

# Flow-Guided Percutaneous Transluminal Angioplasty (PTA) with the Transonic® ReoCath® Flow Catheter System

A vascular access is an End Stage Renal Disease (ESRD) patient's link to life. It is also the Achilles heel for hemodialysis, for if it thromboses, the consequences are dire. For dialysis delivery to continue, the access must either be repaired or replaced, or the patient must have a central venous catheter placed.

Transonic® hemodialysis surveillance detects decreasing access flows that presage access failure.<sup>1-6</sup> When surveillance is complemented by expeditious PTA to treat a stenosis, thrombosis incidences decrease.<sup>3-5</sup> Improvement in access flow defines a successful PTA intervention.<sup>7-8</sup> To enhance PTA success, the Transonic® ReoCath® Flow Catheter system measures intragraft vascular access blood flow. This novel flow measurement capability produces quantitative functional data prior to an intervention, as it unfolds and at its conclusion.

## PTA

Because PTA is generally elective rather than emergent, less invasive than surgery, and preserves future access sites, it is the intervention of choice for a failing vascular access with a hemodynamically significant stenosis. In their landmark Vanderbilt University study, McCarley *et al* reported that, when surveillance was combined with PTA, the graft thrombosis rate decreased almost fourfold, overall costs dropped by approximately 50% and catheter use declined dramatically.<sup>3</sup>

Although the consensus is that flow surveillance is a sensitive and specific predictor of stenosis,<sup>6,7</sup> a few studies have questioned its value in improving outcomes.<sup>10-12</sup> Closer scrutiny discloses that the studies reveal a failure on the part of PTA to improve flow rather than the failure of hemodialysis surveillance to detect significant reductions in flow.<sup>9</sup> Therefore, as long as PTA remains the first line of treatment for access-related stenoses, there is a need to measure access flow before and during PTA in order to improve functional success.<sup>10-12</sup>

## Intragraft Measurements

With the Transonic® ReoCath® Flow Catheter system, the interventionalist introduces a bolus injection of room temperature, isotonic saline into the access during the endovascular procedure. The system calculates intragraft blood flow from thermal changes in the injected saline.<sup>15,16</sup> The flow measurement protocol (page 2) calls for flow measurements before and after insertion of the balloon. By comparing pre-angioplasty baseline flows to post-angioplasty flows, the interventionalist obtains immediate feedback on the procedure's success. If intragraft blood flow has not increased to satisfactory levels, the balloon can be re-inserted until flow is optimized (Figs. 1, 2).

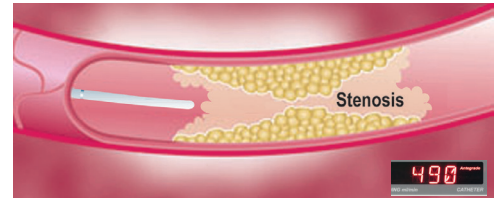


Fig. 1. ReoCath® antegrade flow catheter measuring intragraft flow before angioplasty.

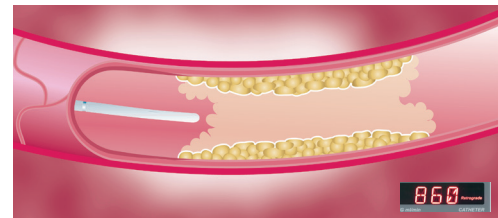


Fig. 2. ReoCath® antegrade flow catheter measuring intragraft flow after angioplasty.

## ReoCath® Flow Catheter System

The ReoCath® Flow Catheter System consists of single-use antegrade or retrograde catheter, a ReoCath® extension cable and the HVT100 Flowmeter. The catheters (Fig. 5, page 3) have an external injection port connected to a central lumen for injection of room temperature saline. Two temperature sensors are located within each catheter. One, located close to the distal tip, is used to determine the thermal dilution. The second, located close to the proximal end of the catheter, is used to measure the temperature of the injected saline solution. The catheter is connected to the HVT100 Endovascular Flowmeter via an extension cable. The Flowmeter displays blood flow in milliliters per minute (mL/min).

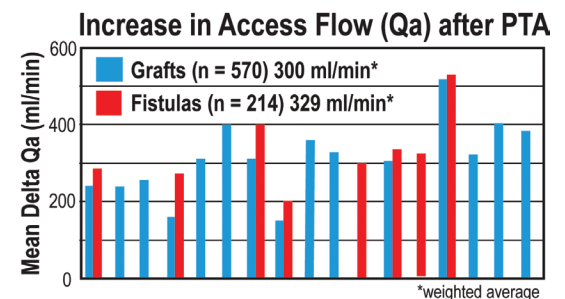


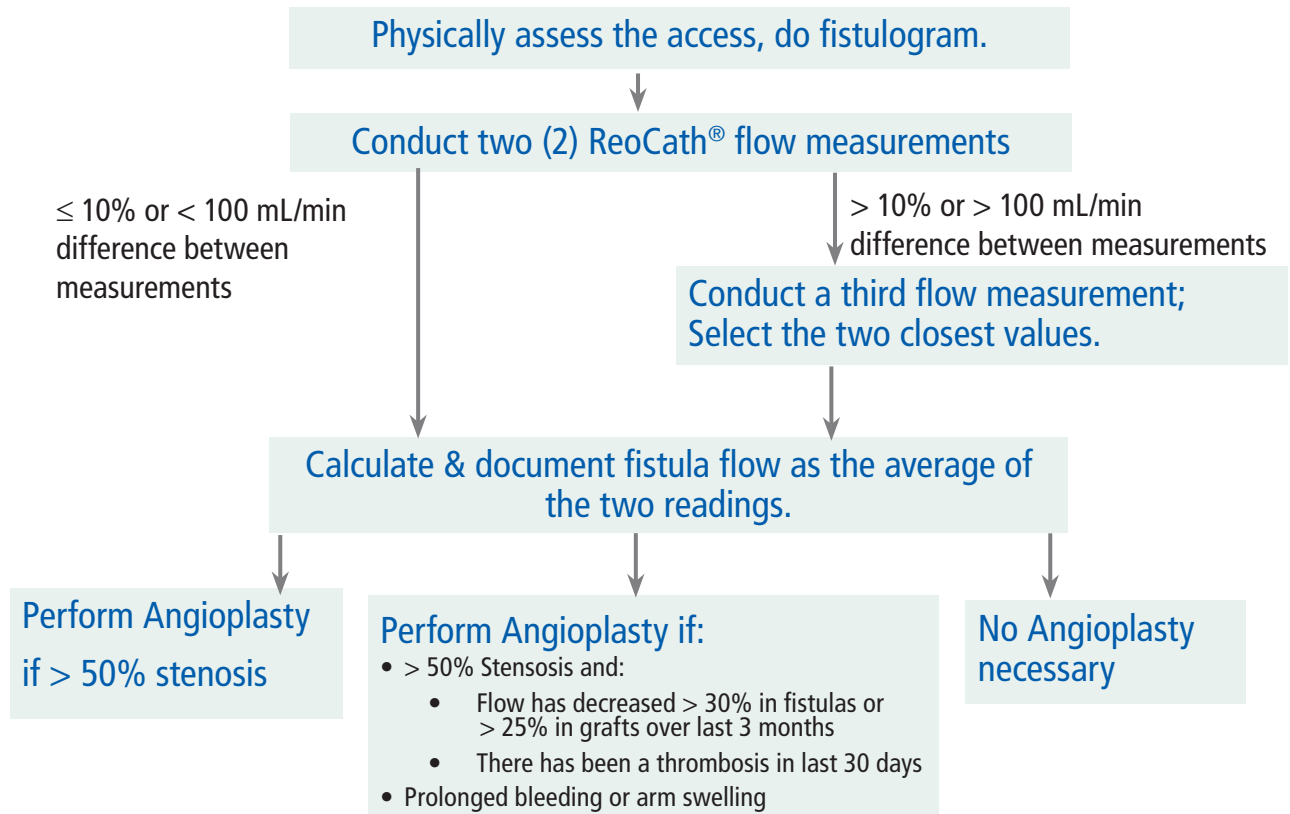
Fig. 3. Chart compiled from 17 studies that show distribution of vascular access flow increase following PTA.

# ReoCath® Flow Catheter Measurement Protocol

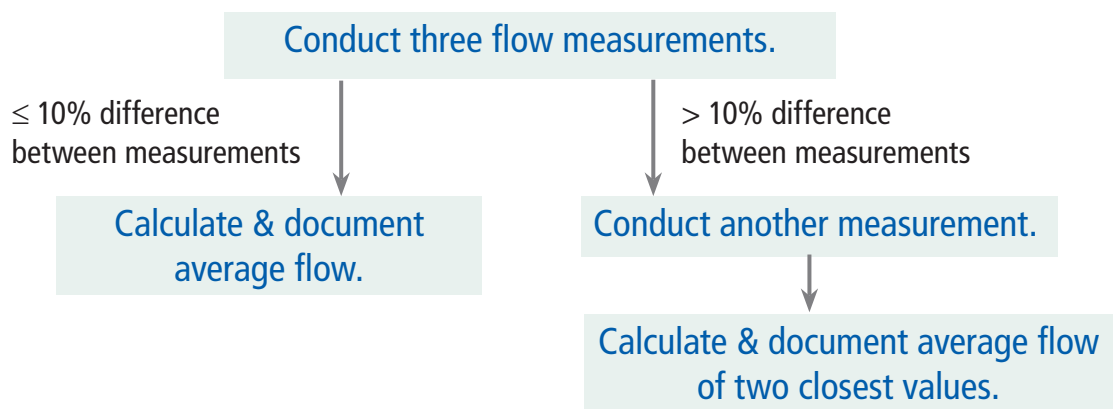
## PRE-INTERVENTION

### 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.

# Flow-Guided Percutaneous Transluminal Angioplasty

## Validation Studies

Transonic® ReoCath® Flow Catheter technology was rigorously validated *in vitro*, *in vivo* and clinically.<sup>16,17</sup> In an *in vitro* model, catheter flow was measured 397 times while water flow in the graft was increased from 150 - 1,700 mL/min.<sup>16</sup> The ReoCath® Flow Catheter and the Transonic® HT109 Volume Tubing Flowmeter measurements demonstrated excellent correlation ( $r = .98$ ). More than 60% of the ReoCath® measurements were within 5% of true flow as measured by the Flowmeter and 95% were within 15% of true flow.

*In vivo* testing in two adult ewes produced 11 ReoCath® Flow Catheter intragraft blood flow measurements that were compared to values measured with a Transonic® Perivascular Flowprobe. Again, the two measurement methodologies demonstrated excellent correlation ( $r = .99$ ).

In one prospective clinical study, intragraft measurements in 25 PTFE loop grafts with the ReoCath® Flow Catheter system were compared to pre- and post-angiography measurements with a Transonic® Hemodialysis Monitor.<sup>16</sup> Twenty grafts were forearm and five were upper arm. Fistulograms identified 40 hemodynamically significant stenoses in the 24 patients. In each of those patients, angioplasty was performed. Prior to balloon insertion, the ReoCath® Flow Catheter was inserted through a vascular sheath so that the catheter was within the graft, but had not entered its stenotic segment (Fig. 1). For each measurement, a 10 mL bolus of sterile room temperature, isotonic saline was injected into the catheter's injection port over 3-4 seconds. The results of two consecutive intragraft blood flow measurements were averaged. If the two measurements differed by more than 10%, a third measurement was taken. Sequential measurements were highly reproducible. Measurements were performed both before and immediately after angioplasty.

On an average of 11.9 days prior to angioplasty, mean vascular access blood flow in the 24 subjects was  $463 \pm 154$  mL/min as measured during dialysis. Mean intragraft flows from the ReoCath® Flow Catheter system, measured just prior to balloon insertion, were  $495 \pm 180$  mL/min. Post-angioplasty correlation between ReoCath® flows and hemodialysis measurements were  $779 \pm 331$  mL/min and  $781 \pm 221$  mL/min respectively (Fig. 4). The mean increase in vascular access blood flow following angioplasty measured by the ReoCath® system was  $324 \pm 267$  mL/min and  $319 \pm 256$  mL/min measured by the Hemodialysis Monitor 4.9 days (average) following angioplasty (Fig. 3).

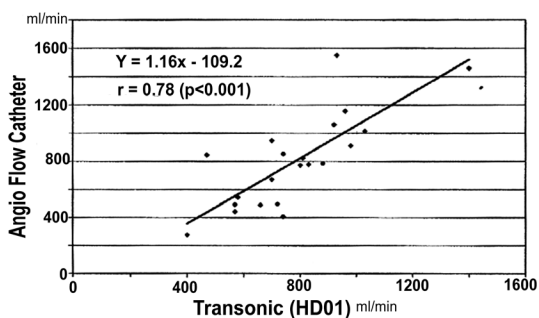


Fig. 4. Correlation of post-angioplasty blood flow measurements (Hemodialysis Monitor) with those obtained with the ReoCath® Flow Catheter system.

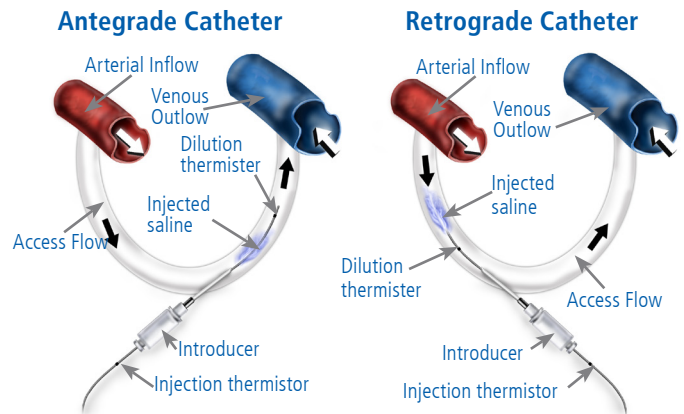


Fig. 5: On the left, an antegrade catheter (6 F, 35 cm length) is shown inserted into an AV access in the same direction as access flow. After injected saline is released from the catheter, a dilution thermister, downstream at the catheter tip, measures the temperature of blood, diluted by the injected 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 thermister 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 thermisters and the saline-diluted blood measured by the dilution thermisters.

## Interventional Success

"The measurement of access flow has also been shown to be a valuable tool in determining the success of a therapeutic intervention. Failure to increase access flow by at least 20% following an intervention reflects failure of the intervention to correct the underlying problem [208,209]."<sup>7</sup>

Murray et al reported that the level of blood flow achieved after angioplasty is predictive of subsequent graft patency. Krivitski reported that patients whose blood flow increased more than 300 ml/min during PTA also showed significant increases in flow measured during subsequent hemodialysis.<sup>18</sup> The weighted mean flow, post-PTA, from 15 graft flow studies was 309 ml/min.<sup>5,12,21-35</sup> The weighted mean flow, post-PTA, from eight fistula studies, was 329 ml/min.<sup>5,12,21</sup>

Grafts with access blood flow rates after angioplasty of less than 1 L/min are more likely to require repeat intervention, to exhibit thrombosis within the first six months, and have a lower one-year survival compared with those with access blood flow rates greater than 1 L/min.<sup>8,25,27,29-30,35</sup>

## Summary

Validation<sup>16,17</sup> and other studies<sup>8,35-39</sup> demonstrate that the Transonic® ReoCath® Flow Catheter system provides reliable, reproducible and accurate measurements of intragraft blood flows. The system measures flow throughout the entire vascular circuit including arterial inflow, intragraft flow and venous outflow. This allows an interventionalist to identify lesions wherever they occur in the circuit.<sup>16</sup> The ReoCath® Flow Catheter system is useful in determining whether PTA is necessary, quantifying improvements in intragraft blood flow as a result of PTA, and in guiding endovascular adjustments when flows do not increase to satisfactory levels.

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\*Numbers in parentheses ( ) are Transonic References #s.



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