ACIST | RXi™
Rapid Exchange
FFR System

The RXi System
A New Rapid Exchange MicroCatheter Approach to FFR

Based on an interview with Dr. Madhav Menon of Waikato District Health Board, Hamilton, New Zealand.

About Dr. Menon

Dr. Menon is a consultant interventional cardiologist, specializing in coronary interventions including chronic total occlusions. He undertook basic medical training in India, followed by advanced medical and cardiology training in New Zealand. He trained in interventional cardiology at the University of Minnesota in the United States, after which he returned to New Zealand in 2008 as a consultant at the Waikato Hospital. Dr. Menon currently leads the chronic total occlusion program, and is in the process of setting up a hybrid coronary revascularization program. He also heads the CT coronary angiogram program, a new, less invasive method of imaging coronary arteries. Fractional flow reserve (FFR) has become a routine part of Dr. Menon's practice over the last 7 years, and he was among the first cardiologists to use the ACIST|RXi™ Rapid Exchange FFR System in the cath lab.

The value of FFR

The 'oculostenotic reflex' describes a traditional paradigm in the field of cardiology whereby an interventionalist will perform an immediate percutaneous coronary intervention (PCI) on identification of a stenosis by angiography. But with this 'see it, fix it' approach, many interventions are unnecessary. **'Anatomy is one thing, physiology is a completely different thing,'** remarks Dr. Menon, also explaining how unnecessary stenting of functionally non-significant lesions introduces further risks to the patient: **'Stents are prone to restenosis and stent thrombosis, so we may be introducing a problem that doesn't need to be there in the first place.'**

Fractional flow reserve (FFR) has become an invaluable diagnostic tool for cardiologists in distinguishing between functionally significant lesions requiring intervention, and those for which intervention can be safely deferred. While angiography can identify a clinically significant stenosis of the vessel, the real value of FFR lies in evaluating intermediate lesions. **'What you think is a severe lesion visually may not be clinically significant physiologically, and vice versa,'** comments Dr. Menon, explaining that in these situations, FFR can distinguish between clinically significant and non-significant lesions. **'If it's not significant, you can leave it alone safely.'**

There is a growing body of evidence showing that FFR-guided treatment decisions lead to significantly better outcomes than standard angiogram-guided PCI.[1,2] In the Fractional flow reserve versus Angiography for Multivessel Evaluation (FAME) trial, significantly more patients with angiography-guided PCI experienced major adverse cardiac events at 1 year compared with patients with FFR-guided PCI decisions **(Table 1)**.[1] A significant reduction in mortality and myocardial infarction of FFR patients in the FAME study was still observed at 2 years.[2]

Calculating and using FFR[3–6]

FFR is calculated as the ratio between the pressures proximal (Pa) and distal (Pd) to a stenosis with the simple formula $\frac{Pd}{Pa}$ to give a value ≤1. The following values are used to guide clinical decisions:

- FFR=1: no stenosis; normal vessel
- FFR>0.80: no intervention indicated; treat medically
- FFR≤0.75: significant stenosis; revascularization is justified
- FFR=0.76–0.80: clinical judgment required

Many studies have been performed examining the 'gray zone' of FFR between 0.76 and 0.80. For an FFR of between 0.76 and 0.80, clinical judgment considering the character of symptoms, results of noninvasive tests, and whether the stenosis is focal or diffuse should balance the final decision.

Table 1. The FAME trial: key data[1]

	Angiography-guided revascularization (n=496)	FFR-guided revascularization (n=509)
Overview	Stent placement for all indicated stenoses	Stent placement only for stenoses with FFR≤0.80
Number of stents placed per patient	2.7±1.2	1.9±1.3
	p<0.001	
Major adverse cardiac events at 1 year*	18.3%	13.2%
	p=0.02	

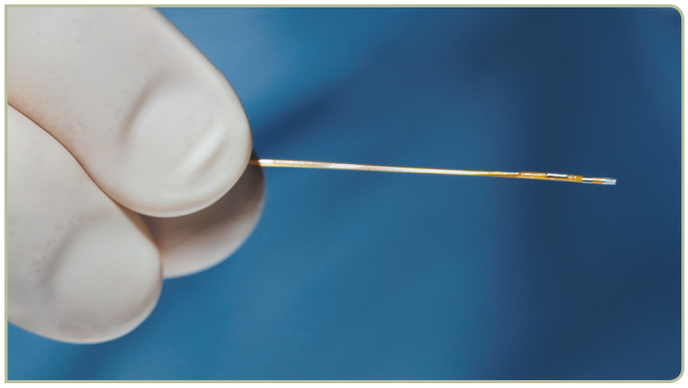
*composite of death, myocardial infarction, and any repeat revascularization

The Navvus MicroCatheter: FFR without a pressure wire

Despite the process of performing an FFR being relatively simple, it is not a routine procedure in many cath labs. Why? The limited steerability and maneuverability of traditional pressure wires can make navigation of vessels difficult and increases the risk of causing vessel dissections, especially in challenging tortuous vasculature. And, using pressure wires in complex lesions such as bifurcations and diffuse or multivessel disease can often result in lengthy procedures, making the performance of an FFR unattractive and unsafe. Together, these factors can make physicians hesitant to perform FFR.

The ACIST | RXi™ Rapid Exchange FFR System, featuring the ACIST Navvus™ Rapid Exchange FFR MicroCatheter, is the first rapid-exchange FFR system. It has been developed for clinicians who would like to quickly and easily validate their clinical decisions at any point before, during, or after an intervention, and those who find pressure wire systems burdensome and restrictive.

The Navvus MicroCatheter is an ultra-thin, rapid-exchange microcatheter that has demonstrated accuracy comparable to commonly used pressure wire systems. The microcatheter has a mean diameter of 0.022″ and fits over a 0.014″ guidewire. It also features a pressure sensor 0.5 cm from the tip of the microcatheter compared with the 3 cm distance from the tip typical of traditional pressure wires. In addition, the distal shaft of the Navvus MicroCatheter is elliptically shaped, and was designed to minimize restrictive flow **(Figure 1)**.



The Navvus MicroCatheter is delivered over a 0.014″ guidewire and has better maneuverability than traditional pressure wires.

Advantages of a microcatheter: Quicker and easier FFR

Having had an opportunity to use RXi, Dr. Menon is upbeat: **'We were quite excited by the concept and the way it performed.'** An important advantage of delivering the Navvus MicroCatheter over a 0.014″ guidewire is ease of navigability. **'To have the ability to use your own workhorse wire, or any wire which will navigate tortuosity quite easily, is a big advantage.'** As guidewires offer better maneuverability and steerability over pressure wires, Navvus gives cardiologists access to complex vasculature that may have been previously unreachable with traditional FFR systems. **'It is a low-profile microcatheter, and we've found it to be easily deliverable,'** says Dr. Menon. Furthermore, the closeness of the sensor to the tip means that the Navvus MicroCatheter is not required to go very far past the lesion when measuring FFR.

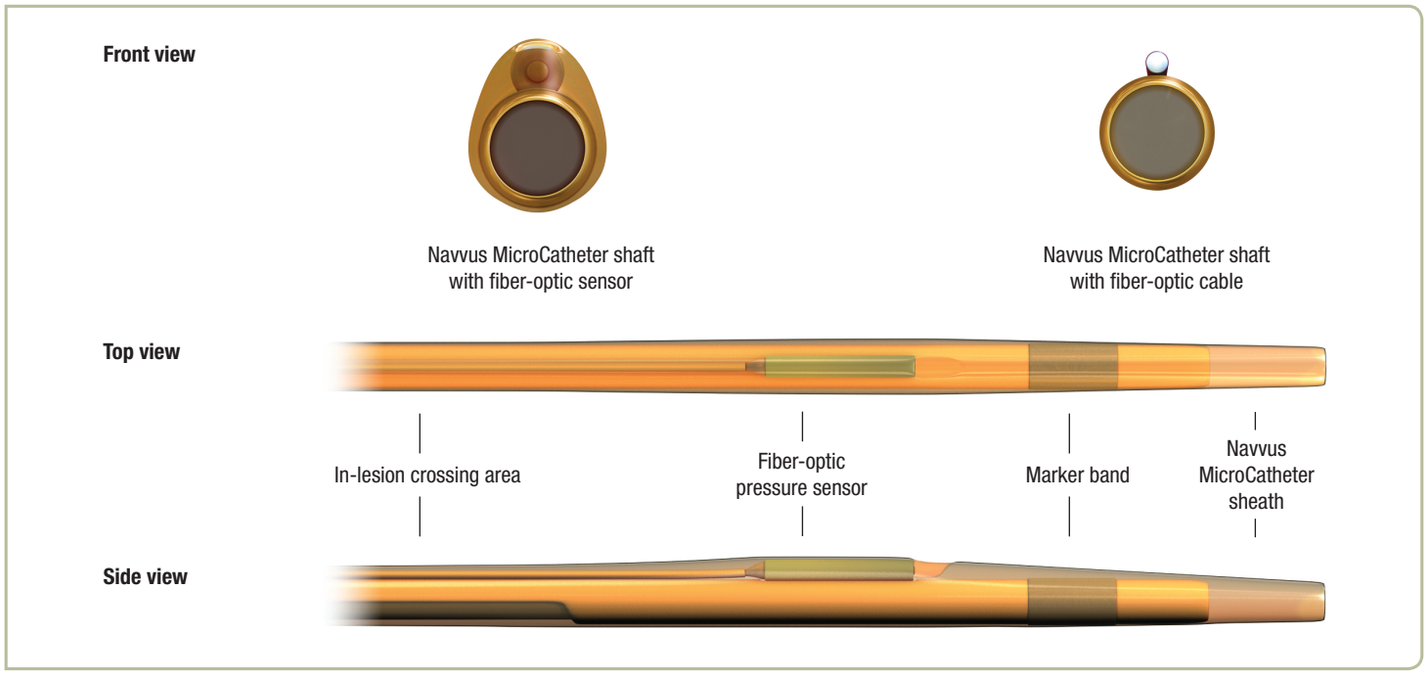


Figure 1. The ACIST Navvus™ Rapid Exchange FFR MicroCatheter

The RXi system allows wire position to be maintained throughout the procedure, and hence a lesion only needs to be crossed once by the guidewire. This feature not only saves time, but also improves safety. **'In general, the fewer times you recross a lesion, the lower the risk of exposure to wire complications,'** remarks Dr. Menon. Once the guidewire is in place, the operator can quickly swap between Navvus and PCI catheters, and multiple FFR readings can be taken easily without recrossing a lesion or renavigating a wire. This is particularly appealing after placing a stent, as Dr. Menon explains: **'A normalized FFR post-stent means better long-term outcomes.[7] The Navvus MicroCatheter can easily confirm a post-stent FFR value as the guide wire is already in situ. The simpler and safer it is to take FFR measurements, the more likely one is to do more of them.'**

An important difference between the Navvus MicroCatheter and pressure wires is that Navvus uses fiber-optic technology to measure pressure. This eliminates the need for the electrical wires that make pressure wires stiffer than guidewires. **'We got good comparable readings with the Navvus versus the pressure wire, and the presence of the RXi system did not alter the values significantly,'** explains Dr. Menon. In addition, the device has demonstrated a reduced frequency of baseline signal drift, which serves to save time by reducing the requirement for recalibration and repeat readings, both of which increase procedure time. **'We found that the rapid exchange system was a lot more stable, which makes it more robust,'** remarks Dr. Menon. Furthermore, the RXi system can speed up procedure time by eliminating the need for initial calibration; it is found in a ready 'plug and play' state, and can be permanently mounted to the bedside in a cath lab. **'The setup, the connectivity, and the console are very easy to use; it's very user friendly.'[8]**

The 'plug and play' status makes the RXi system quick and easy to use.

Concluding remarks

FFR is of great clinical value to cardiologists in guiding physiology-based PCI. Despite positive recommendations in American and European guidelines, the regular use of FFR is not as widespread as it could be, but an increase in FFR-guided PCI would undoubtedly lead to greater clinical benefit. Currently, barriers such as poor maneuverability of wires, the need to recross lesions, and the occurrence of signal drift mean that FFR is not used to its full potential, and consequently, as Dr. Menon notes, **'there's still a lot of angiographically-driven management.'** The Navvus MicroCatheter is designed to make FFR quicker and easier than traditional systems, saving time and providing cardiologists with reassurance about their clinical decisions. The ability to use a 0.014″ guidewire of choice and maintain wire position for the entire procedure, as well as the easy calibration process provided by the 'plug and play' status, are obvious advantages of the Navvus MicroCatheter. In addition, the fiber-optic based technology that gives significantly reduced signal drift and accuracy from start to finish makes the device very attractive.[8]

Dr. Menon believes that the guidelines will probably change in the future, in particular to put more emphasis on the use of FFR in multivessel disease. Under this guidance, a traditional surgical case could be re-classified as a nonsurgical case, requiring only targeted PCI. **'From the patient perspective this makes a huge difference downstream, because you can avoid the morbidity associated with bypass surgery. By using targeted intervention, we know that the long-term outlook is safe.'**

Will an easier, more rapid FFR system like RXi help to increase the frequency with which lesions are assessed by FFR? Only time will tell. Dr. Menon, however, believes it can: **'There is plenty of scope to do more FFR in the real world, and if you have a system that is a little bit more user friendly, I think that would sway people to use it more.'**

The Navvus MicroCatheter's fiber-optic technology provides accuracy from start to finish.

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