Clinical evidence for CAAS vFFR

FAST Study series

Pre-stent scenario

- The initial FAST I¹ study evaluated 100 patients and assessed the diagnostic accuracy of vFFR to predict invasive $\text{FFR} \leq 0.8$. The diagnostic accuracy was 0.93 and a high reproducibility was shown with a correlation coefficient of 0.95.

- In the FAST Extend² study 303 were evaluated confirming the high diagnostic accuracy (0.94) of vFFR to predict $\text{FFR} \leq 0.8$.

- The FAST Left Main³ study investigated the correlation between vFFR and IVUS for left main coronary stenosis.

- The FAST II⁴ study was an international multi-center prospective trial in 6 countries (Netherlands, Germany, Italy, France, Unites States and Japan) evaluating the diagnostic accuracy and reproducibility of vFFR in an in-hospital and off-line core laboratory setting. The diagnostic accuracy to predict $\text{FFR} \leq 0.8$ for both corel and in-hospital were very high 0.93 and 0.91, respectively. Reproducibility between in-hospital and corelab also demonstrated to be very high at 0.87.

- The FAST III⁵ trial is an ongoing international multi-center prospective trial in 7 European countries at 35 sites enrolling 2228 patients investigating a vFFR vs FFR guided stenting strategy. The principal investigator is Dr. Joost Daemen and the study is led by the European Cardiovascular Research Institute: [https://www.ecri-trials.com/studies/fast-iii/](https://www.ecri-trials.com/studies/fast-iii/)

Post-stent scenario

- The FAST Post⁶ study evaluated 100 patients and assessed the diagnostic accuracy of vFFR to predict invasive $\text{FFR} \leq 0.9$ after stent implantation. The diagnostic accuracy was 0.98 and high reproducibility was shown with a correlation coefficient of 0.95.

- In the FAST Outcome⁷ study vFFR was carried out post-stenting in 800 patients and related to 1-year clinical outcome in these patients. The study demonstrated that patients with a

¹ Masdjedi et al. Validation of 3-Dimensional Quantitative Coronary Angiography based software to calculate Fractional Flow Reserve: Fast Assessment of STenosis severity (FAST)-study. EuroIntervention 2019
² Neleman et al. Extended Validation of Novel 3D Quantitative Coronary Angiography-Based Software to Calculate vFFR: The FAST EXTEND Study. JACC Cardiovasc Imaging. 2021
⁴ Masdjedi et al. Vessel fractional flow reserve (vFFR) for the assessment of stenosis severity: the FAST II study. EuroIntervention 2021.
⁵ Clinicaltrials.gov identifier: NCT04931771
⁶ Masdjedi et al. Validation of novel 3-dimensional quantitative coronary angiography-based software to calculate fractional flow reserve post stenting. Catheter Cardiovasc Interv. 2020
post-stent vFFR < 0.9 showed a significantly higher rate of target vessel revascularization at 1 year.

Various scenarios

- The FAST Residual vFFR study evaluated the correlation of residual vFFR as calculated on the pre-stent angiogram with the post-stent invasive FFR. The results will be presented at TCT 2021.

- The FAST dPR study evaluated the correlation of vFFR with a non-hyperaemic pressure ratio dPR. The results will be presented at TCT 2021.

- The FAST OCT trial is an ongoing international multi-center prospective trial associating vFFR with OCT.

LIPSIA STRATEGY

Pre-stent scenario

- The LIPSIA STRATEGY study is an ongoing German multi-center prospective trial at 7 sites enrolling 2000 patients investigating a vFFR vs FFR guided stenting strategy. The study is led by Prof. Holger Thiele (principal investigator) from Herzzentrum Leipzig

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8 Clinicaltrials.gov identifier: NCT04683133  
9 Clinicaltrials.gov identifier: NCT03497637