



Doe, John

Patient ID 10-028-KHE

CT Study Date 06/20/2016

Birth Date 07/24/1961

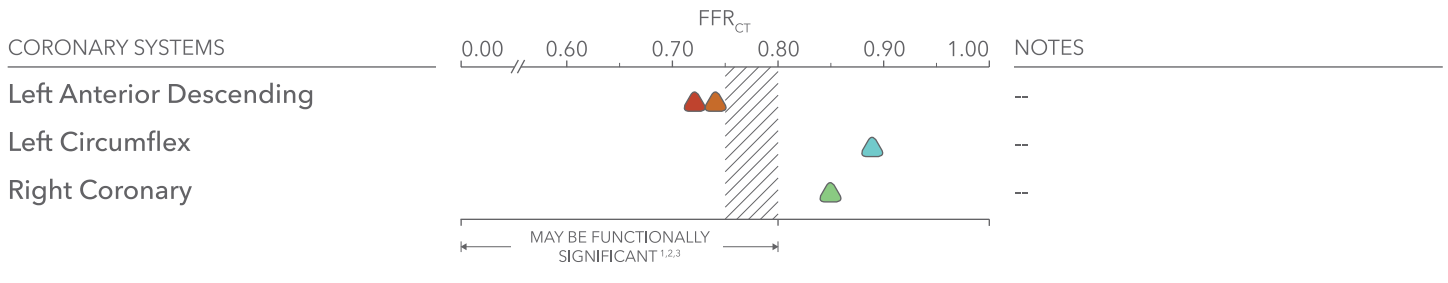
Referring Physician Dr. Jim Cardiologist

HeartFlow ID ANYT-160620-JKD7

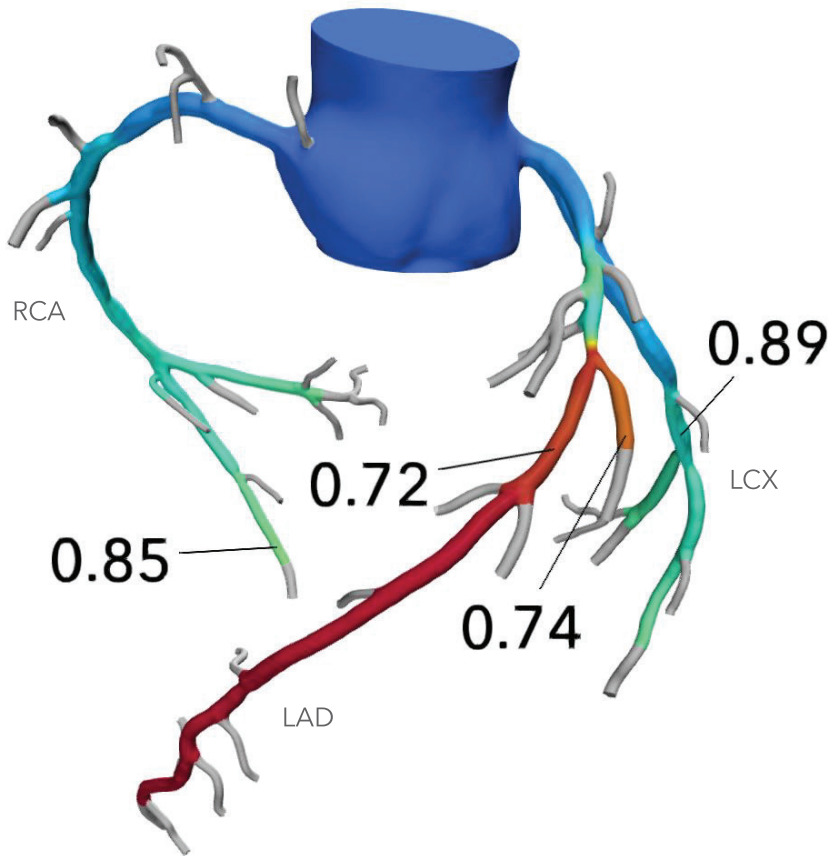
Institution Anytown Cardiology

OVERVIEW

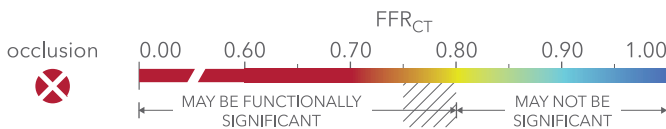
FFR_{CT} is ≤ 0.80 and may indicate functional significance.^{1,2,3}



OVERVIEW



FFR_{CT} values are specified distal to modeled stenoses > 30%.



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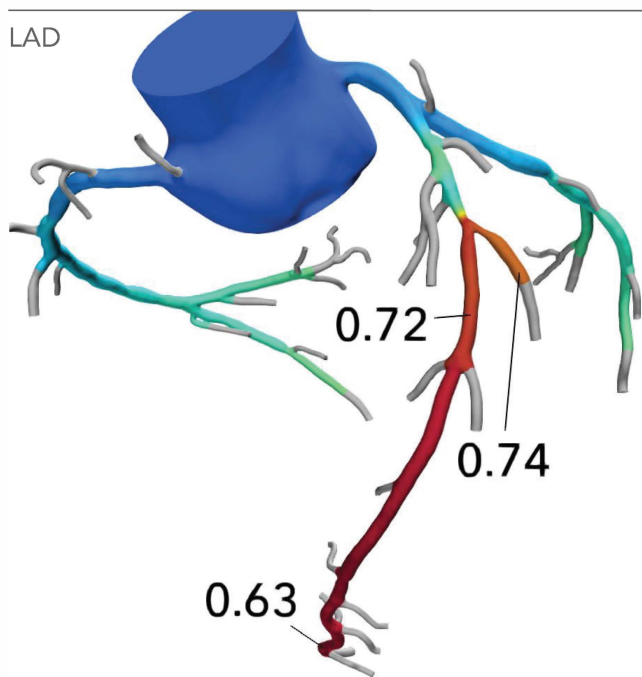
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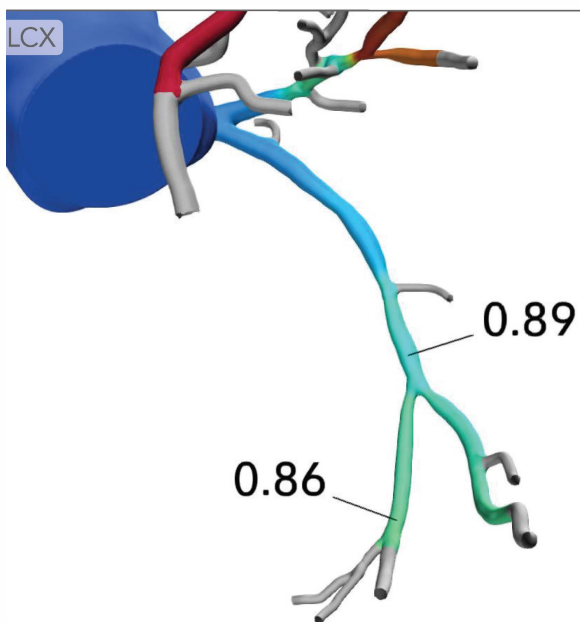
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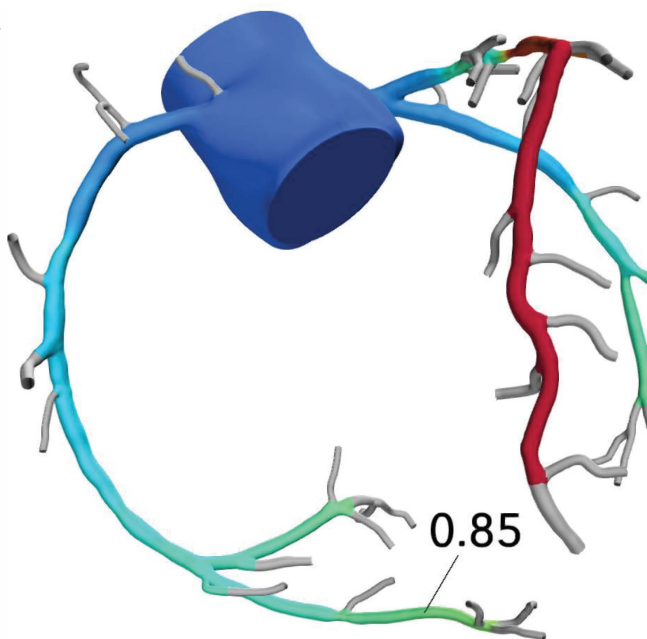
LAD










LCX



RCA



WARNINGS

-  Absence of nitrate administration during cCTA acquisition may adversely affect the accuracy of the HeartFlow FFR_{CT} Analysis. HeartFlow Analysis simulates maximal coronary hyperemia. Induction of coronary hyperemia commonly includes vasodilation of the epicardial coronary arteries via nitrate administration. Therefore, HeartFlow recommends following SCCT Guidelines for cCTA acquisition, which include the use of sublingual nitrates at the time of image acquisition.⁴
-  HeartFlow Analysis represents patient conditions at the time of CT acquisition. The duration of time and changes to patient health after CT acquisition must be assessed when interpreting the results. Clinical validation that supports FFR_{CT} was limited to subjects whose CT acquisition occurred within 60 days of FFR_{cath} (mean 18 +/- 13 days).
-  Qualitative anatomical information presented on the 3D/2D computer generated anatomical models is for orientation purposes only. Quantitative lumen diameter is representative of the geometric model, and the accuracy is dependent on the quality of the CT data provided. It does not represent artery diameter and should not be used for treatment decisions.
-  Diagnostic performance of FFR_{CT} using FFR_{cath} as the reference standard is: 86% accurate, 84% sensitive, and 86% specific.³ Refer to product Instructions For Use for patient populations in which FFR_{CT} has been clinically evaluated, relevant clinical data, and product warnings.
-  The performance of FFR_{CT} has not been fully characterized in small vessels. Vessels with computed lumen diameters less than 1.8 mm are grayed and FFR_{CT} is unavailable. When lumen diameter decreases below 1.8 mm due to disease, but distally recovers to 1.8 mm or greater, FFR_{CT} remains available. In some instances, continued distal disease and/or recovery may not be presented in the model.
-  FFR_{CT} has been studied in patients with prior PCI, but the results have only been validated in vessels without metallic stents.
-  Because of physiologic changes in pressure and flow within regions of complex or turbulent flow (i.e. stenosis, bifurcations), pressure measurements may vary, potentially affecting measured FFR. Similarly, computed FFR_{CT} may be affected by flow disturbances in stenoses and bifurcations.

FFR_{CT} ERROR

FFR _{CT}	COLOR	AVERAGE ERROR TO FFR _{cath} * ± 1SD
≤0.70		-0.11 ± 0.15
0.71 - 0.75		-0.08 ± 0.10
0.76 - 0.80		-0.06 ± 0.09
0.81 - 0.85		-0.06 ± 0.06
0.86 - 0.90		-0.02 ± 0.07
0.91 - 1.0		-0.02 ± 0.04
0.0 - 1.0		-0.05 ± 0.09

* Error from the FFR_{CT} v2.0 Clinical Validation Population. Not indicative of all patient populations. Please refer to complete summary of clinical data provided in the Instructions For Use to determine the population in which the FFR_{CT} technology has been clinically validated.

REFERENCES

1. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. Tonino PA, et al. NEJM 2009; 360:213-224.
2. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. De Bruyne B, et al. NEJM 2012; 367:991-1001.
3. Diagnostic performance of non-invasive fractional flow reserve derived from coronary CT angiography in suspected coronary artery disease: The NXT trial. Norgaard B, et al. JACC 2014; 63(12):1145-1155.
4. SCCT guidelines for the performance and acquisition of coronary computed tomographic angiography. Abbara S, et al. JCCT 2016; DOI: 10.1016/j.jcct.2016.10.002.