

# Cath Lab Digest

A Product, News and Clinical Update for the Cardiac Catheterization Laboratory Specialist

October 2004

Volume 12, Number 10



Left to right, front to back: Ben Glorioso, Brenda Shortt, Jason Rogers, Steve Rodriguez, Tom Forrester, Eva DeLeo, Teresa Cannon, Marsha Lang, Bob Roper, Viet Do, Sage Loebs, Kevin Vierra

## CATH LAB SPOTLIGHT

### Sutter Medical Center - Sacramento

Brenda McCulloch RN MSN, Cardiovascular Clinical Nurse Specialist, Carol Prinzo RN, Cath Lab Director, and Margaret Mette RN MN, Assistant Administrator, Sacramento, California

**S**utter Medical Center, located in California's capital city Sacramento, is a 550-bed, two-campus, tertiary care facility that serves patients throughout the greater Sacramento-Sierra region.

Sutter is proud of our many cardiovascular "firsts" in the greater Sacramento region: First successful open heart surgery on adults and children, first heart transplant, first coronary angioplasty, first electrophysiology study, first transmyocardial laser revascularization, first minimally invasive coronary bypass surgery, first extracorporeal membrane oxygenation (ECMO) and treatment with nitric oxide to newborns with lung dysfunction,

See SPOTLIGHT, page 22



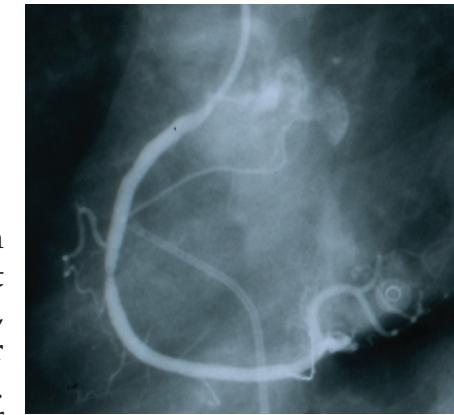
**HMP COMMUNICATIONS**  
**cathlabdigest.com**

## CLINICAL UPDATE

### Non-invasive Testing is Not Specific Enough:

*Why and How to Obtain Objective Signs of Ischemia in the Cath Lab*

**Nico H.J. Pijls, MD, PhD**  
Department of Cardiology  
Catharina Hospital  
Eindhoven, The Netherlands



Why do we need an invasive assessment of ischemia? In effect, this question can be further divided into two questions: 1. Do we need assessment of ischemia, and if we do; 2. How is functional information about ischemia obtained? Why should it be invasive?

#### Question 1.: Do we need assessment of ischemia?

Let's start with two provocative examples.

See INVASIVE ASSESSMENT, page 12

## OFF-SITE OPEN HEART BACKUP

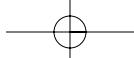
### Cardiovascular Laboratory Performance Improvement:

*A 27-Month Angioplasty Program Evaluation*

Submitted by Jill Price RN,  
Head Nurse Cardiovascular  
Lab/Cardiology  
Governor Juan F. Luis  
Hospital and Medical Center  
St. Croix, United States  
Virgin Islands



See PERFORMANCE IMPROVEMENT, page 6

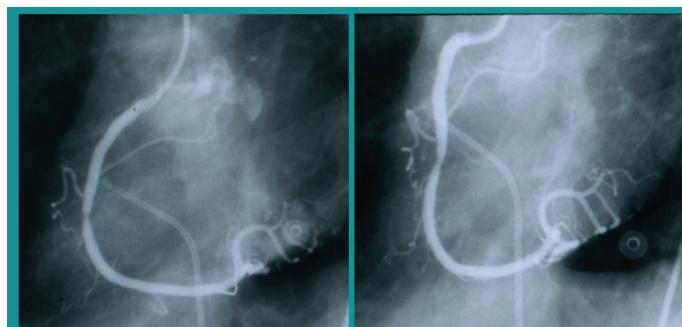

**ISCHEMIA: INVASIVE ASSESSMENT**  
 Continued from page 1

**Case No. 1.** Figure 1 is from a live case. It was in a famous course earlier this year, and shows a female, 58 years old, who had PCI of a severe left circumflex stenosis. The physicians accidentally found a 50% stenosis in the mid-RCA. They measured fractional flow reserve (FFR) which was 0.87, and did intravascular ultrasound (IVUS), which revealed an area of about 7 square millimeters. Ultimately, they chose to place a Taxus stent.

Now, why did they do that? Didn't they know about evidence-based medicine? Actually, this physician was a famous interventionist, but nevertheless, couldn't resist placing the stent, probably based upon the opinion that every plaque is dangerous.

If we really adhere to evidence-based medicine, we should conclude that this lesion is functionally not significant, based upon the fractional flow reserve of 0.87. The evidence-based literature shows that if we do not stent such a stenosis and just treat it with aspirin and statins, the combined mortality and myocardial infarction rate due to that plaque is only 1% per year for the next five years! (DEFER study).<sup>1</sup>

In contrast, the TAXUS IV study demonstrated that if you place a Taxus stent in that RCA stenosis, the combined mortality and infarction rate is more than 4% in the next nine months.<sup>2</sup> Admittedly, the restenosis rate will be low, but the mortality and infarction rate is still much higher than in case of medical treatment. There was a similar study in *Circulation* recently about experience with the Cypher stent, giving about the same data.<sup>3</sup> So, after all we must conclude that there was no reason at all for the physician to place a stent in the mid-RCA stenosis, and that both costs and risk of complications were



- Female, 58-y-old, PCI of severe LCX lesion
- 50% stenosis in mid-RCA
- FFR 0.87
- IVUS 6.9 mm<sup>2</sup>

→ Taxol stent !!! → WHY ??? Figure 1

! non-culprit lesions do generally not need to be treated !

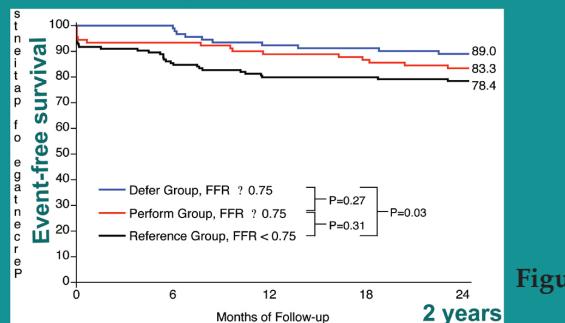
**The DEFER Study: 2 year Event-free Survival**


Figure 3

**Mortality / AMI per year for non-sign lesion: 1 %**  
**PCI rate per year for non-significant lesion : 4 %**

*Circulation 2001; 103:2928-34*

just increased instead of decreased by placing the stent.

**Case No. 2.** Now let's look to the other side of the same coin with a second patient (Figure 2). This is a 47-year-old male, a frenetic bike rider, with typical chest pain and positive MIBI SPECT. He had a coronary angiogram, and the physician performing the angiogram concluded there were no major abnormalities. There was some long, insignificant narrowing of the proximal left anterior descending artery (LAD), which is not very impressive. The patient was reassured, went home and was admitted again one week later, after out-of-hospital resuscitation because of cardiac arrest during exercise. At repeated angiography, the fractional flow reserve was measured and was 0.67, a clear ischemic value. So, this patient almost died because the

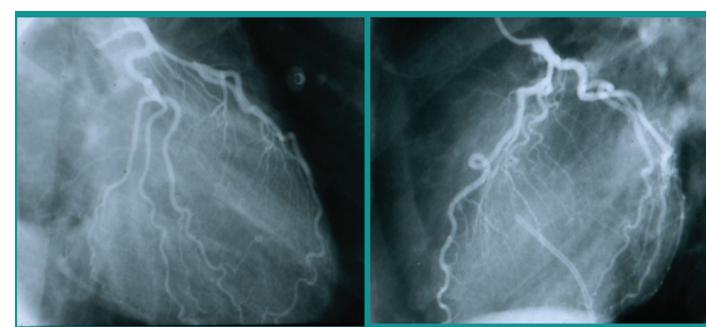
ischemic nature of the stenosis and need for subsequent interventional treatment was not recognized.

**Ischemia and CAD**

The most important factor with respect to both symptoms and outcome in patients with coronary artery disease is the presence and extent of inducible ischemia. This is not a new concept, but is something we've known for twenty years from many studies.

In a study of 12,000 patients, published in 1998, patients with ischemic lesions had a mortality and acute myocardial infarction (AMI) rate 20 times higher than patients with angiographic stenosis of identical severity but without inducible ischemia.<sup>4</sup>

In a similar way, in the invasive ACIP study, published by Davies in *Circulation* in 1997, it was convincingly demonstrated, in a prospective and randomized way, that if a particular coronary stenosis is responsible for inducible ischemia (functionally significant), percutaneous intervention of such lesion improves outcome, and that serious events during follow-up are 6 times lower than in comparable patients not treated by intervention.



- 47-year old male, fanatic byke-rider
- typical chest pain at exercise, posit MIBI
- angio: "no major abnormalities" → reassured
- cardiac arrest one week later, during exercise

→ admitted to Catharina Hospital → FFR

Figure 2

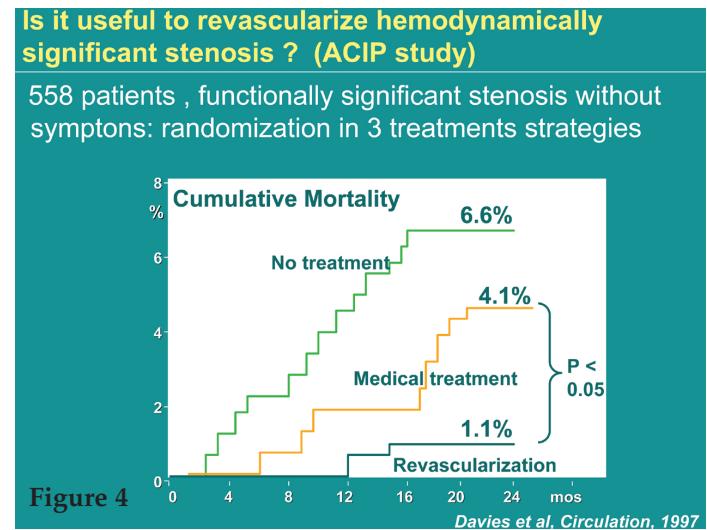


Figure 4

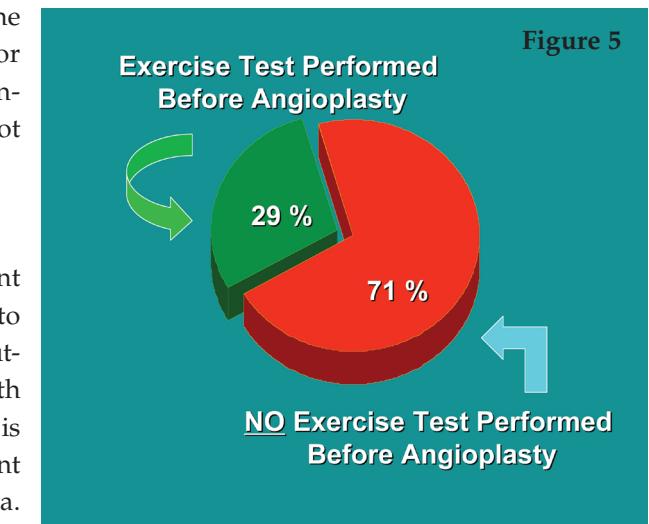


Figure 5

Therefore, there is no doubt that if a stenosis is functionally significant, interventional treatment is warranted.

On the other hand, interventional treatment of a non-significant stenosis without reversible ischemia has no symptomatic benefit, and neither does it improve outcome, as we know from the DEFER study mentioned above.<sup>1</sup> In that randomized study, half of the patients with a non-ischemic lesion got a stent and half of them did not. In the deferred group, the mortality and infarction rate was only 1% per year, the lowest of all the groups.

Total number of events, including revascularization, was only about 5% per year. This event rate compares favorably to the recent studies on

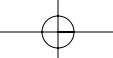
See ISCHEMIA ASSESSMENT page 14

**What is FFR?**

**Fractional flow reserve (FFR) has become the gold standard in physiologic assessment of coronary artery stenosis. This especially holds true for the functional evaluation of angiographically intermediate lesions. An FFR value of < 0.75 is considered a reliable physiologic parameter indicating a functionally significant lesion.**

Brosh D, Higano ST, Slepian MJ, et al. The Effect of Lesion Length on the Functional Significance of Coronary Lesions. *European Heart Journal* Aug 2002;4(abstr. suppl.):12.

**FFR = hyperemic Pd/Pa, where Pa is mean aortic pressure and Pd mean distal coronary pressure.**



# quick & safe

## Quick closure is good. Quick and safe closure is better.

Elite's new, advanced Micropore™ collagen expands rapidly for quick hemostasis in interventional patients.

Because there are no long-term intra-arterial components, Elite is the only vascular closure device proven safe & effective in patients with PVD.

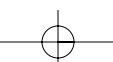
With Elite you can be confident of getting the efficacy of mechanical closure with extravascular safety.

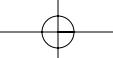
Elite™  
extravascular closure

[www.datascope.com](http://www.datascope.com)  
or call: 800.225.5827

Datascope®  
INTERVENTIONAL

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. **Indications and Contraindications:** Elite is indicated for use in sealing the femoral arterial puncture site in patients who have undergone diagnostic and interventional catheterization procedures using a 5-8 French procedural sheath and using a retrograde approach. Elite reduces time to hemostasis and ambulation in patients who have undergone diagnostic or interventional procedures. In addition, Elite reduces time to discharge in diagnostic patients receiving 5-6 French procedural sheaths. Elite is also indicated for use in reducing time to hemostasis and ambulation in interventional patients when immediate sheath removal is desired. Elite is contraindicated in patients requiring greater than a 2.5" needle to access the femoral artery. **Warnings and Precautions:** As with any foreign substance, use of VasoSeal® collagen in contaminated sites may potentiate infection. For Elite, small femoral artery size (<4mm in diameter) may prevent the locator from engaging properly. The safety and effectiveness of Elite has not been established in the following patient populations: patients receiving stents requiring post-procedure warfarin or intra-procedural abciximab; patients that are younger than 18 or older than 80 years, morbidly obese, pregnant or lactating; patients that are punctured through a vascular graft; or patients with: known allergies to beef and/or collagen products; pre-existing autoimmune diseases; bleeding disorders; antegrade or double wall punctures; hematomas (>6cm) present prior to sheath removal; elevated blood pressure not controlled with drug therapy. In the event that hemostasis is not achieved following delivery of VasoSeal® collagen, apply manual compression over the puncture site in order to achieve hemostasis. For complete details please refer to the current Elite Instructions For Use.





## ISCHEMIA: INVASIVE ASSESSMENT

Continued from page 12

drug-eluting stents.<sup>2,3</sup> Drug-eluting stents are a blessing for humanity. However, we should use them in a right way.

### The DEFER Study: PCI of Culprit vs. Non-culprit Lesions

Figure 3 shows the event-free survival rate in the DEFER study. The blue line represents deferred patients with a stenosis that was not functionally significant. The red lines are the patients with functionally non-significant stenosis treated by stenting. The black line is the control group, patients who had ischemia and who had an ischemic FFR below 0.75. Of course, at the time that the study was performed, restenosis rate was about 20% in the latter group, but this was counterbalanced by the fact that these patients previously had symptoms which were relieved by PCI.

Figure 4 shows the data from the ACIP study, indicating that if a stenosis is functionally significant, the best treatment is by coronary intervention (lower line), resulting in a serious event rate of only 1% per year - versus 6% per year if patients are untreated and 4% per year if medical treatment is instituted.

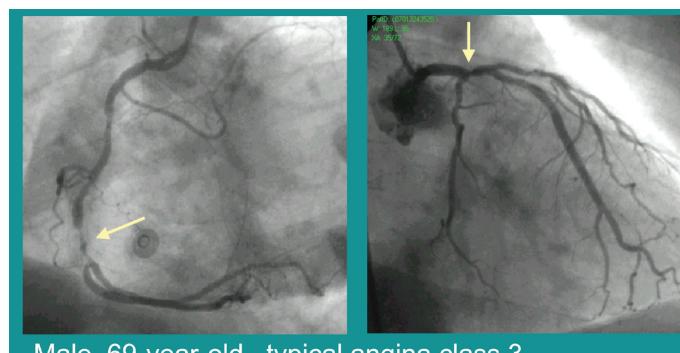
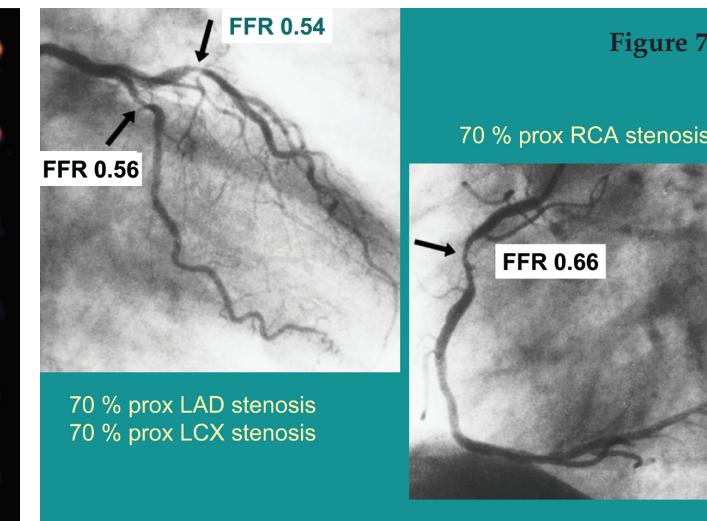
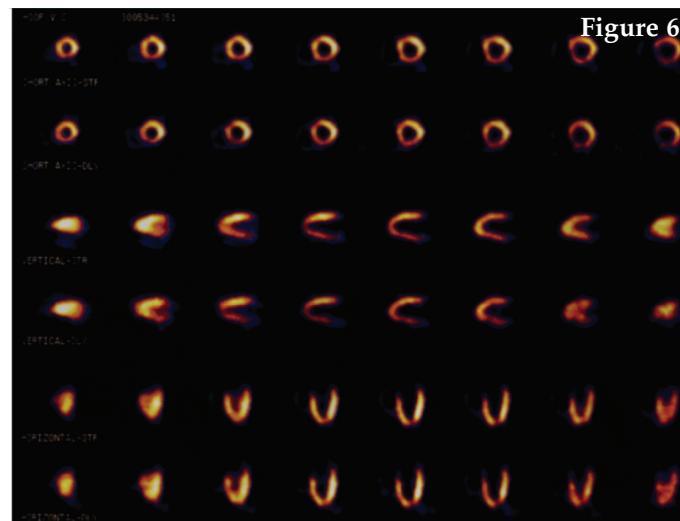
The conclusion at this point is that percutaneous coronary intervention of culprit stenosis — i.e., stenosis associated with inducible ischemia — makes sense. It improves symptoms and prognosis. However, PCI of non-culprit lesions has no benefit; neither is it supported by evidence-based medicine. It is either potentially harmful or unnecessarily expensive. Therefore, it is paramount to know if a stenosis is responsible for ischemia or not and to treat those stenoses which are.

Therefore, our first question, whether we need functional information about ischemia, can be answered unequivocally with "yes."

### Question two: How is functional information about ischemia obtained?

Why should it be invasive?

Traditionally, we know we should obtain objective signs of ischemia before having the patient in the cath lab, by exercise testing, MIBI SPECT, stress echo, etc. We also know that in true life, this is performed in only a minority of patients. Figure 5 shows that only 30% of the patients have a non-invasive test before they enter



Male, 69-year-old, typical angina class 3,  
positive Mibi-Spect inferior wall,  
Referred for intervention of severe RCA stenosis

Figure 8

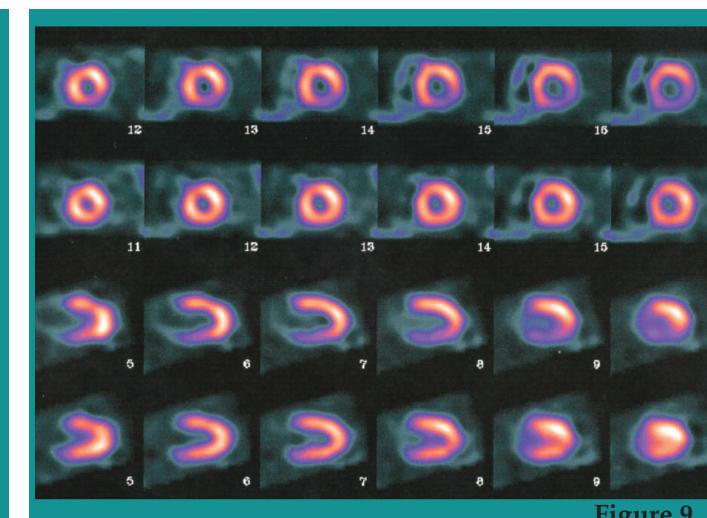


Figure 9

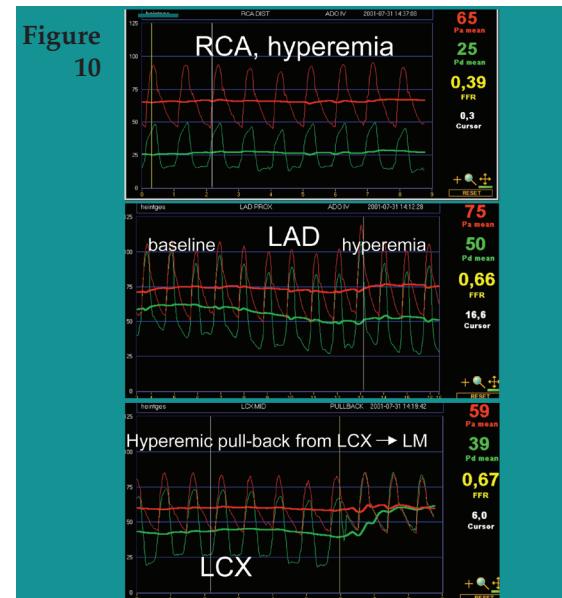
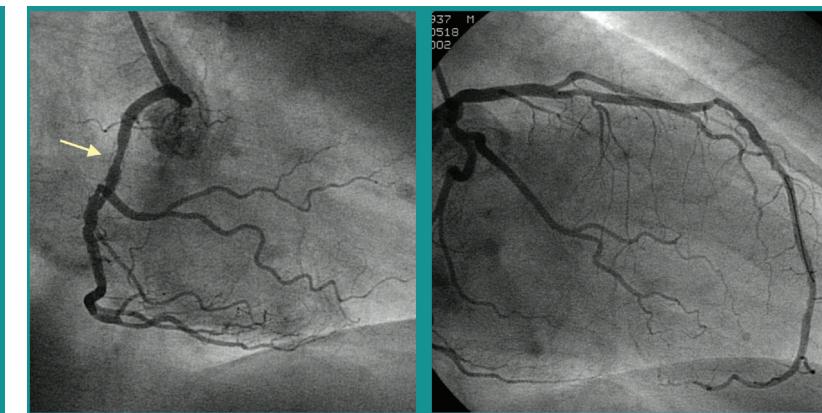


Figure 10



• male 64-year-old; stent mid-RCA 3 years earlier  
• Recurrent angina since several months  
• MIBI: reversible defect apex  
• referred for brachytherapy of RCA

Figure 11

the cath lab. This is not different for the big centers in the U.S. nor in Europe.<sup>6</sup> Only 25-30% of patients have non-invasive testing before arriving in the cath lab. Why is it such a low number of patients? The reason is that for many patients, non-invasive testing has a number of conceptual, practical and logistical limitations. This is even more the case in today's population, with its many multi-vessel disease patients.

### Limitations of Non-invasive Testing

Let's first look at some conceptual limitations of noninvasive testing. In the first place, the diagnostic accuracy is not optimal. In a paper we published in *The New England Journal of Medicine* in 1996,<sup>7</sup> we performed exer-

cise testing, a pharmacological MIBI scan, and dobutamine stress testing, all within 24 hours. We found that the reliability of an individual noninvasive test in patients with an intermediate lesion to be only in the range of 60-70%.

Secondly, the MIBI SPECT has a limited spatial resolution, especially in patients with more complex disease, which is the prominent type of patient today. Let's look at a patient with advanced three-vessel disease. Figures 6 and 7 show a male who is 53 years old, with typical class-3 angina but negative MIBI testing. This patient came to the clinic several times and was reassured several times. A MIBI was even repeated a few times. However, with what is

usually the case in these patients, he ultimately received an angiogram. Figure 6 is the MIBI SPECT of this patient. There is no difference between the resting images and the stress images. Yet when we looked at the angiogram, we were surprised to find about a 70% stenosis in all three major coronary arteries (Figure 7). This is typical of three-vessel disease.

When we measured the FFR in the LAD, we found a value of 0.54, severely depressed, and then we measured it in the circumflex (0.56) and then we measured it in the right, (0.66). In this patient, we have three areas which are ischemic, but ischemic to about a similar degree.

See ISCHEMIA ASSESSMENT page 16

# Advance With Strength and Flexibility

**FLEXOR®**

**Shuttle Select™**  
INTRODUCERS

## Carotid Access and Intervention

The new Flexor® Shuttle Select features a stiffened proximal shaft design that enables superior trackability and support for devices. Its selective feature allows the sheath to be paired with a compatible selective catheter (sold separately), minimizing the exchange of parts. Additionally, the Flexor's atraumatic tip with unique transition zone reduces vessel trauma during engagement.

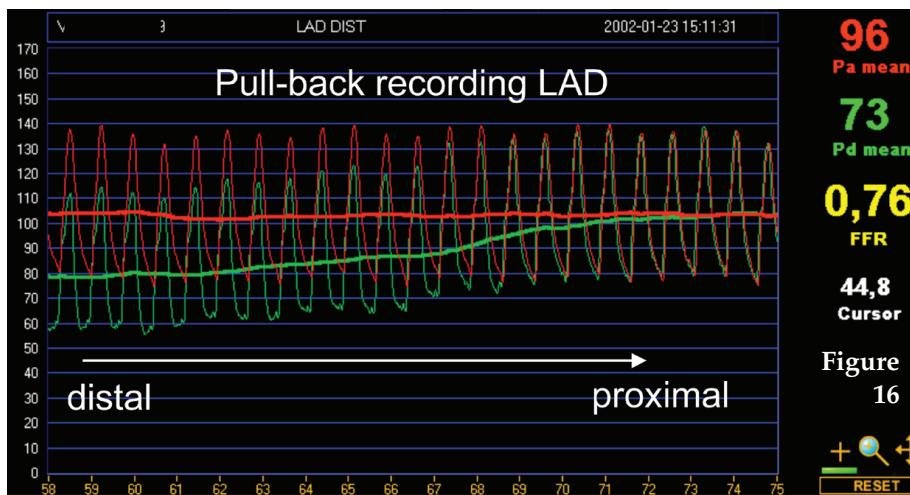
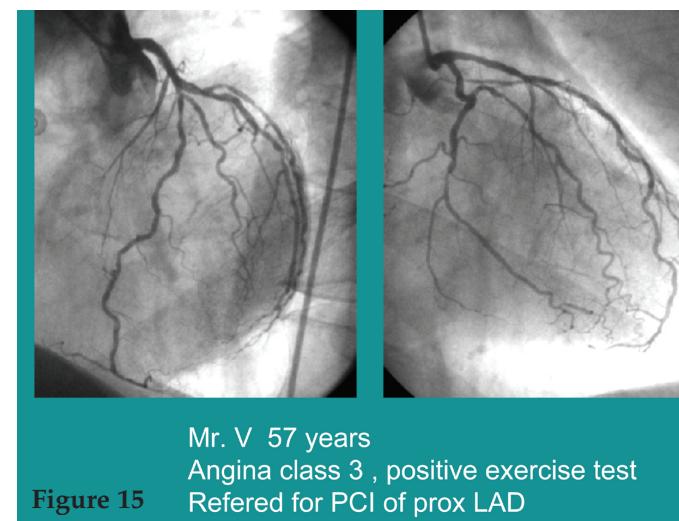
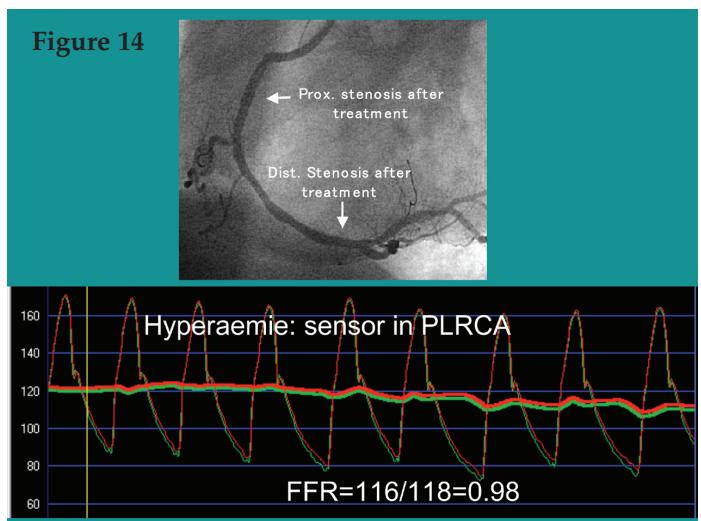
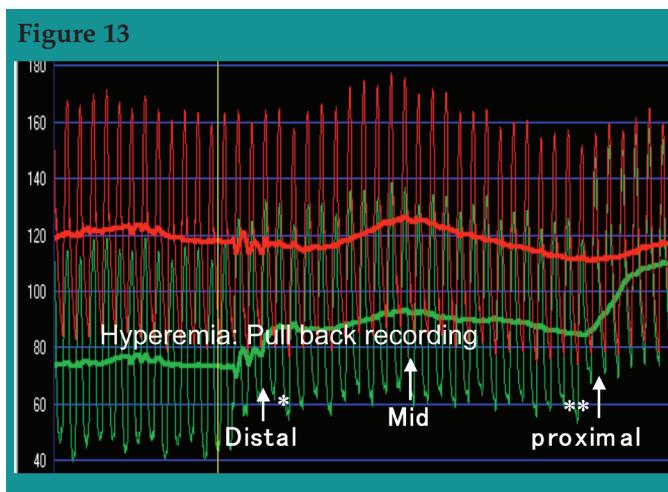
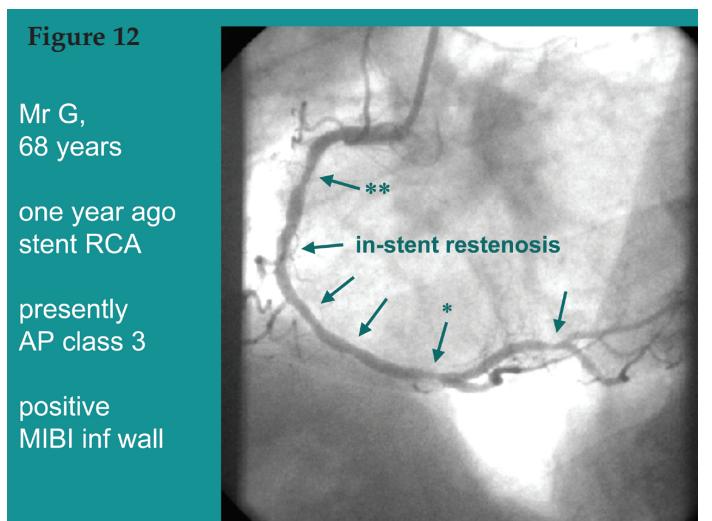
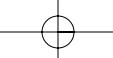
**Flexor: Advancing vascular  
intervention to a new peak.**

**COOK®**

[www.cookgroup.com](http://www.cookgroup.com)

1-800-457-4500

© COOK INCORPORATED 2004



#### ISCHEMIA: INVASIVE ASSESSMENT

Continued from page 14

MIBI did not identify the reversible defects because the areas were balanced. We know that this is a pitfall, but it has never been demonstrated so well, and we can do that with coronary pressure measurements. A group from Virginia<sup>8</sup> performed MIBI SPECT in patients with severe angiographic three-vessel disease and had a correct diagnosis in all three areas in only 10% of patients. In 18% of patients with three-vessel disease, you wouldn't see any reversible defect at all, and in about one-third of the patients, one ischemic area was detected and in another third, two ischemic areas.

There is also the problem that one ischemic area can be masked by another. Let's look at a patient: 69

years old, clear angina, and a positive exercise test with a reversible defect in the inferior wall at the MIBI SPECT. Figure 8 shows a tight stenosis in the right coronary artery, so you can imagine why the MIBI SPECT was positive in the inferior wall. Figure 9 is the MIBI of this patient, which shows a reversible defect in the inferior wall.

If you would place a stent in that stenosis, nobody would blame you. It would probably be a good clinical decision. However, if you look carefully at the angiogram, there is also a problem somewhere in the origin of the LAD, or at the end of the left main stem.

We decided to do pressure measurements and of course, in the right coronary artery, there was a very low FFR. This was not surprising. You didn't need to do pressure measurements to conclude that the stenosis in

the right coronary artery is significant. But we also looked at the left main and LAD, and found a significant gradient with further increases at hyperemia, with an FFR of 0.66 (Figure 10). This means there is a severe problem somewhere in the LAD or in the left main.

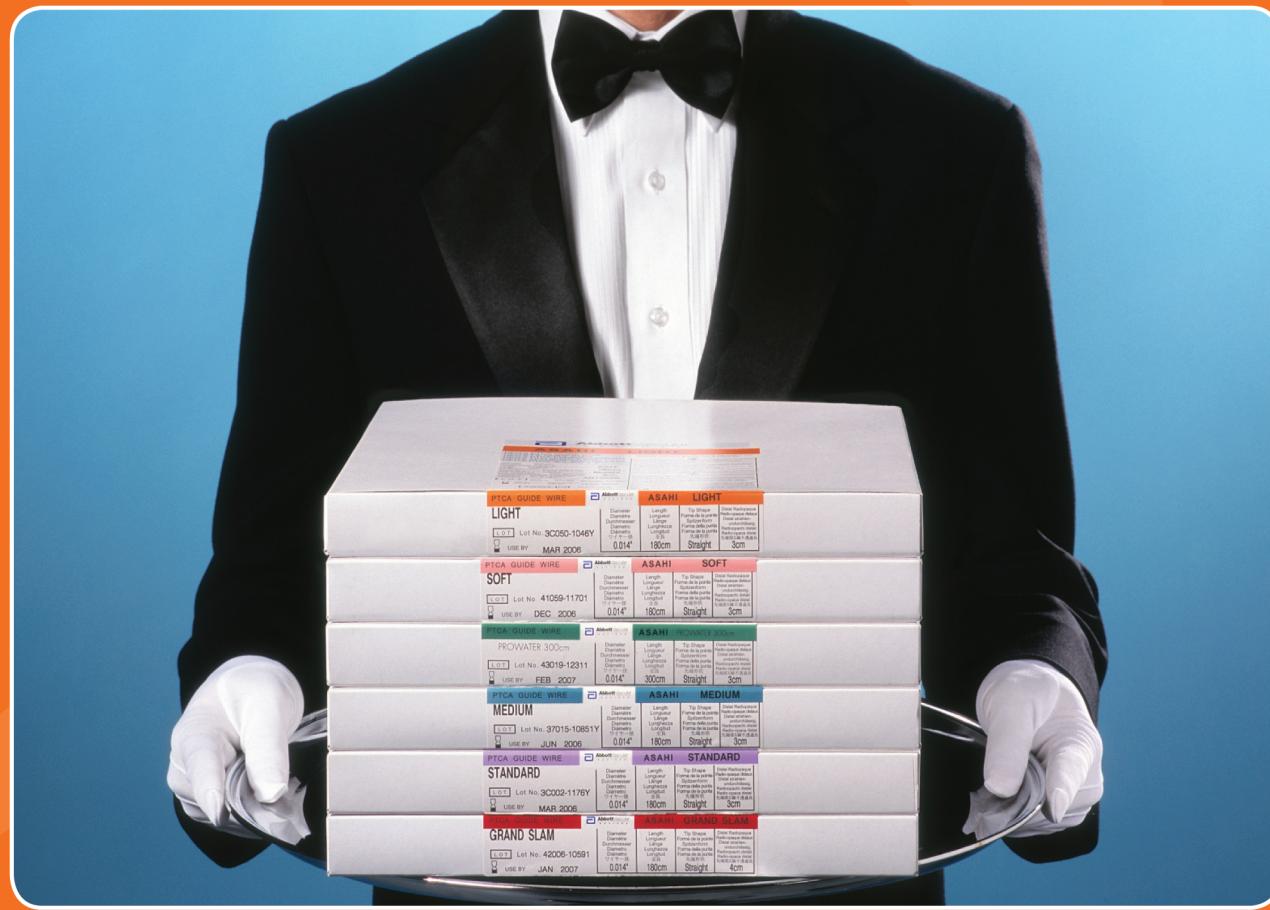
If you're not convinced yet, you could put a PressureWire® (Radi Medical Systems, Reading, MA) in the intermediate branch, and see the same low FFR. You then make the pullback and see a sudden pressure increase at the moment that the wire is crossing the end of the left main, proving unequivocally that there is a severe left main indeed (Figure 10).

In this patient, the FFR in the right coronary artery area was 0.39, and the left main 0.66, so a MIBI SPECT only revealed the ischemia in the most severe area because it is a relative measure of perfusion. The ischemia due to the left main stenosis was masked by the ischemia due to the RCA stenosis. If you would have just stented the RCA, of course the patient would have come back to your lab a couple of weeks later, telling you that he still had angina pectoris. Probably you would have thought of in-stent restenosis, done another angiogram, and there would have been intimal hyperplasia in the stent. Worst case, you would first have done

brachytherapy or placed another stent. Only after a while would you have come to the conclusion that indeed, there was something else in the coronary tree going on, and there was also a left main problem.

Another drawback of the MIBI SPECT is the uncertainty about the exact perfusion territory. Figure 11 is a male, 64 years old, who got a stent in the RCA three years earlier. He developed angina again during the past several months. He was, in fact, referred to us for brachytherapy, of the so-called "in-stent restenosis" (long-arrow). The MIBI SPECT showed reversible ischemia at the apex. If you compare the stress and the resting images, there is indeed a reversible defect at the apex. But in this patient, if you look carefully at the angiogram, you cannot tell if the positive MIBI in the apex was due to the right coronary artery or maybe to the LAD, which also has several plaques indicated by the bold arrows. FFR in the right coronary artery was 0.89, indicating that the stent in the RCA was in good shape, whereas both plaques in the LAD were significant (FFR of 0.65) and had to be stented. Such decision could never have been taken correctly without pressure measurement.

A further limitation of the MIBI SPECT is that it doesn't discriminate between epicardial and microvascular disease. Neither does it discriminate between a local stenosis and diffuse epicardial disease or between several stenosis within the same coronary artery. In many patients today, we have multiple abnormalities or diffuse disease in one artery, with a number of superimposed lesions. We can also have a combination of epicardial and microvascular disease. Figure 12 is an RCA which has numerous abnormalities. This patient has a positive MIBI in the inferior wall, but a MIBI doesn't help very much because you don't know if it's one or more of these plaques causing the positive MIBI, or whether it's the diffuse disease. The hyperemic pressure pullback recording, however, unequivocally answered all questions with respect to the multiple abnormalities in this vessel (Figure 13). During sustained maximum hyperemia, the pressure sensor is pulled back slowly while observing both the fluoroscopic screen and the pressure tracing. In this way, spots

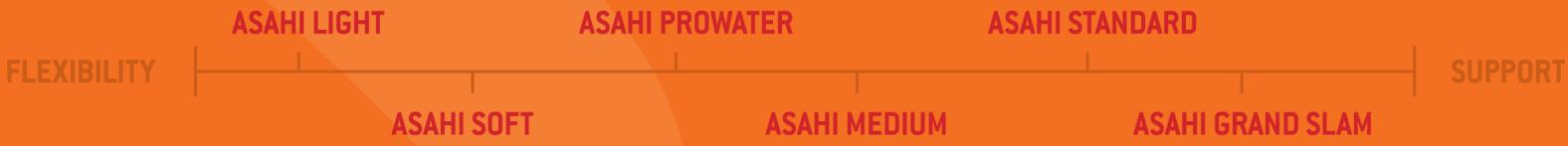


## EXTRAORDINARY WIRES FOR ORDINARY LESIONS

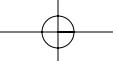
### IF YOU THINK ALL WORKHORSE WIRES FEEL THE SAME, YOU HAVEN'T FELT ASAHI.

Performance starts at the core. TruTorq™ technology provides exceptional steerability – with 1:1 torque – along with the support and pushability you need to access and treat coronary lesions. Additionally, our **single-joint spring coil** design enables smooth tracking, enhancing access to lesions while providing exceptional tactile response.

### FEEL THE DIFFERENCE, EVERY DAY, WITH ASAHI WIRES:



To set up an evaluation, contact your Abbott Vascular Devices representative. For additional information call customer service at 800-222-6883 or visit [AbbottVascularDevices.com](http://AbbottVascularDevices.com)



## ISCHEMIA: INVASIVE ASSESSMENT

*Continued from page 16*

responsible for the ischemia can be identified elegantly.<sup>9</sup> Stenting these spots, instead of the whole artery, led to a beautiful result with normalization of FFR (Figure 14). There is no other invasive or non-invasive methodology which is so accurate in terms of spatial resolution.

In the same way, if you have a patient like in Figure 15, you can do a pullback curve to tell whether you can help the patient or not. This patient also had a positive exercise test, and was sent to us with a letter and an angiogram from another hospital asking us to do a PCI of the proximal LAD. You can imagine there is something wrong in the proximal LAD, but there are at least five other

spots in the LAD where you could consider placing a stent. When you do the pressure measurement, the FFR is 0.76, so it is possible that this vessel contributed to ischemia. However, when you make the pullback, there is no sudden pressure drop (Figure 16). It is a completely diseased coronary artery. There is actually a very gradual increase in pressure when you make the pullback,

so fundamentally, you cannot help this patient by placing stents. You cannot stent a complete LAD —you are destroying all the septal branches and that doesn't make much sense.

Finally, there are some practical reasons why non-invasive testing is often not performed. It needs to be performed in another department. Often the patient has to wait a couple of days, the hospital stay will be prolonged, treatment becomes more expensive. As we have seen, many patients are encountered in the cath lab today with typical or atypical chest pain, but without objective proof of ischemia or with uncertainty about the arteries or lesions where the chest pain originates. If the complaints are typical, and there is just one focal severe stenosis, of course you do not have a problem. You can go on and stent. But frequently today, we have complex and multiple abnormalities. What to do then? Well, you could say: I send the patient back to the ward, do a MIBI SPECT and wait for the results. It means repeating an invasive procedure, with associated inconvenience and risk of costs, and that is not very attractive or practical. It often also means a prolonged hospital stay. And moreover, as we have seen, the MIBI in these patients often cannot truly identify the culprit lesions.

What options do you have in the cath lab if you want to avoid these long paths? You can say, I'm a very practical physician, I just put in a number of stents in the patient at every abnormal spot, without bothering about evidence-based medicine. If you put in one stent too many at a place where it is not necessary and man-made restenosis occurs or complications occur, it doesn't matter, because nobody blames you or knows that it wasn't necessary to stent that spot. The patient doesn't realize it and the physician often doesn't realize it either. The patient will even say, wow, this was a truly severe lesion because it came back, and insurance is paying for it anyway. Similarly, if you forget to stent a particular spot because you overlook it on the angiogram, the patient will still have complaints, and will come back to your clinic. You will treat him again. Of course it is an



### CAUTION

Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

### INDICATIONS FOR USE

ASAHI PTCA guide wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA guide wire is not to be used in the cerebral blood vessels.

### WARNINGS

- This guide wire is for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of the guide wire may be compromised and there is a risk of complications, including infection.
- Do not use the guide wire after the expiration date indicated on the label. Discard any guide wire that exceeds the expiration date.
- This guide wire must be used only by a physician who is fully trained in PTCA/PTA treatment.
- The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the guide wire may be damaged.
- Do not use a damaged guide wire. Using a damaged guide wire may result in blood vessel damage and/or inaccurate torque response. Injury to the patient may result.
- Always advance and withdraw the guide wire slowly.
- Observe guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque a guide wire without observing corresponding movement of the tip; otherwise, the guide wire may be damaged and/or vessel trauma may occur. In addition, ensure that the distal guide wire tip and its location in the vessel are visible during wire manipulations.
- Never push, auger, withdraw, or torque a guide wire that meets resistance. Torquing or pushing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation or direct damage to a vessel. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed, do not allow the tip to remain in a prolapsed position; otherwise damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.
- If any resistance is felt due to spasm or the guide wire being bent or trapped while operating the guide wire in the blood vessel or removing it, do not move or torque the guide wire. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the guide wire is moved excessively, it may break or become damaged, which may cause blood vessel injury or result in fragments being left inside the vessel.
- When torquing this guide wire inside the blood vessel, do not torque continuously in the same direction. This may cause the guide wire to become damaged or break apart, causing injury to the blood vessel or leaving fragments inside the vessel. When torquing the guide wire, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (720°) in the same direction.
- Do not push the guide wire more than is necessary to advance the tip through the narrowed part of the vessel. (For example, do not push the guide wire when the distal tip of the guide wire is bent by the force of manipulation.) After crossing the targeted area, do not roughly twist, push or pull the guide wire. If the guide wire is moved excessively, it may be damaged or break apart, which may injure the blood vessel or leave fragments inside the vessel.
- Use proper technique to ensure and verify that no air enters the interventional device when pulling the guide wire from the interventional device or re-inserting it. Otherwise air embolism could occur.
- Flush the guide wire with heparinized saline or other suitable solution while removing and reinserting it to prevent air from entering the interventional device. Perform guide wire exchanges carefully to prevent air entry and/or trauma. When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and is not against the vessel wall. Failure to do so may result in vessel trauma when the guide wire is removed. Use the radiopaque marker of the interventional device to confirm position.
- Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.
- Do not use in areas of vessel that are not or cannot be visualized.

- **For ASAHI CONFIANZA and ASAHI MIRACLEbros Series Only:**  
ASAHI CONFIANZA and ASAHI MIRACLEbros Series have stiff distal ends. Operate these guide wires carefully so as not to injure the blood vessel, observing information in these instructions. The higher torque performance, stiffer ends, and/or higher advancement force may present a higher risk of perforation or injury than if using a more flexible guide wire. Therefore, use the most flexible guide wire that will treat the lesion (i.e., the guide wire with the smallest flexibility number that will treat the lesion), and take due care to minimize the risk of perforation or other damage to blood vessels.

### FOR ALL GUIDE WIRES:

**Use the most suitable guide wire that will treat the lesion.** There are patient risks when using any guide wire including those that may result from damage to, or breakage of, the guide wire. If guide wire damage or breakage occurs, it may cause damage to the vessel and injury to the patient, or death. Accordingly, care should be taken that all persons who operate guide wires are properly trained in their use, that they observe proper technique, and that guide wires are used carefully in accordance with the Instructions for Use.

### ADVERSE EVENTS OF GUIDE WIRE USE INCLUDE, BUT ARE NOT LIMITED TO:

- Failure to cross a lesion
- Separation or breakage of the guide wire
- Damage to a vessel, including possible vessel perforation
- Coronary artery dissection
- Cardiac tamponade due to coronary artery perforation
- Air embolism
- Infection
- Coronary artery spasm
- Coronary artery thrombus
- Hematoma at puncture site
- Cardiac perforation

### PRECAUTIONS

- If the package is opened or damaged, do not use the product. Do not open the package until just prior to use. Use aseptic technique in handling and using the guide wire.
- Contraindications, warnings, precautions, and intended uses of interventional devices that are compatible with ASAHI PTCA guide wires are described in the user manuals supplied with the respective interventional devices. Before using an ASAHI PTCA guide wire with other interventional devices, read the user manual of the other devices to ensure the other devices are compatible with ASAHI PTCA guide wire. Ensure you choose the correct ASAHI PTCA guide wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and ASAHI PTCA guide wire.
- Guide wires are delicate instruments and should be handled carefully. When taking the guide wire out of the holder tube, do not handle the guide wire roughly or pull it out abruptly.
- Inspect the guide wire carefully for bends, kinks, or other damage prior to use and whenever possible during the procedure.
- Take due care when using the guide wire to prevent bending or kinking, and stay within standard practice when using the guide wire.
- When shaping the distal end, use the minimum force needed so that the coil is not damaged. Inspect the coil and guide wire for damage after shaping and before using.
- Verify which is the distal end before insertion and be sure to insert the distal end (coiled end).
- Do not wipe this guide wire using an organic solution such as alcohol.

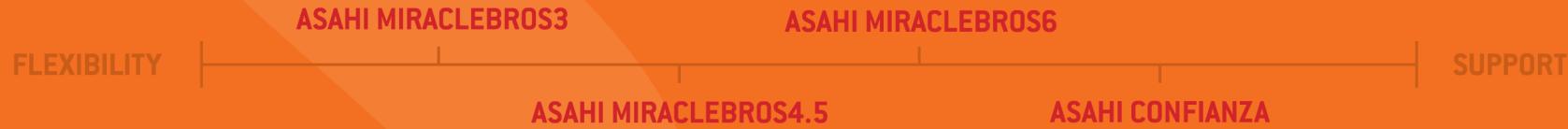


## SPECIALTY WIRES FOR EXTRA-ORDINARY LESIONS

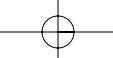
### THE DELIVERABILITY YOU NEED, WHEN YOU NEED IT MOST.

Performance starts at the core. TruTorq™ technology gives you the support and pushability you need to access and treat highly stenosed lesions. Additionally, our **jointless spring coil** design enables smooth tracking, enhancing access to difficult lesions while providing exceptional tactile response.

#### FEEL THE DIFFERENCE WITH ASAHI WIRES:



To set up an evaluation, contact your Abbott Vascular Devices representative. For additional information call customer service at 800-222-6883 or visit [AbbottVascularDevices.com](http://AbbottVascularDevices.com)



## ISCHEMIA: INVASIVE ASSESSMENT

Continued from page 18

inconvenience and risk for the patient, but nobody is blamed for it and it is financially rewarding.

On the other hand, it is clear that if you take such a non-evidence-based approach, the advantages of drug-eluting stenting will be completely ameliorated by such oversimplified multi-

stenting. Of course, the restenosis rate per lesion is very low. But if you put in five stents in one vessel, the total restenosis rate of the patient will not decrease. As we can conclude from the TAXUS study and the RESEARCH study,<sup>23</sup> the mortality and the infarction rate will most likely increase with such approach, and the costs will increase dramatically. So this is not an attractive option either.

Therefore, if you have such a case, demonstrate presence and severity of ischemia invasively, measure it on the table, and then decide what to do. If you have a patient where you make the pressure pullback curve, you can easily see some stenoses are significant and instead of stenting the entire coronary artery, one or several drug-eluting stents can help your patient.

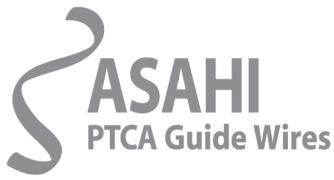
In conclusion, we can say that functional assessment of ischemia is mandatory because it determines if a patient will profit from PCI or not. The easiest way to do so is in the catheterization laboratory by coronary pressure measurement. That is the most accurate, quickest, and probably cheapest way to go. It provides you with an immediate and accurate identification of the culprit spots or segments. In the case of complex disease, it enables a rapid, easy, complete and effective diagnosis and treatment, all in one. It shortens hospital stay, saves money, and is beneficial for the patient.

## References

1. Bech GJW, De Bruyne B, Pijls NHJ, et al. Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial. *Circulation* 2001;103:2928-2934.
2. Stone GW, Ellis SG, Cox DA, et al. One-year clinical results with the Taxus stent. The Taxus IV trial. *Circulation* 2004;109:1942-1947.
3. Lemos PA, Serruys PW, Van Domburg T, et al. Unrestricted utilizations of sirolimus-eluting stents compared with conventional bare stent implantation in the real world. *Circulation* 2004;109:190-195.
4. Iskander S, Ikandrian AE. Risk assessment using SPECT Tc-99m Sestamibi Imaging. *J Am Coll Cardiol* 1998;32:57-62.
5. Davies RF, Goldberg AD, Forman S, et al. Asymptomatic cardiac ischemia pilot (ACIP) study two year follow-up. *Circulation* 1997;95:2037-2043.
6. Topol EJ, Ellis SG, Cosgrove DM, et al. Analysis of coronary angiography practice in the United States with an insurance — claims database. *Circulation* 1993;87:1489-1497.
7. Pijls NHJ, De Bruyne B, Peels K, et al. Measurement of fractional flow reserve to assess the functional severity of coronary-artery stenoses. *N Engl J Med* 1996;334:1703-1708. Key paper of prospective study showing the high specificity (100%) and sensitivity (90%) of FFR validation versus a unique gold standard.
8. Lima RSL, Watson RD, Goode AL, et al. Incremental value of combined perfusion and function over perfusion alone by gated-SPECT myocardial perfusion imaging for detection of severe three-vessel coronary artery disease. *J Am Coll Cardiol*. 2003;42:64-70.
9. Pijls NHJ. Optimum guidance of complex PCI by coronary pressure measurement. *Heart* 2004;9:1085-1093.

Dr. Pijls discloses he has received a research grant from Radi Medical, Inc.

CLD



### CAUTION

Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

### INDICATIONS FOR USE

ASAHI PTCA guide wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA guide wire is not to be used in the cerebral blood vessels.

### WARNINGS

- This guide wire is for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of the guide wire may be compromised and there is a risk of complications, including infection.
- Do not use the guide wire after the expiration date indicated on the label. Discard any guide wire that exceeds the expiration date.
- This guide wire must be used only by a physician who is fully trained in PTCA/PTA treatment.
- The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the guide wire may be damaged.
- Do not use a damaged guide wire. Using a damaged guide wire may result in blood vessel damage and/or inaccurate torque response. Injury to the patient may result.
- Always advance and withdraw the guide wire slowly.
- Observe guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque a guide wire without observing corresponding movement of the tip; otherwise, the guide wire may be damaged and/or vessel trauma may occur. In addition, ensure that the distal guide wire tip and its location in the vessel are visible during wire manipulations.
- Never push, auger, withdraw, or torque a guide wire that meets resistance. Torquing or pushing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation or direct damage to a vessel. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed, do not allow the tip to remain in a prolapsed position; otherwise damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.
- If any resistance is felt due to spasm or the guide wire being bent or trapped while operating the guide wire in the blood vessel or removing it, do not move or torque the guide wire. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the guide wire is moved excessively, it may break or become damaged, which may cause blood vessel injury or result in fragments being left inside the vessel.
- When torquing this guide wire inside the blood vessel, do not torque continuously in the same direction. This may cause the guide wire to become damaged or break apart, causing injury to the blood vessel or leaving fragments inside the vessel. When torquing the guide wire, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (7200) in the same direction.
- Do not push the guide wire more than is necessary to advance the tip through the narrowed part of the vessel. (For example, do not push the guide wire when the distal tip of the guide wire is bent by the force of manipulation.) After crossing the targeted area, do not roughly twist, push or pull the guide wire. If the guide wire is moved excessively, it may be damaged or break apart, which may injure the blood vessel or leave fragments inside the vessel.
- Use proper technique to ensure and verify that no air enters the interventional device when pulling the guide wire from the interventional device or re-inserting it. Otherwise air embolism could occur.
- Flush the guide wire with heparinized saline or other suitable solution while removing and reinserting it to prevent air from entering the interventional device. Perform guide wire exchanges carefully to prevent air entry and/or trauma. When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and is not against the vessel wall. Failure to do so may result in vessel trauma when the guide wire is removed. Use the radiopaque marker of the interventional device to confirm position.
- Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.
- Do not use in areas of vessel that are not or cannot be visualized.

### • For ASAHI CONFIANZA and ASAHI MIRACLEbros Series Only:

**ASAHI CONFIANZA and ASAHI MIRACLEbros Series have stiff distal ends.** Operate these guide wires carefully so as not to injure the blood vessel, observing information in these instructions. The higher torque performance, stiffer ends, and/or higher advancement force may present a higher risk of perforation or injury than if using a more flexible guide wire. Therefore, use the most flexible guide wire that will treat the lesion (i.e., the guide wire with the smallest flexibility number that will treat the lesion), and take due care to minimize the risk of perforation or other damage to blood vessels.

### FOR ALL GUIDE WIRES:

**Use the most suitable guide wire that will treat the lesion.** There are patient risks when using any guide wire including those that may result from damage to, or breakage of, the guide wire. If guide wire damage or breakage occurs, it may cause damage to the vessel and injury to the patient, or death. Accordingly, care should be taken that all persons who operate guide wires are properly trained in their use, that they observe proper technique, and that guide wires are used carefully in accordance with the Instructions for Use.

### ADVERSE EVENTS OF GUIDE WIRE USE INCLUDE, BUT ARE NOT LIMITED TO:

- Failure to cross a lesion
- Separation or breakage of the guide wire
- Damage to a vessel, including possible vessel perforation
- Coronary artery dissection
- Cardiac tamponade due to coronary artery perforation
- Air embolism
- Infection
- Coronary artery spasm
- Coronary artery thrombus
- Hematoma at puncture site
- Cardiac perforation

### PRECAUTIONS

- If the package is opened or damaged, do not use the product. Do not open the package until just prior to use. Use aseptic technique in handling and using the guide wire.
- Contraindications, warnings, precautions, and intended uses of interventional devices that are compatible with ASAHI PTCA guide wires are described in the user manuals supplied with the respective interventional devices. Before using an ASAHI PTCA guide wire with other interventional devices, read the user manual of the other devices to ensure the other devices are compatible with ASAHI PTCA guide wire. Ensure you choose the correct ASAHI PTCA guide wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and ASAHI PTCA guide wire.
- Guide wires are delicate instruments and should be handled carefully. When taking the guide wire out of the holder tube, do not handle the guide wire roughly or pull it out abruptly.
- Inspect the guide wire carefully for bends, kinks, or other damage prior to use and whenever possible during the procedure.
- Take due care when using the guide wire to prevent bending or kinking, and stay within standard practice when using the guide wire.
- When shaping the distal end, use the minimum force needed so that the coil is not damaged. Inspect the coil and guide wire for damage after shaping and before using.
- Verify which is the distal end before insertion and be sure to insert the distal end (coiled end).
- Do not wipe this guide wire using an organic solution such as alcohol.