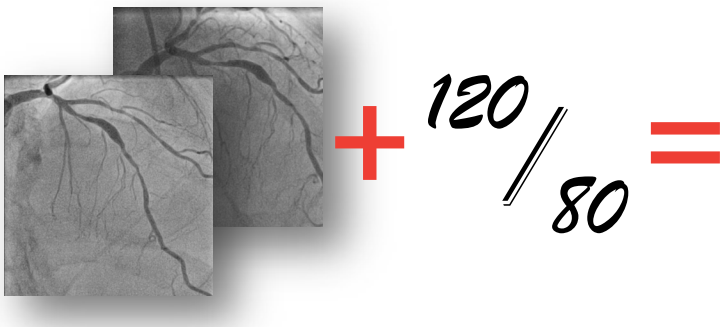
Caas vFFR

A novel angio-based functional lesion assessment: wire and hyperemic agent free

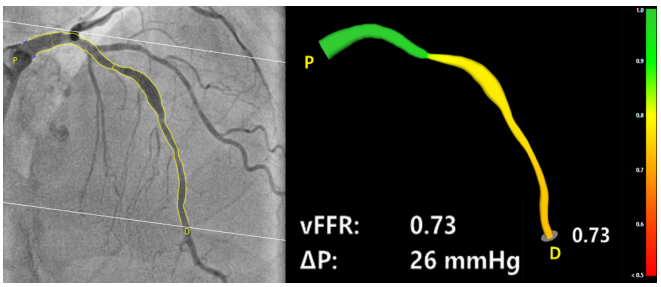
Introduction

CAAS vFFR calculates the pressure drop in coronary vessels without the need of a pressure wire. The vFFR module builds a 3D reconstruction of two angiograms and assesses pressure-drop, resulting in a vFFR value. Additionally, the 3D reconstruction will enable assessment of severity and percentage of stenosis.

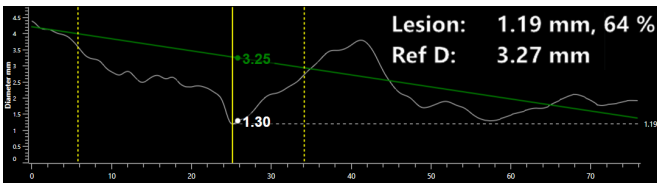


2 Angiograms ES + ED pressure

Physiological results



Anatomical results



Why?

- No invasive pressure wire needed
- No hyperemic agent needed
- Easy, one-minute analysis
- Pre- and post stenting analysis

Strengths

- Only 2 angiograms needed
- X-Ray system independent
- Functional and anatomical measurements
- 510(k) Cleared and CE Marked

"In the FAST II trial," said Joost Daemen MD, PhD, principal investigator "We confirmed that vFFR as calculated using CAAS vFFR has a high diagnostic accuracy to detect FFR ≤ 0.80 in an international multi-center setting. vFFR is an accurate, fast and easy to use tool to assess coronary physiology."

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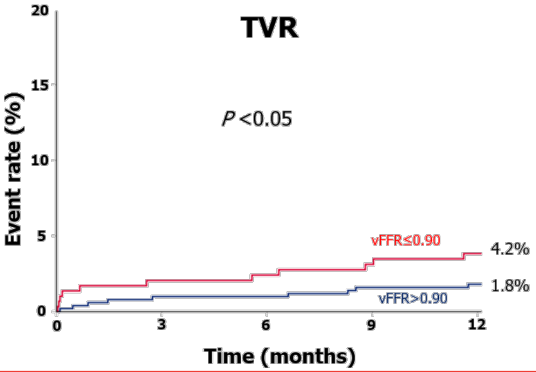
Caas vFFR

High diagnostic accuracy and good correlation with invasive FFR

	FAST 1 [1] + FAST Extend [2]	FAST II multicenter trial [3]
Number of patients	294	334
Diagnostic accuracy to predict FFR ≤ 0.8	94 %	93 %
Interobserver variability	r = 0.95	r = 0.87 [4]

[1] Published in EuroIntervention (2019; doi: 10.4244/EIJ-D-19-00466)
[2] Published in JACC Cardiovasc Imaging (2021; doi: 0.1016/j.jcmg.2020.08.006)
[3] Presented at EuroPCR 2021
[4] Between site operator and corelab

Broad clinical use



Optimize patient outcome using post stenting vFFR assessment

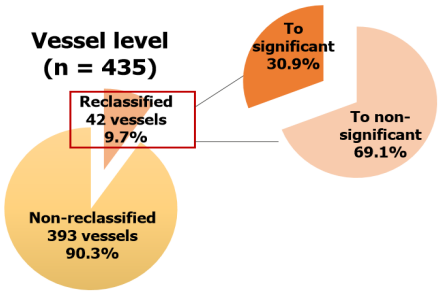
- Lower rate of MACE for the patient group with a post stenting vFFR value above 0.9 [5]

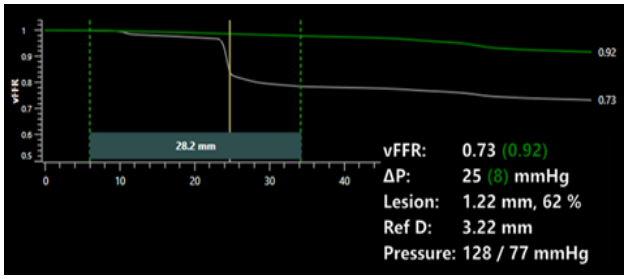
[5] Presented at TCT 2019

vFFR can be used for HeartTeam decision making

- vFFR might impact the way HeartTeam consensus is reached. As functional assessment of 3-vessel disease using vFFR is used in stead of anatomical assessment. [6]

[6] Presented at TCT 2020





vFFR can be used to predict the effect of the treatment using the residual pressure drop and residual vFFR value.

Conclusion

The 3D-QCA derived vFFR has a high linear correlation to invasively measured FFR, a high diagnostic accuracy to detect lesions with an FFR ≤ 0.80 and a low interobserver variability.

Quality Assurance:
Pie Medical Imaging develops, produces and sells products in accordance with international accepted standards. CAAS Workstation is FDA 510(k) cleared and MDD compliant (CE marked). CE 0123

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Doc ID: SMS2821 v1.0

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