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Non-Invasive Fractional Flow Reserve

CORONARY
ARTERY
STENOSIS
EVALUATION
SOFTWARE



ABOUT US

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Cardiovascular diseases (CVDs) are the leading cause of death in the world. Among them, disorders in blood vessels are the most common. About 25 percent of all deaths in adults over the age of 30, and in 70 percent of adults over the age of 75 are attributed to cardiovascular diseases globally.

In order to provide a faster, more accurate, and safer method to diagnose stenosis in coronary artery flow . Mobtakeran Salamat Fakher (MSF), in line with its mandate to be a leader in delivering the best medical technologies and solutions available in the world, and by employing advanced computational science, has developed a visualization software to better aid physicians to make more accurate, less risky, and non-invasive diagnoses and assessments of coronary artery diseases.

The system makes use of angiograms or CT Angiograms and other information (e.g., patients' systolic and diastolic pressure and blood flow) provided by the physician to construct two and three-dimensional images of the coronary artery, and thereby determine the boundaries of arterial walls, analyze and determine the degree of artery narrowing (expressed in terms of percentage), and detect other abnormalities or stenoses in the blood vessels.

This has been made possible with the combined experience of MSF's highly educated and talented research and development team, as well as numerous clinical studies, while also benefiting from the valuable feedback obtained from Iran's leading healthcare centres.



In addition, MSF has successfully met the most stringent requirements of leading international management and operations standards bodies to obtain ISO14971, IEC62304, and ISO13485 certificates. Furthermore, the software has successfully received the approval, and has satisfied the safety and efficacy standards under Class C (high risk) of Iran's National Medical device Directorate (the equivalent of America's FDA's Class III and Europe's Class IIB).

MSF is proud to be the first in Iran to have developed and introduced this revolutionary non-invasive technology that diagnoses stenosis in coronary artery flow, and to be playing an important role in and positively contributing to Iran's self sufficiency with respect to the medical devices industry.





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Fractional Flow Reserve (FFR)

Atherosclerosis is brought about by the pathological aggregation of lipid deposits along the blood vessel walls. Such aggregation in turn causes narrowing of the arteries and disturbance of arterial blood flow. Atherosclerosis is implicated in many diseases of the circulatory system. Atherosclerosis commonly involves the coronary arteries of the heart which in turn predisposes the patient to ischemic cardiac events. Currently, coronary artery bypass graft surgery (CABG), and stent placement are the mainstay of treatment for patients not adequately managed with medical management alone. During coronary catheterization the cardiologist uses the pressure wire based FFR value to assess the severity of blood flow restriction, as well as to guide his decision as to whether or not revascularization is indicated.

As a result, FFR is a useful tool in angiography. Currently FFR is the gold standard study to evaluate the physiologic significance of intermediate and borderline stenotic lesions. Increased diagnostic accuracy brought about by FFR-guided decision making has been shown to result in favourable clinical outcomes. Such outcomes include but are not limited to reduced cost, improved procedural efficiency and resource management.



Currently FFR is used in less than 10% of percutaneous intervention (PCI) procedures. This is due to the need for a pressure wire as well as adenosine (a vasodilator) to measure the pressure difference between the proximal and distal sides of a stenotic lesion under optimal blood flow. Hence, FFR is expensive and of course invasive. Here we will discuss the use of far less invasive and advanced computational software to accurately characterize arterial occlusion.

Coronary Artery Stenosis Evaluation Software

Non-Invasive Fractional Flow Reserve developed by the Coronary Artery Stenosis Evaluation Software Produced by Mobtakeran Salamat Fakher company is a software that accurately simulates the physiologic coronary blood flow allowing for meaningful qualitative assessment of coronary artery perfusion. Our Coronary Artery Stenosis Evaluation Software draws upon mathematical equations and algorithms to accurately and reliably estimate the FFR. This software provides a non-invasive method of estimating FFR, Wall Shear Stress (WSS), and Index of Microvascular Resistance (IMR) using standard angiographic images. Using this software not only eliminates the need for a pressure wire and adenosine but also makes the procedure shorter and far less invasive since it eliminates the need for catheter advancement past the stenotic lesion. NIFFR is hence a safer, more convenient and more cost effective method for evaluation of coronary artery disease in intermediate and borderline cases.

The claimed benefits of NIFFR :

- A. Analysis is done using standard X-ray angiography images with the need for three additional views and adenosine injection.
- B. Like FFR, it allows accurate evaluation of stenotic lesions responsible for cardiac ischemia but reduces the need for invasive FFR.
- C. It reduces the need for unnecessary revascularization by reliably identifying physiologically significant stenotic lesions (responsible for ischemic damage) as opposed to the lesions with less physiological significance.
- D. It parallels the efficacy of FFR without the need for pressure wire.



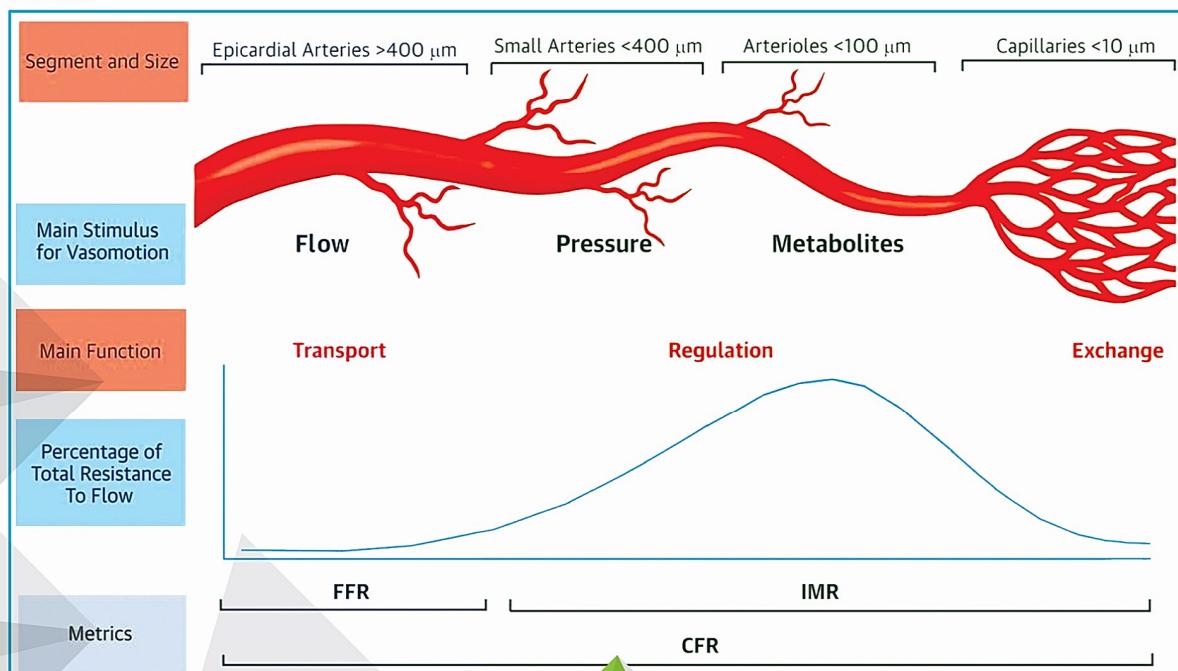
Invasive

- E. It reduces the cost burden associated with inconclusive and inaccurate diagnostic studies.
- F. It reduces the number of staff and procedure time, and also helps the physicians to avoid unnecessary procedures.

Below we will further expand on the meaning and significance of IMR and WSS measures

Index of Microvascular Resistance (IMR)

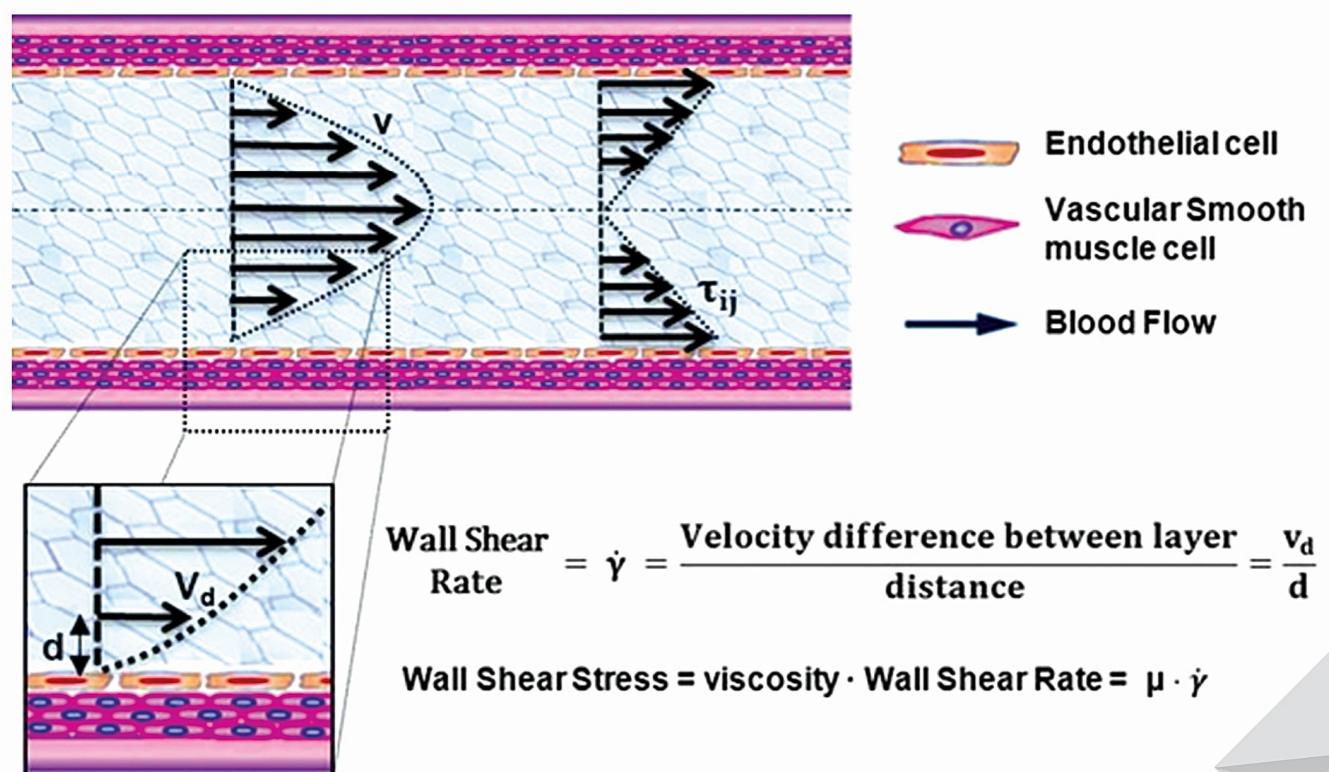
Epicardial coronary artery stenosis is not a prerequisite for ischemic heart disease. Although it has not been established that microvascular coronary disease is independent of macro vascular disease, clinical studies show that microvascular disease is an independent predictor of poor clinical outcomes in patients. However, clinical events occur even in patients with high FFR. Index of microvascular resistance (IMR) can provide additional diagnostic and prognostic insights for stable patients. Integration of microvascular assessment by using CFR and IMR with FFR can provide additional information on coronary circulation and improve the risk stratification of patients with high FFR. The resistance of a microvascular system is defined as the ratio of the pressure gradient divided by the flow across that particular system during maximal hyperemia.





Wall Shear Stress (WSS)

Atherosclerosis can affect any artery in the body, including arteries in the heart, brain, arms, legs, pelvis, and kidneys, and mainly affects middle and large sized arteries near side branches and at the inner bend of curved segments. At these locations, the average normalized drag force of the flowing blood acting on the vessel wall, the wall shear stress (WSS), is low and/or turbulent leading to endothelial dysfunction and ingress of lipids into the vessel wall, initiating an inflammatory response. Thus in the early phases of the disease WSS can predict locations of plaque initiation and progression.



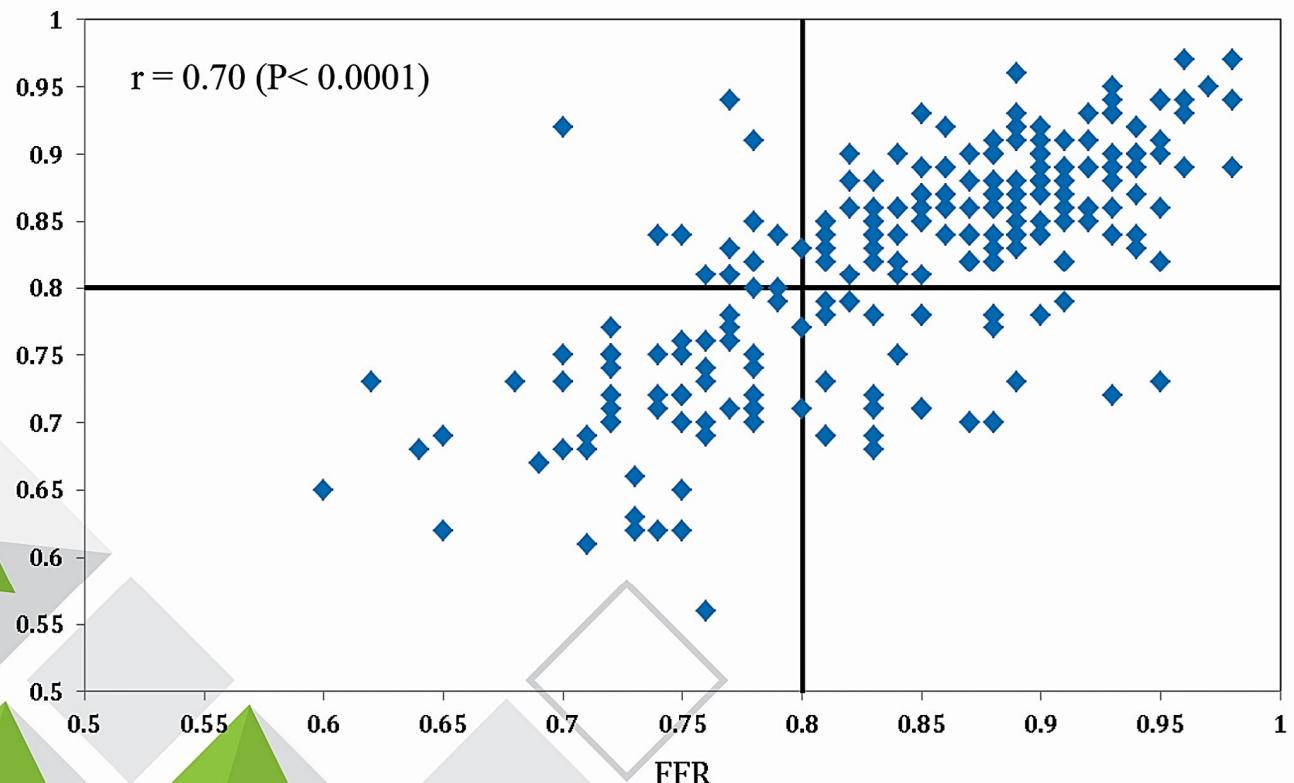
In more advanced stages of disease, when plaque growth results in lumen narrowing, the local WSS patterns will change such that certain plaque regions that mainly locate upstream are exposed to elevated WSS. Evidence is accumulating that the elevated WSS influences plaque composition in such a way that it induces local weakening of the plaque, making plaque regions exposed to high WSS prone to rupture.

Fractional Flow

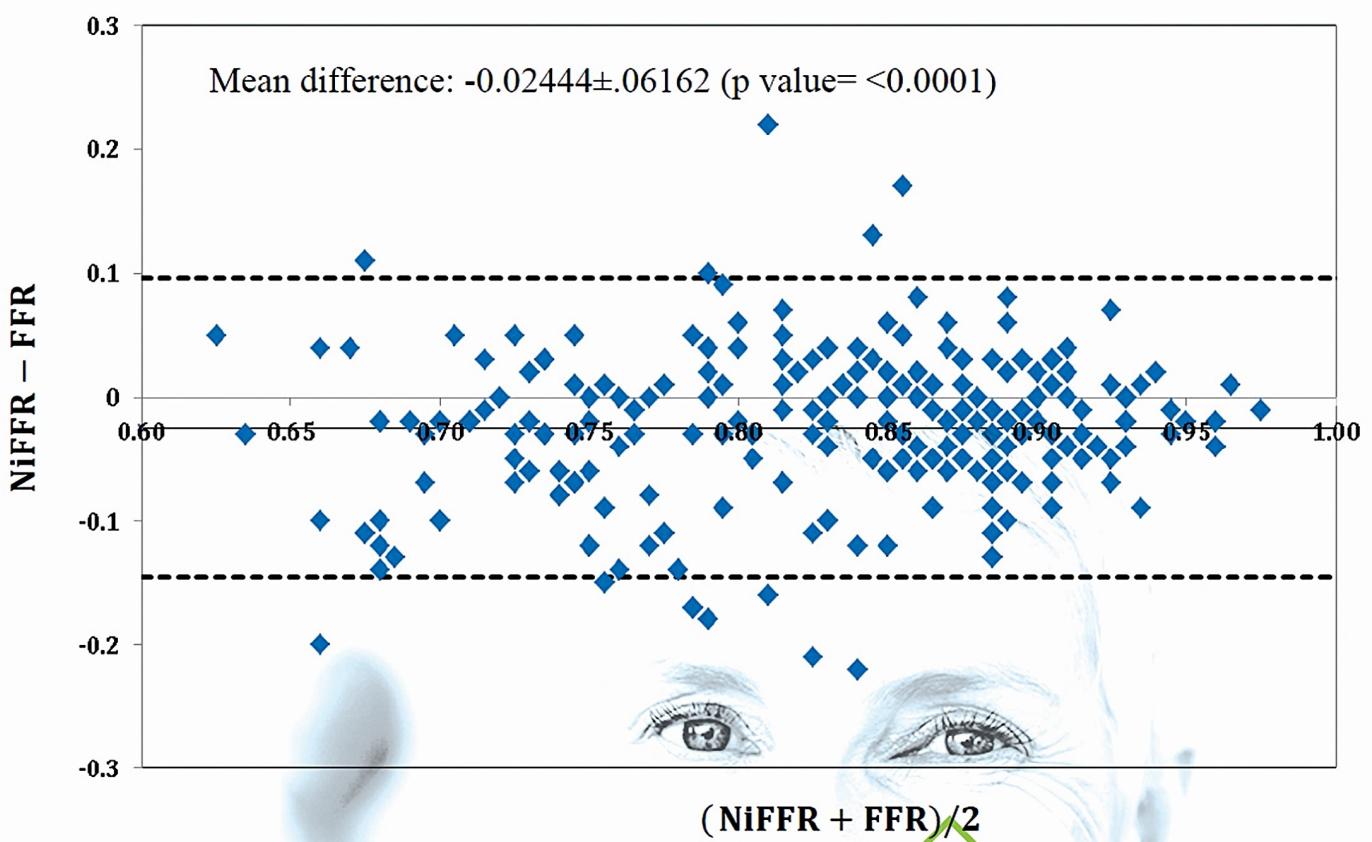
Clinical studies have confirmed that plaque rupture, both in coronaries and carotids occur more frequently upstream of the plaque. Shear stress with a low mean or maximum value along with varying direction has been associated with increased plaque vulnerability. Therefore, different diseased states may develop based on the affected artery. For example acute myocardial infarction is mostly brought about secondary to the rupture of the so called vulnerable plaques in the coronaries associated with coronary stenosis.

Result (Compared with Invasive FFR)

Pearson correlation was used to evaluate the correlation between NiFFR and FFR. The NiFFR (correlation coefficient $r=0.70$, $p<0.0001$) showed strong correlation with FFR for 245 patients (Multi-center).



NiFFR (Mean difference -0.02444, Standard deviation 0.06162) demonstrated slight but non-significant differences as compared with FFR in assessing significance of stenosis.



R eserve result

Our company conducted a literature search on the diagnostic accuracy of NIFFR and the existing tests in the current treatment pathway for patients with coronary artery disease, against a reference standard of invasive FFR testing. the company presented diagnostic accuracy per-patient results for NIFFR compared with:

- **Heart Flow FFR-CT**
- **Single-Photon Emission CT (SPECT)**
- **Stress Echocardiogram (ECHO)**
- **Magnetic Resonance Imaging (MRI)**



Index test	Number of Patients	Sensitivity	Specificity	AUC Area Under Curve
MRI	129	0.95	0.91	0.93
HeartFlow FFRCT	254	0.93	0.85	0.89
MSF Company NIFFR	245	0.81	0.83	0.88
Stress ECHO	261	0.57	0.9	0.73
SPECT	293	0.73	0.74	0.73



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