

Real-time Intra-access Flow Data Enhances Angioplasty & Banding Outcomes

- Verifies the Need for Angioplasty
- Detects Flow-limiting Stenoses
- Quantifies Flow Improvement



transonic
THE MEASURE OF  BETTER RESULTS.

ReoCath® Intra-access Flow Measurements: Real-time Quantitative Data during Interventions

The ReoCath® Flow Catheter and HVT100 Endovascular Flowmeter offer on-the-spot feedback about the functionality of arteriovenous fistulas and grafts. The measurements tell the interventionalist:

- If angioplasty is necessary. Pre-assessment of intra-access flow may indicate no need to perform angioplasty until a future date.¹
- If angioplasty was effective. A ReoCath® measurement can affirm flow improvement after angioplasty.
- Whether target flow is reached during a banding procedure. The ReoCath® is used during the MILLER banding procedure to reach the target flow.

¹ Leontiev O, Trerotola SO et al, "Catheter-based Intraaccess Blood Flow Measurement as a Problem-solving Tool in Hemodialysis Access Intervention. J Vasc Interv Radiol. 2013; 24(5): 717-21.

How the ReoCath® Flow Catheter Works

ReoCath® 6 French antegrade or retrograde Flow Catheters are introduced via a 6 F sheath into an access during angioplasty.

A bolus of room temperature saline is injected into the vascular access blood stream. An injection thermistor located close to the proximal end of the catheter records the temperature of the injected saline. A second thermistor located close to the distal tip of the catheter then records the thermodilution within the access. The HVT100 Endovascular Flowmeter calculates and displays intragraft blood flow in mL/min.

US patents 6,623,436; 6,746,408; 6,868,739; 6,986,744; 7,112,176; 7,121,150; 7,210,359; 7,275,447;



Transonic Systems Inc. is a global manufacturer of innovative biomedical measurement equipment. Founded in 1983, Transonic sells "gold standard" transit-time ultrasound flowmeters and monitors for surgical, hemodialysis, pediatric critical care, perfusion, interventional radiology and research applications. In addition, Transonic provides pressure and pressure volume systems, laser Doppler flowmeters and telemetry systems.

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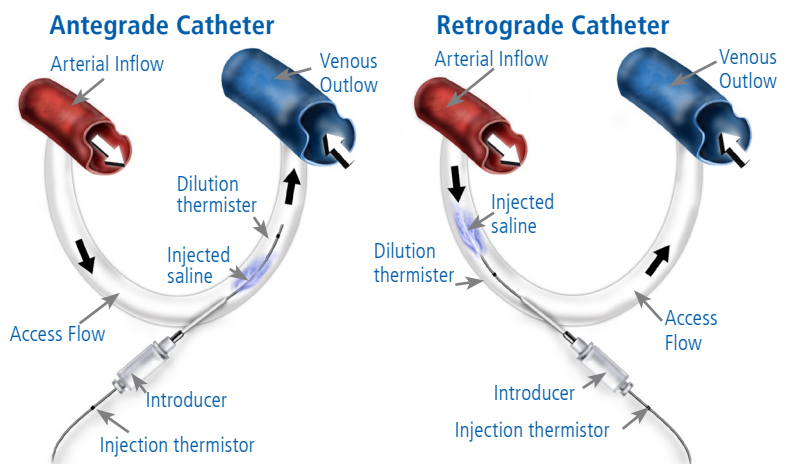
"...the use of the Transonic flow meter system to measure intragraft blood flow during endovascular procedures allowed immediate post treatment evaluation of the stenosis and also provided additional insight into the hemodynamic status of the entire vascular circuit." Vesely TM, J Vasc Interv Radiol 2002; 13(4): 371-378.

In conclusion, flow measurements may be used as a problem-solving tool during hemodialysis access interventions." Leontiev O et al, J Vasc Interv Radiol 2013; 24: 717-721

"Having the ability to measure flows has allowed me to better know what I'm doing with my flow reductions, my venous angioplasty and imaging and whether or not I am actually making a difference."

Gregg Miller, Chief Medical Officer, Vascular Access Care

THERMAL DILUTION TECHNOLOGY MEASURES INTRAGRAFT FLOW



On the left, an antegrade catheter (6 F, 35 cm length) is shown inserted into an AV access in the same direction as access flow. After injected saline is released from the catheter, a dilution thermistor, downstream at the catheter tip, measures the temperature of blood, diluted by the injected saline. On the right, a retrograde catheter (6 F, 48 cm length) is likewise inserted into an AV access, but against the direction of access flow. After injected saline is released from the tip of the catheter, a proximal dilution thermistor measures the temperature of the saline-diluted blood. Classic dilution equations are used to extrapolate blood flow in mL/min from the temperature changes between the saline measured by injection thermistors and the saline-diluted blood measured by the dilution thermistors.

Endovascular Measurement Protocol

Flow Measurements in Fistulas & Grafts

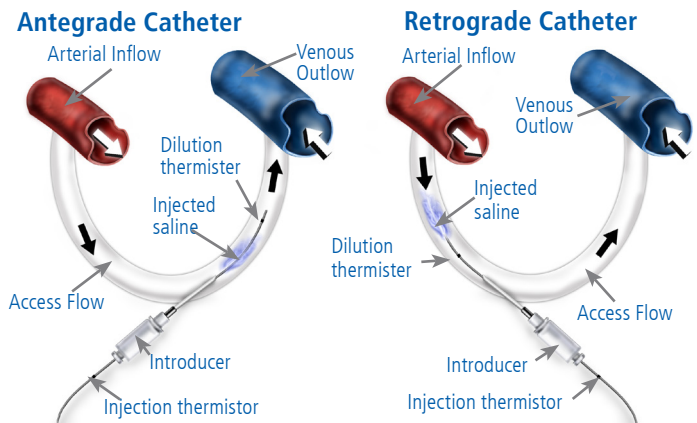
- 1) Connect the HVT100 Endovascular Flowmeter to a grounded power receptacle. Turn on POWER.
- 2) Record flow information by plugging in a USB on the rear panel of a computer and start the data acquisition software.
- 3) Select either an Antegrade or Retrograde sterile ReoCath® Flow Catheter, open pouch and pass the connector to the non-sterile field.
- 4) Remove the distal cap, curve retainer, and tag from catheter.
- 5) Have a nurse outside the sterile field attach the connector of the ReoCath® to the extension cable and connect the extension cable to the HVT100.

NOTE: The system will not determine the type of catheter until it is inserted into the introducer.

- 6) Open the stopcock on the ReoCath® Flow Catheter and fill the catheter with isotonic saline. Close the stopcock.
- 7) Insert the catheter through the 6F or larger introducer until the marker band is visible outside the sheath.
- 8) Press the START button on the front of the Flowmeter.
- 9) The HVT100 will display "WAIT". The catheter indicator light will display which catheter type is attached, either "Antegrade" or "Retrograde".
- 10) After 15-20 seconds the HVT100 will display "READY". Open the stopcock on the ReoCath® Flow Catheter and inject 10 mL bolus of room temperature saline (20-25°C) into the catheter in one smooth, continuous motion over 2 - 3 seconds. When the dilution thermistor detects the start of an injection the display switches to "INJ. 03" and counts down to "INJ. 00" Use this countdown to help make consistent injections.

REOCATH® FLOW MEASUREMENT TIPS

- Once the stopcock is opened, perform injection immediately. Do not let blood flow into the injection lumen.
- After the injection, close the stopcock to avoid blood from entering the injection lumen.
- Do not stop the injection or change rate of injection when the display changes from "READY" to "INJ. 03". Make sure the injection is complete by the time the countdown reads "INJ. 00". Variability or disruptions in the injection will invalidate the flow measurements and cause the display to read "REPEAT".
- The FULL 10 mL syringe must be injected. Variability in injection volume or time will cause errors and variability in measurements.



On the left, an antegrade catheter (6 F, 35 cm length) is shown inserted into an AV access in the same direction as access flow. After injected saline is released from the catheter, a dilution thermistor, downstream at the catheter tip, measures the temperature of blood, diluted by the injected saline. On the right, a retrograde catheter (6 F, 48 cm length) is likewise inserted into an AV access, but against the direction of access flow. After injected saline is released from the tip of the catheter, a proximal dilution thermistor measures the temperature of the saline-diluted blood. Classic dilution equations are used to extrapolate blood flow in mL/min from the temperature changes between the saline measured by injection thermistors and the saline-diluted blood measured by the dilution thermistors.

- 11) Close the stopcock.
 - 12) The HVT100 display will change to "PROC. 21" and countdown to "PROC. 00".
 - 13) The HVT100 display will change to "CALC. 10" (at this point the HVT100 is calculating the flow) and then will countdown to "CALC 00".
- NOTE:** At some point during the CALC. process, the display may pause momentarily (this is normal).
- 14) Blood flow will be displayed in mL/min on the HVT100.
 - a) If there was a problem with the injection, the display will read "REPEAT". Repeat the measurement from Step 7.
 - 15) Repeat steps 7-12 above, an additional one to two times to ensure the reproducibility of the first measurement.
 - 16) Remove the catheter from the introducer and keep it in the sterile field if more measurements are to be performed.
 - 17) Dispose of catheter according to standard hospital procedures.
 - 18) The HVT100 and extension cable can be cleaned with alcohol.

CAUTION

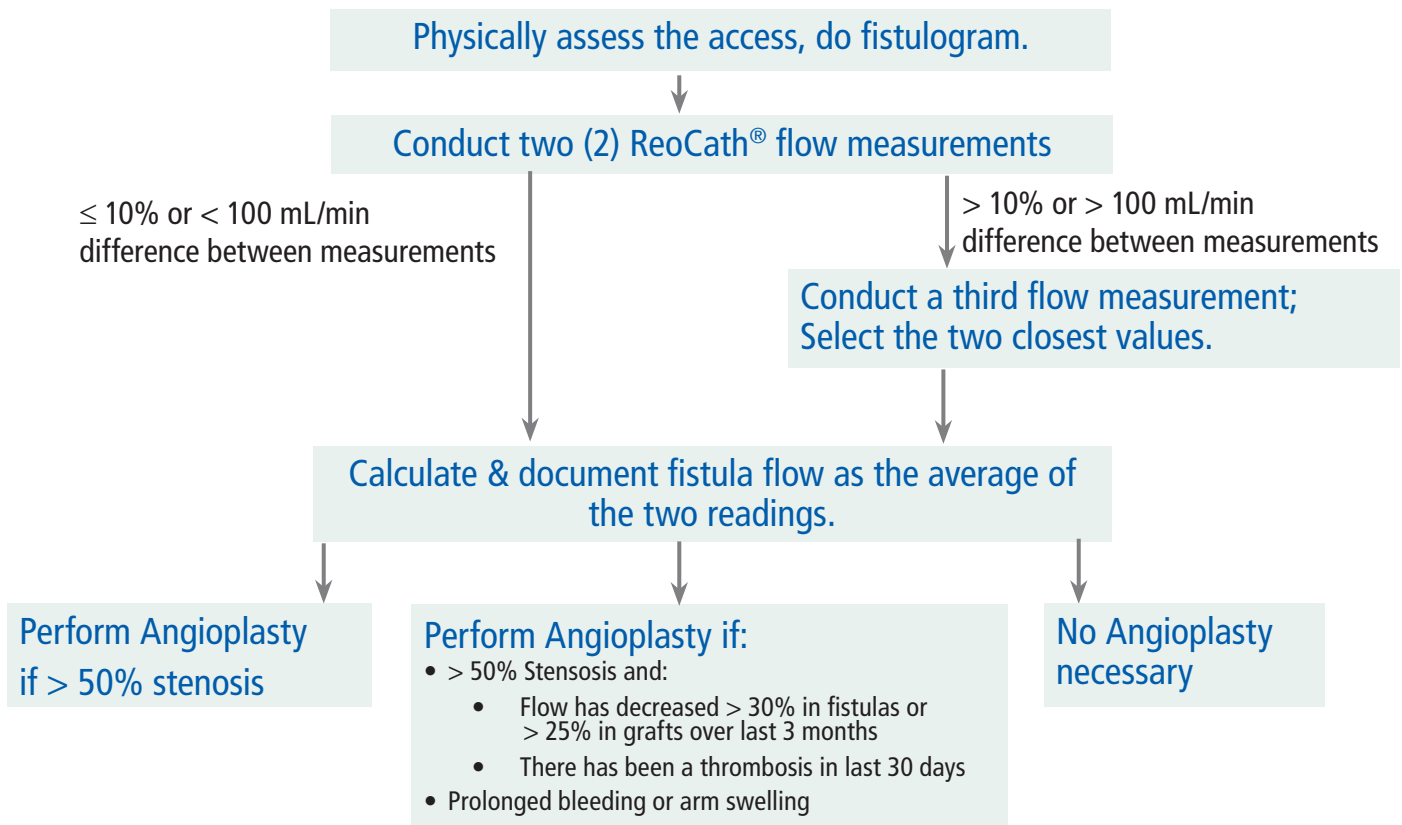
A ReoCath® Flow Catheter is pre-sterilized and intended for single patient use. Do not re-use or re-sterilize.

ReoCath® Flow Measurement Protocol

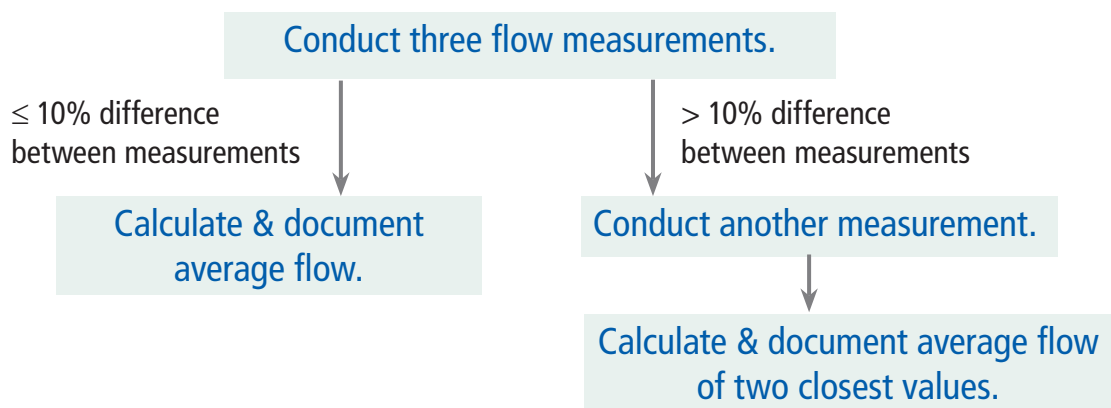
PRE-INTERVENTION

Pre-intervention Notes:

1. Do not cross a stenosis with the catheter.
2. Avoid catheter tip placement near side branches or within an aneurysm.



POST-INTERVENTION



Post-intervention Notes:

1. A progressive decline in observed blood flow values may be due to elastic recoil of the stenosis. Wait 5 minutes and repeat the fistulogram.
2. A progressive increase in blood flow values may be due to relaxation of spasm. Wait 2-3 minutes and repeat blood flow measurement.

Medical Note

MILLER Banding: Minimally Invasive Limited Ligation Endoluminal-assisted Revision

Courtesy of G. A. Miller, M.D., American Vascular Access, Brooklyn, NY

Two conditions create the need to increase venous outflow resistance in an arteriovenous fistula (AVF) used to deliver hemodialysis.

STEAL SYNDROME: Peripheral ischemic symptoms from hypoperfusion distal to the hemodialysis access due to the access diverting flow from the periphery.

HIGH FLOW ACCESS: As an AV fistula ages, high flow (~>2 L/min) can develop which can lead to high flow access problems including:

- Post-dialysis bleeding
- Elevated venous pressures
- Pathologically accelerated access growth
- Cardiac overload

FISTULA BANDING

A high resistance band is used in both instances to correct steal or high flow in pathological accesses by restoration of sufficient distal flow and perfusion. With accesses that have induced symptoms of steal, it is critical to balance the demands of the access with restoration of sufficient flow to alleviate the steal symptoms. For a high flow access, the diameter of the band must also be precisely controlled as not to induce thrombosis.

MILLER BANDING

The MILLER procedure uses an inflated angioplasty balloon as a sizing dowel inside an access as a ligature is tightened around the outside of an access. The band restricts flow through the access to improve distal perfusion and alleviate symptoms.

PRE-INTERVENTION: Patients are examined and categorized as "Steal" or "High Flow" according to their symptoms and the physical examination.

1. ANGIOGRAPHIC/PRE-BANDING INTERVENTIONS

A 21-g microaccess needle and catheter with intravenous contrast are introduced into the access to identify any outflow obstruction. A 5F vascular sheath, guide wire and Bernstein catheter are used to access the inflow artery for arterial imaging. With the catheter in the feeding artery, extremity imaging is performed. A pre-procedure flow measurement with a Transonic® Endovascular Flowmeter and ReoCath® Flow Catheter measures access flow. Steal patients also undergo an upper arm extremity arteriogram.

2. BANDING SITE IDENTIFIED

The arm is palpated to locate a banding site as close to the AV anastomosis as possible (1-3 cm), yet superficial enough to allow for easy dissection.

3. DISSECTION

Under local anesthesia, two parallel lateral 0.5 cm incisions are made. A peri-access tunnel is dissected subcutaneously under the access, using Kelly clamp blunt dissection.

4. BANDING

A 2-0 mono filament Prolene ligature is pulled under the access. The suture is then looped over the access (under the skin) using a Kelly clamp. An angioplasty balloon is inflated to 18 atmospheres of pressure in the area encircled by the suture loop.

Note: Balloon sizing is critical to the procedure's success. In steal patients, the band should be equal or smaller than the size of the downstream artery to ensure that access resistance is significantly increased with respect to the resistance of the downstream artery. In high flow patients, the diameter of the access lumen must be reduced by 60-80% in order to significantly affect flow, (per Murray).

The ligature is then tightened around the balloon until there is no flow in the access. The ligature is secured, the balloon is deflated and removed, and flow is restored in the access.

5. PROCEDURE COMPLETION/MODIFICATIONS

Immediately after banding, flow measurements are performed to quantify the flow reduction. The access is palpated to assess flow. If flow is too sluggish, a balloon with a diameter 1 mm larger is used to stretch the band. If a patient reports no symptomatic improvement and angiographic evidence of steal persists, the procedure is repeated with a second ligature (using a balloon with a diameter 1 mm less than the first).

Thermal Dilution Technology

HVT100 Endovascular Flowmeter Principle of Operation

Principle of Operation

The HVT100 Endovascular Flowmeter and ReoCath® Flow Catheter system (Fig. 2) uses classical dilution-based equations for flow measurements adapted to the unique hemodynamic conditions that exist within an arterio-venous (AV) access.

Intra-access blood flow measurements obtained using the HVT100 Endovascular Flowmeter are based upon the following equation:

$$Q = k (T_b - T_i) V / S - 0.5 V/t$$

Where:

- Q = intra-access blood flow;
- k = a coefficient related to the thermal properties of blood, saline = 1.08
- T_b = temperature of the blood prior to injection;
- T_i = temperature of injected saline;
- V = volume of injected saline (10 mL);
- S = the area under the temperature-time dilution curve resulting from the mixing of blood and injected saline;
- t = width of the dilution curve at 50% height (Fig. 1).

The expression (0.5V/t) is an average expected increase in blood flow due to the saline injection.

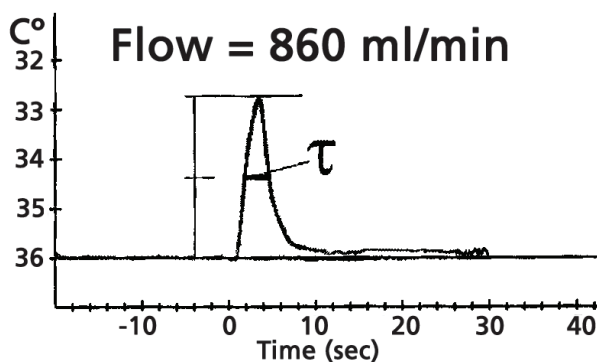
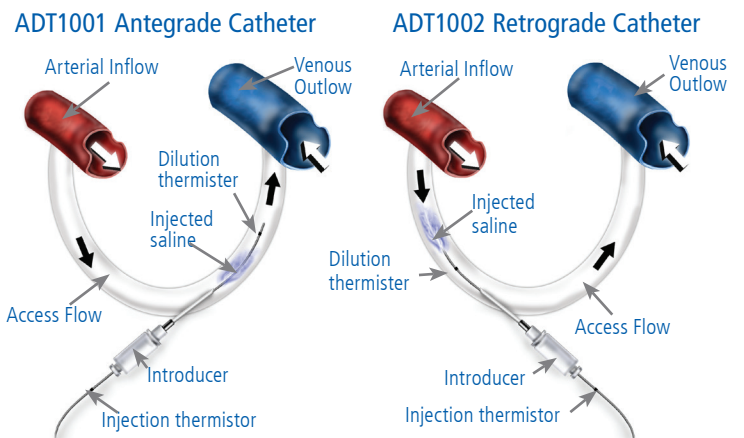


Fig. 1: Example of thermal dilution curve generated by the change in temperature between isotonic saline injected into the AV access and the diluted temperature registered by the catheter thermistor within the access.



Fig. 2: HVT100 Endovascular Flowmeter, extension cable and ReoCath® Antegrade Catheter.

The HVT100 Endovascular Flowmeter & ReoCath® Flow Catheters measure intragraft blood flow in the arteriovenous (AV) vascular access to provide quantitative information about access functionality during an interventional procedure.



The left ADT1001 antegrade catheter (6F, 35 cm length) inserts into an AV access in the same direction as access flow. After injected saline is released from the catheter, a dilution thermistor, downstream at the catheter tip, measures the temperature of blood, diluted by the injected saline. The right ADT1002 retrograde catheter (6F, 48 cm length) is inserted into an AV access against the direction of access flow. After injected saline is released from the tip of the catheter, a proximal dilution thermistor measures the temperature of the saline-diluted blood. Classic dilution equations are used to extrapolate blood flow in mL/min from the temperature changes between the saline measured by injection thermistors and the saline-diluted blood measured by the dilution thermistors.

Flow-guided MILLER Banding Cont.

FLOW MEASUREMENT PROTOCOL

Pre-procedure:

- Patients have physical examination and designated "Steal" or "High Flow"
- Inflow artery imaged
- Extremity imaged; Steal: upper arm imaged
- Intra-access ReoCath® flow measurement
- Banding site identified through palpation

1. Dissection: two parallel lateral 0.5 cm incisions are made; a peri-access tunnel is dissected subcutaneously under the access.

2. 2-0 mono filament Prolene ligature pulled under the access. The suture is then looped over the access (under the skin).

3. An angioplasty balloon is inflated to 18 atmospheres of pressure in the area encircled by the suture loop.

4. Band tightened & secured.

5. Balloon deflated & removed. Flow restored.

6. Intra-access Flow measured and quantified with ReoCath®.

7. Post-banding: access palpated to assess flow.

- If flow sluggish, a larger balloon is used to stretch the band.
- If no alleviation of symptoms, and steal persists, the procedure is repeated with a smaller second ligature.

EQUIPMENT



HVT100 Endovascular Flowmeter, extension cable and ReoCath® 6 F Antegrade Flow Catheter.

REOCATH® FLOW MEASUREMENT TIPS

- Once the stopcock is opened, perform injection immediately. Do not let blood flow into the injection lumen.
- After the injection, close the stopcock to avoid blood from entering the injection lumen.
- Do not stop the injection or change rate of injection when the display changes from "READY" to "INJ. 03". Make sure the injection is complete by the time the countdown reads "INJ. 00". Variability or disruptions in the injection will invalidate the flow measurements and cause the display to read "REPEAT".
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References:

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Publication Brief: (IR9785A Leontiev, Trerotola)

Catheter-based Intraaccess Blood Flow Measurement as a Problem-solving Tool in Hemodialysis Access Intervention

PURPOSE

To investigate the use of catheter-based intraaccess blood flow measurements as a problem solving tool in hemodialysis access interventions by identifying how measurements affected the chosen course of action.

STUDY

One hundred four (104) catheter-based flow measurements were performed from a total of 1,540 dialysis interventions performed between January 2009 and August 2011. A 600 mL/min flow rate threshold generally prompted intervention, with some variation. Blood flow was measured in the following:

ACCESS INTERVENTIONS	<i>n</i>	<i>n</i> PATIENTS	GENDER	TYPE OF FISTULA	THROMBOSED ACCESSES
Fistulas	50	55	36 male, 19 female	24 = upper arm transposed basilic vein 20 = upper arm brachiocephalic 11 = forearm radiocephalic	3
Grafts	34	31	14 male 17 female	N/A	12
Total)	104 (6.7%)	86	50 male 36 female	N/A	15

RESULTS

Flow measurements helped determine hemodynamic significance and influenced decision to treat in the following:

INDICATION FOR INTRAGRAFT FLOW MEASUREMENTS						
ACCESS TYPE	FISTULA INFLOW STENOSIS	NON-INFLOW LESIONS	NO VISIBLE LESION	HIGH FLOW CARDIAC RISK IN ANEURYSMAL FISTULAS	SUBOPTIMAL INFLOW EVALUATION	SUBOPTIMAL PHYSICAL EXAM
Fistulas	25 (4 interventions)	10	17	13	8	6
Grafts	N/A	23		N/A		

Flow measurements supported decisions to perform angioplasty (n = 11) or stent placement (n = 3) in 17% of fistula interventions and 35% of graft interventions.

CONCLUSION

Flow measurements helped in the decisions not to further treat a stenosis where it had demonstrated some clinical indication. Thus, angioplasty was avoided in 83% AV fistula patients (29 of 35) and 65% AV graft patients (15 of 23).

TAKE HOME POINTS

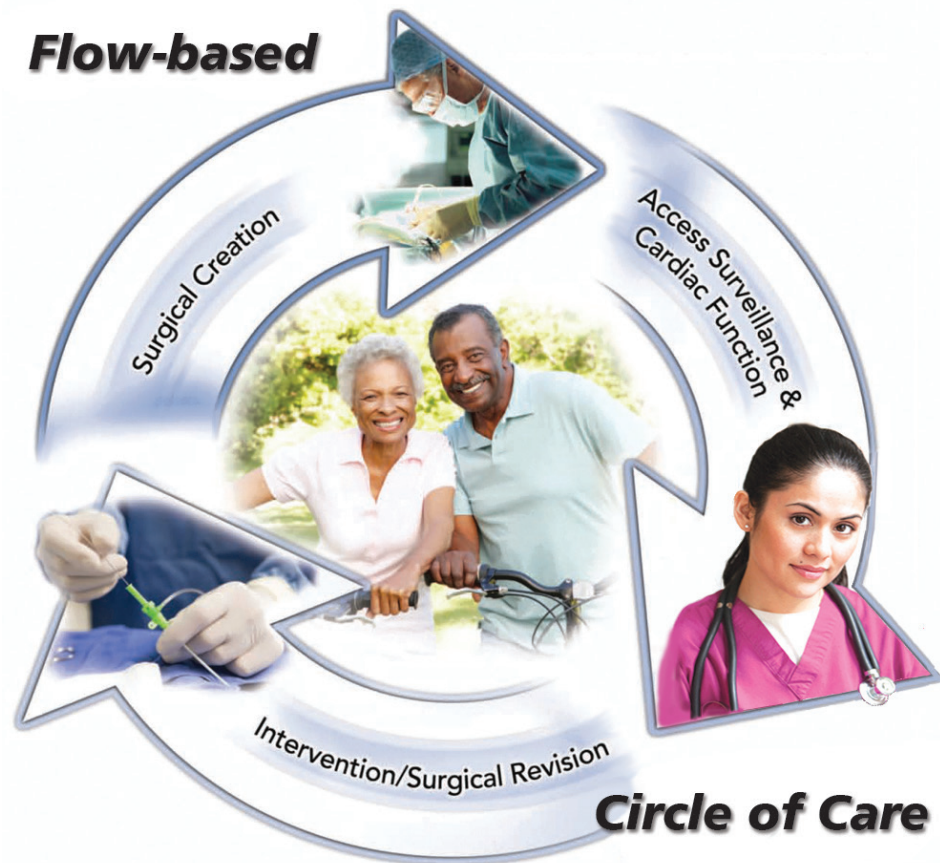
- **Study used intragraft flow measurements as a real-time problem solving tool.**
- Study demonstrated the use of flow measurements to support decisions not to treat significant appearing lesions.
- Fewer angioplasties translate into potential cost savings; less patient morbidity and improved outcomes.
- Intragraft flow measurements provide useful information to referring providers for patients with difficult punctures, aneurysms and in patients with stents where it is impossible to palpate a THRILL.

Reference:

Leontiev O, Mondschein JJ, Dagli MS, Clark TW, Soulen MC, Stavropoulos SW, Farrelly C, Shlansky-Goldberg RD, Trerotola SO. Catheter-based Intraaccess Blood Flow Measurement as a Problem-solving Tool in Hemodialysis Access Intervention. J Vasc Interv Radiol. 2013 May;24(5):717-21. (Transonic Reference # IR9785A)



Vascular Access Management "A Circle of Care[®]"



Proactive vascular access management depends upon a trio of Transonic[®] flow measurements that guide the surgeon, the nephrologist and the interventionalist throughout the natural history of a vascular access.

- Surgical creation of AV access: Transit-time ultrasound (intraoperative) flow measurements foretell successful maturation.
- During hemodialysis: Transonic[®] ultrasound dilution measurements provide ongoing surveillance and trending to detect development of hemodynamically significant stenoses.
- Intervention/Revision: When an access problem is identified, intragraft flow measurements guide the interventional radiologist during percutaneous transluminal angioplasty (PTA). Intraoperative flow measurements guide surgical revisions to resolve complications such as "steal" syndrome.

Vascular Access Management

AV Access Creation, Surveillance

Access Creation: Intraoperative Blood Flow Measurements

The Centers for Medicare and Medicaid Services (CMS) Fistula First Break-through Initiative's success has transformed the hemodialysis access in the United States from a "graft-oriented culture" to a "fistula-oriented culture." Since 2012 more than 60% of American hemodialysis patients have AV fistulas.¹ Yet, the number of fistulas that do not mature (estimated to be between 28-50%)² continues to confound and challenge the hemodialysis care provider.

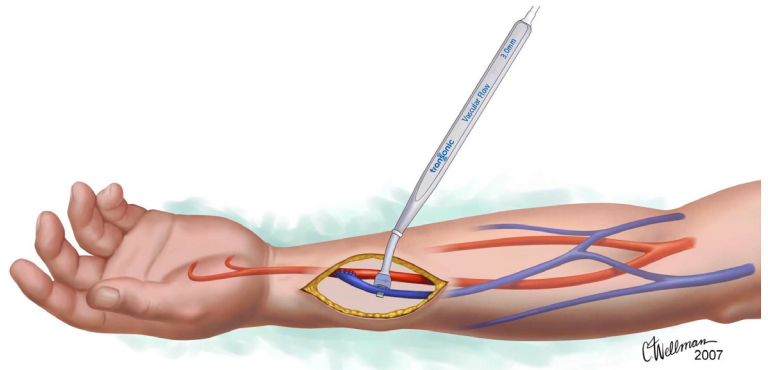


Fig. 1: Measuring arteriovenous (AV) fistula venous outflow with Transonic® Perivascular Flowprobe.

In his landmark 1998 study in *Surgery*, Johnson *et al* reported that for an AV fistula to mature, a venous outflow equal or greater than 100 mL/min at its creation is advised. For an AV prosthetic graft, an initial venous outflow of less than 250 mL/min is associated with a higher rate of initial graft failure.³ As the access matures and arterializes, flow generally increases to levels needed for hemodialysis (greater than 500 mL/min). To ensure adequate flow for hemodialysis, Transonic® intraoperative blood flow measurements provide the surgeon with quantitative flow values during creation of the access (Fig. 1). Johnson and others report that intraoperative blood flow rates at access creation directly correlate to access outcomes including: patency, number of interventions, and length of hospital stays.

“Adequate blood flow in peripheral hemodialysis fistulae and grafts is vital to the success of hemodialysis and to the survival of the patient. Reduction in flow ... presages failure of the access device itself. Access flow can therefore be considered a fundamental property of the access that should be monitored.”

Depner, TA et. al.

"A Circle of Care[®]"

Intervention and Revision

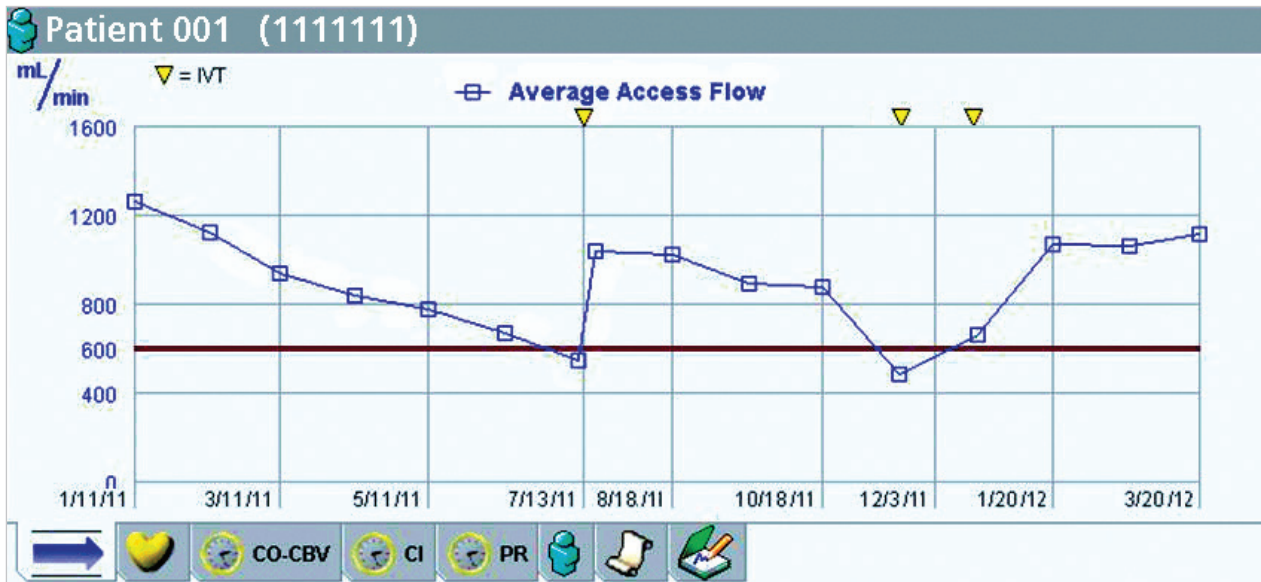


Fig. 2: Trending of vascular access flow over a one year time frame with PTA interventions noted by arrows.

Hemodialysis: Surveillance

The Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Vascular Access and the National Kidney Foundation codified Dr. Depner's advocacy of access flow monitoring by stating "prospective surveillance of AV grafts and fistulas for hemodynamically significant stenosis, when combined with correction, improves patency and decreases the incidence of thrombosis."⁵ Canadian, Australian and European Guidelines also call for surveillance during hemodialysis to forestall stenosis formation and prolong the life of the access. Intra-access measurements (ultrasound dilution technology) are cited as the preferred method for surveillance.

Transonic's ultrasound dilution technology is recognized as the "gold standard" intra-access flow measurement technology for hemodialysis patient surveillance.⁶ The method uses Transonic Flow-QC[®] Hemodialysis Monitors and Flow/dilution Sensors to directly measure dialysis adequacy (delivered blood flow, recirculation) for on-the-spot correction of problems during hemodialysis and to trend vascular access flow to detect flow limiting problems wherever they occur in a vascular access (Fig. 2). Cardiac output and associated parameters can also be measured with this technology during the dialysis treatment.

Vascular Access Revision

Intra-graft Flow Measurements

During angioplasty, a Transonic® ReoCath® Flow Catheter and Endovascular Flowmeter provide the interventionalist with immediate flow feedback (Fig. 3)⁷ for quantitative confirmation that a hemodynamically significant stenosis has been corrected or that elastic recoil has not compromised the flow correction.

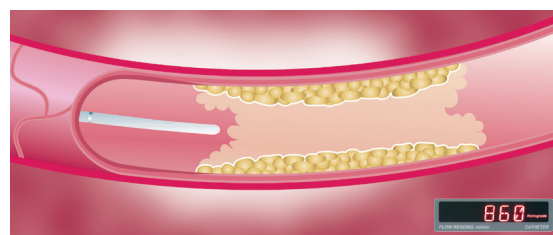


Fig. 3: ReoCath® Flow Catheter measuring intragraft flow post-angioplasty.

Intraoperative Flow Measurements

When surgery is the access revision option, intraoperative flow measurements inform during the revision. Transonic® quantitative measurements replace guesswork especially when an access needs to be banded to mitigate ischemic steal syndrome.

Conclusion

In the outcomes-driven climate of proactive end-stage renal disease (ESRD) care, Transonic® quantitative flow measurements are integral to successful and comprehensive vascular access management. During creation of the access, during hemodialysis and/or during interventions or revisions, respective Transonic® flow measurements inform and guide the surgeon, nephrologist and/or interventionalist as they seek to create and maintain a healthy access for their patients. Transonic® flow-based “Circle of Care” is a cornerstone for proactive Vascular Access Management.

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