Y, Coles M, Desai ND, Honjo O, Caldarone CA, Coles JG, Van Arsdell GS. "The Utility of Aortic Blood Flow Measurements in the Prediction of Pulmonary Artery Banding Outcome," *Ann Thorac Surg.* 2015; 99(6): 2096-100. (Transonic Reference # 10795AH) *Twelve patients who underwent a Pulmonary Artery Banding between September 2008 and March 2013 who also had intraoperative aortic blood flow measurements were reviewed. Aortic blood flow was measured at the time of surgery by Transonic flow probe (Transonic Systems Inc., Ithaca, NY). Aortic flow, intraoperative hemodynamics, and clinical outcomes were analyzed to determine the potential predictive utility of intraoperative variables on postoperative outcomes. "The efficacy of the PAB procedure was found to be directly related to the percentage increase in aortic blood flow measured intraoperatively. ... patients with successful PAB had more than 40% increase in aortic blood flow. ... This study identifies the change in the aortic blood flow as a new, physiologically based parameter to help predict PAB outcome."*
- 8 Lindberg L, Johansson S, Perez-de-Sa V, "Validation of an ultrasound dilution technology for cardiac output measurement and shunt detection in infants and children." *Pediatr Crit Care Med* 2014; 15(2): 139-47. *In 21 children undergoing heart surgery, cardiac output was simultaneously recorded by ultrasound dilution and a transit-time ultrasound probe applied to the ascending aorta, and when possible, the main pulmonary artery. The pulmonary to systemic blood flow ratio estimated from ultrasound dilution curve analysis was compared with that estimated from transit-time ultrasound technology.*

Flow Protocol

Continuous Cardiac Output Measurements with Ventricular Assist Devices (LVADs)

There are nearly 100,000 Americans with end-stage heart failure unresponsive to maximal medical therapy, and for whom heart transplantation remains the gold standard therapy. Only 2-4% will actually undergo transplantation. Currently, the most promising treatment for end-stage heart failure is a Left Ventricular Assist Devices (LVAD), which can be used as a bridge to heart transplant or as definitive destination therapy.

Transonic Linked to VAD Development

Transonic history is providentially intertwined with the development of circulatory support and LVADs. In 1971, Transonic President Cornelis Drost moved from the Netherlands to the USA at the invitation of Dr. Yukihiro Nosé, to design an ultrasonic flowsensor for an artificial heart that Dr. Nosé was developing at the Cleveland Clinic. Grant funding fell through and Mr. Drost went to the NYS Veterinary School at Cornell University to work with Professor Alan Dobson. His assignment was to design a more reliable flowmeter to measure blood flow in conscious animals. His invention was a transit-time volume flowmeter that would ultimately be used in the engineering and testing of almost every circulatory support device developed in the next three decades. The Cornell sojourn morphed into Transonic Systems and the realization of Dr. Nosé's original assignment to Mr. Drost, "Design me a flowsensor for the artificial heart."

Transit-time Technology Advantage

From the onset, Transonic transit-time ultrasound flowmeters had distinct advantages over other technologies. The perivascular probes could be implanted on native vessels in animal subjects for months to validate adequate blood distribution by the mechanical hearts. And ultimately, the flowprobes would be positioned on the artificial vessel outlet graft of the pumps to directly measure pump performance. The first tubing flowsensors developed in 1987 could readily measure volume flow of water, saline and blood analogs like glycerin & water solutions used to mimic the viscosity of blood and best assess pump design on the bench. For extracorporeal devices, clamp-

on tubing flowsensors had no contact with the fluid and would keep blood lines sterile.

Customers

Transonic Systems' reference/customer list reads like a "Who's Who" in circulatory support research and development. The Cleveland Clinic was among Transonic's first customers, with other notable centers for heart assist device development: University of Utah Artificial Heart Lab, Univ. of Pittsburgh Medical Center, McGowan Research Institute, Texas Heart Institute, and their biomedical engineering icons: Yukihiro Nosé, Michael DeBakey, Robert Bartlett, O.H. "Bud" Frazier, George Magovern, Sr., Denton Cooley, Robert Jarvik, George Pantalos and Harvey Borovetz.

Clinical Measurements

The first adapter of transit-time ultrasound for clinical LVAD was MicroMed which had an A-style Flowprobe customized to measure flow through the outflow cannula of the DeBakey MicroMed VAD, a 2002 NASA Invention of the Year, which was developed using supercomputer simulation ion originally designed to model fluid flow through NASA rocket engines^{5,6}. Its derivative, the Heart Assist 5 (HA5) pump has now taken this continuous monitoring to a new level for post-op monitoring by being able to monitor LVAD patients from a remote location.

Furthermore, Transonic clinical flowprobes have been recommended during implants of the HeartMate II and Jarvik 2000. Transonic A-Probes, especially calibrated for the graft material, check flow in the outlet graft at implant to ensure adequate flow from the pump to ensure that there is no obstruction during the graft placement.

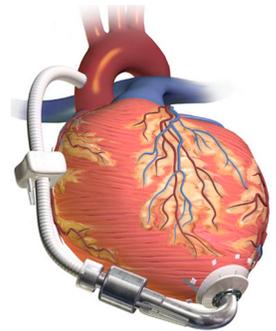


Fig. 1: Flowprobe on outflow cannula of HeartAssist 5 LVAD.

Case Report

LVAD Patient's Arrhythmia Detected by Transonic True Flow Monitoring

LVADs: Bridge to Transplant or Destination Therapy

Today, more than 20,000 heart failure patients throughout the world have been implanted with LVADs temporarily as a "bridge to transplant" or, in some instances, permanently as a "destination therapy." Throughout the history of ventricular assist device development, Transonic True Flow technology has been used to test prototype VADs/LVADs.

True Flow in Heart Assist 5

In the case of the Heart Assist 5 (HA5), Transonic True Flow has been incorporated in its clinical axial pump with a true-flowsensor on board, the other performance parameters of the VAD (current and pressure waveforms, power consumption) become performance and quality measures to identify problems such as the onset of thrombosis.

Twelve days after a HeartAssist5® (HA5) left ventricular assist device (LVAD) was implanted in a patient, clinicians at a remote monitoring center noticed a change in the normal pulsatile flow waveform transmitted from the LVAD to the monitoring site. The doctors diagnosed heart arrhythmia. The patient was told to see her cardiologist immediately. The cardiologist prescribed medication that corrected the problem for the time being.

LVAD's True Flow Averts Crisis

Thus, continuous True Flow measured in the LVAD, transmitted to a remote diagnostic site and monitored by clinicians averted a potential crisis for this heart failure patient. For the woman whose arrhythmia was detected by monitoring of True Flow by the customized Transonic® Flowsensor positioned on the HA5 outflow cannula, the dividend was far more immediate: the True Flow monitor in her life saving implant became a life saving diagnostic tool as well.

Annotated VAD References

- Ishino K, "A hemodynamic study of the biventricular bypass total artificial heart with special reference to intrarenal flow distribution", *Jpn J Surg* 1991; 21(3): 312-21. *"It was thus concluded that the biventricular bypass total artificial heart operated in an independent variable rate mode maintains physiological circulation and is therefore able to substitute for native heart function in any situation."*
- Massiello A et al, "The Cleveland Clinic-Nimbus total artificial heart. Design and in vitro function," *J Thorac Cardiovasc Surg* 1994; 108(3):412-9. *"In vitro studies on a mock circulatory circuit demonstrated preload-sensitive control of pump output over the operating range of the blood pump. ...Thus the Cleveland Clinic-Nimbus total artificial heart meets the National Heart, Lung, and Blood Institute hemodynamic performance goals for devices being developed for permanent heart replacement."*
- Pantalos GM et al, "The effect of gravitational acceleration on cardiac diastolic function: a biofluid mechanical perspective with initial results. *Curr Pharm Biotechnol* 2005; 6(4): 331-41." *In the same range of flow rates and stroke volumes, similar flows were observed in the 1-G supine posture for atrial pressures intermediate to the 1-G upright and micro-G values, also consistent with the hypothesis. Additional experiments on board the Space Shuttle are in preparation to gather data across the rest of the normal physiologic range of the ventricular function curve."*
- Bruschi G et al, "Bridge to transplantation with the MicroMed DeBakey ventricular assist device axial pump: a single centre report." *J Cardiovasc Med (Hagerstown)*. 2006; 7(2):114-8. *"In our experience with the continuous axial flow DeBakey VAD, a high success rate was obtained associated with a low risk of complications. All the patients tolerated continuous blood flow for extended periods that makes this device a valuable alternative to pulsatile VADs as a bridge to transplantation."*
- Noon GP, et al, "Clinical experience with the MicroMed DeBakey ventricular assist device," *Ann Thorac Surg* 2001; 71(3 Suppl):S133-8. *"The clinical trial demonstrated that the MicroMed DeBakey VAD is capable of providing adequate circulatory support in patients with severe heart failure, sufficient to recover and return to normal activities while awaiting a heart transplantation. Much has been learned about the function of the device and its continuous flow in humans. Subsequent transcatheter fenestration closure can be performed after hemodynamic assessment."*

Flow Protocol

Continuous Cardiac Output Measurements during Delayed Sternal Closure after Left Ventricular Device (LVAD) Implantation

Introduction

A common complication following implantation of a VAD for left ventricular circulatory support is edema resulting in acute right heart failure that forces a delay in closing the sternal operative site. To optimally manage this condition and close the chest expediently requires a reliable estimation of left ventricular preload and contractility. A Transonic Ultrasonic Perivascular CONfidence Flowprobe® placed on the right pulmonary artery or aorta for up to 24 hours post-surgery provides continuous real-time measurements of arterial flows to assist with the timing of these critical surgical decisions.

Equipment: 28, 32 mm or 36 mm CONfidence Flowprobe (Fig. 1)

CONfidence Flowprobe® Placement

1. Measure the diameter of the pulmonary artery or aorta to determine the ideal size for the CONfidence Flowprobe and Ultrafit Liner to be used. The flowprobe should snugly fit the vessel without constricting it.
2. Remove the Ultrafit Liner (B) from its sterile packet identifying its parts (Fig. 3). Pre-soak the Flowprobe shell and Ultrafit Liner in sterile saline to enable quicker and stronger ultrasonic coupling with the vessel.
3. Position the Ultrafit Liner around a skeletonized vessel (Fig. 4) making sure that the Liner fully encircles the vessel.
4. After applying a small amount of ultrasonic gel to the inside of the Flowprobe shell, slide the Flowprobe all the way over the Ultrafit Liner body so that the opening of the Flowprobe coincides with the opening of the Liner (Fig. 5).
5. If desired, secure the Liner to the Flowprobe by twisting the Liner wire around the Flowprobe (Fig. 5). As an alternative, pass a suture through one of the holes in the Liner and tie it off.
6. Position the Liner ring outside of the surgical field for easy retrieval of the Flowprobe.

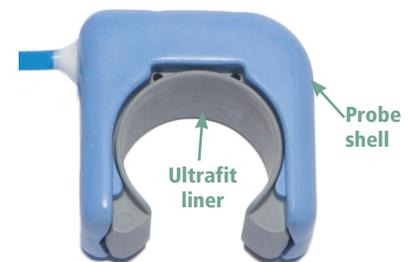


Fig. 1: A CONfidence Flowprobe (AU-Series) consist of a plastic shell and a soft, flexible liner that cushions a vessel during measurements.

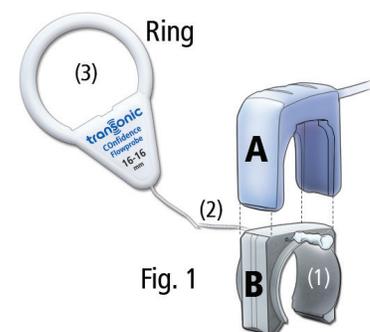


Fig. 1

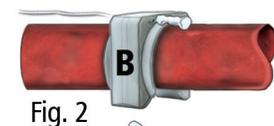


Fig. 2

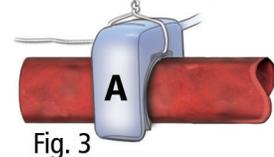


Fig. 3

Case Report

Beneficial Aspects of Real Time Flow Measurements for the Management of Acute Right Ventricular Heart Failure Following Continuous Flow Ventricular Assist Device (VAD) Implantation

INTRODUCTION

Optimal management of acute right heart failure, a common complication following implantation of a VAD for left ventricular circulatory support, requires a reliable estimation of left ventricular preload and contractility. This is possible with real-time pump blood flow measurements from a Transonic® ultrasonic Flowprobe on the outflow cannula of the VAD.

BACKGROUND & DIAGNOSIS

A 66-year-old female presented with end-stage heart failure due to dilated cardiomyopathy. Signs included severe left ventricular function impairment (EF 10%); right ventricular dysfunction, systolic pulmonary arterial pressure, 48 mmHg, and Cardiac Index, 1.92 L/min/m². After four days of milrinone intravenous therapy, the patient was implanted with a HeartAssist 5 (Micromed Cardiovascular Inc. Houston, TX) with a custom Transonic Flowprobe on the outflow graft to continuously measure real-time pump blood flow. Edema and severe fluid retention prevented complete closure of the thorax. On days one and two post-op, mean flow, accompanied by a pulsatile waveform, was 4.8 L/min.

On day three post-op, real-time flow began a progressive decline and loss of pulsatility accompanied by an increase in central venous pressure and progressive renal failure. Thermodilution measurements and echocardiography confirmed acute right heart failure.

TREATMENT

On day ten post-op, the patient was placed on VA extracorporeal membrane oxygenation (ECMO). The ECMO circuit included a CentriMag pump with a “Transonic Inside” flow board and a H9XLA Flowsensor. Real-time flow and pulsatility recovered immediately and the ECMO circuit was disconnected on day 14 post-op. On day 17 post-op, the thorax was closed. Further recovery was uneventful.

CONCLUSION

By enabling the monitoring of the left ventricular preload and contractility throughout the post-operative period, Transonic real-time flow measurement proved to be a useful tool both for the diagnosis and the management of right heart failure, including weaning from ECMO. It was a reliable alternative to conventional techniques for the measurement of cardiac output in the clinical setting.

- Thermodilution measurements validated Transonic real-time flow measurements.
- The loss of flow pulsatility foreshadowed insufficient LV preload, which allowed earlier intervention.
- Other currently available continuous flow VADs can only estimate pump blood flow by calculating the motor’s power consumption and the pump’s rotational speed which is subject to external factors such as blood viscosity and loading of the ventricle.

REFERENCE

Spiliopoulos S, Guersoy D, Koerfer R, Tenderich G, “Beneficial aspects of real time flow measurements for the management of acute right ventricular heart failure following continuous flow ventricular assist device implantation,” J Cardiothorac Surg. 2012; 7:119. (Transonic Reference # 9760AH)