



Landmark Study of Heartflow's New Non-Invasive Diagnostic Test Demonstrates High Diagnostic Performance in Patients with Suspected Coronary Artery Disease

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Computed FFR_{CT} Identifies Flow-Restricting Arterial Blockages with High Accuracy

REDWOOD CITY AND SAN FRANCISCO, Calif., October 30, 2013 – [Heartflow, Inc.](#) today announced positive data from a study of the company's newest-generation non-invasive computed fractional flow reserve FFR_{CT} technology. Results from the HeartflowNXT study demonstrate that, when compared to standard coronary CT angiography (CT) or invasive coronary angiography (ICA), FFR_{CT} provides a more accurate determination of which arterial blockages are associated with coronary ischemia and which are not, suggesting that FFR_{CT} may aid physicians in making decisions regarding further invasive testing or treatment.

The study's findings were presented today in a First Report Investigation session at the 25th Annual Transcatheter Cardiovascular Therapeutics (TCT) meeting in San Francisco.

Heartflow's patient-specific coronary blood flow modeling technology is a new non-invasive test that uses proprietary algorithms based on computational fluid dynamics and data from a patient's coronary CT scan to assist physicians in the diagnosis of coronary artery disease and identification of specific flow-restricting blockages in the coronary arteries. The prospective international Heartflow NXT study enrolled 254 stable patients with suspected coronary artery disease (CAD) at 10 centers in seven countries. The objective of the study was to compare diagnostic performance of FFR_{CT}, coronary CT, and ICA, to invasive FFR measurement (the current gold standard for determining flow-restricting arterial blockages). All patients underwent coronary CT, invasive coronary angiography (ICA), and invasive FFR, and then had FFR_{CT} analysis performed using the latest generation of Heartflow's software technology.

The findings of the study suggest the potential to eliminate the need for risky and expensive invasive evaluation and treatment in some patients. FFR_{CT} demonstrated superior ability to correctly identify those patients without coronary ischemia compared to coronary CT (specificity 79% vs. 34%). The study also showed a specificity of 79% compared to invasive angiography of 51%. FFR_{CT} correctly identified patients who had coronary ischemia with a high sensitivity (86%) and high negative predictive value (92%). There was also a striking improvement in the ability of FFR_{CT} to discriminate patients with and without flow-restricting arterial blockages compared to CT alone (area under the curve [AUC] on receiver operating characteristics analysis 0.82 vs. 0.63, $p < 0.0001$). AUC is a robust measure of diagnostic test reliability and accuracy.

"Proper selection of patients for invasive diagnosis and treatment is a crucial element of taking care of people who may have coronary artery disease. These procedures entail risk and expense. This new tool will be an exciting step forward for cardiology and may significantly improve how we guide coronary artery disease patients towards effective and efficient care," said principal investigator Bjarne Norgaard, M.D., Ph.D., department of Cardiology, Aarhus University Hospital Skejby, Aarhus, Denmark. Dr. Norgaard presented the data today at TCT.

Studies have shown that treatment guided by invasive FFR results in better clinical outcomes, including a 34% reduced risk of death or major cardiac event, and significantly lower healthcare costs. 1-3 Currently available noninvasive diagnostic tests do not provide stenosis-specific functional data, and therefore have limited diagnostic accuracy compared to invasive FFR. [4-6](#)

Heartflow's noninvasive technology is designed to provide physicians with FFR_{CT} values at every point along the coronary tree. [7](#) Traditional FFR measurements can only be obtained invasively during coronary angiography with a pressure-sensing guidewire.

"The results of HeartflowNXT allow us to consider for the first time the real possibility of a single non-invasive standardized test which can help physicians determine the impact of patients' coronary artery disease, offering the promise of a new standard for diagnosis of coronary artery disease," said John H. Stevens, M.D., chairman and CEO of Heartflow. "This technology will substantially improve the ability of physicians to accurately determine which patients need or do not need coronary angiography, potentially resulting in better patient outcomes and reduced costs."

An analysis of the potential positive impact of FFR_{CT} on healthcare costs and on patient outcomes was recently published by Mark A. Hlatky, M.D., professor of Health Policy and Research at Stanford University. In his analysis, Dr. Hlatky noted that using FFR_{CT} to guide selection of patients for invasive evaluation and PCI might "reduce costs and improve clinical outcomes compared

to current treatment pathways.” The model showed potential savings of more than \$3,000 per-patient when compared to the conventional angiography-based treatment strategy.⁸

About Heartflow, Inc.

Founded in 2007, Heartflow, Inc., is a cardiovascular company based in Redwood City, Calif. A pioneer in the field of non-invasive coronary artery disease diagnosis, Heartflow is committed to developing technology designed to help physicians noninvasively diagnose coronary artery disease and improve patient outcomes while reducing health care costs. For more information visit www.Heartflow.com.

1. Fearon, W.F., B. Bornschein, P.A. Tonino, R.M. Gothe, B.D. Bruyne, N.H. Pijls, and U. Siebert, Economic evaluation of fractional flow reserve-guided percutaneous coronary intervention in patients with multivessel disease. *Circulation*, 2010. 122 (24): p. 2545-50.
2. Pijls, N.H., P. van Schaardenburgh, G. Manoharan, E. Boersma, J.W. Bech, M. van't Veer, F. Bar, J. Hoorntje, J. Koolen, W. Wijns, and B. de Bruyne, Percutaneous coronary intervention of functionally nonsignificant stenosis: 5-year follow-up of the DEFER Study. *J Am Coll Cardiol*, 2007. 49 (21): p. 2105-11.
3. Tonino, P.A., B. De Bruyne, N.H. Pijls, U. Siebert, F. Ikeno, M. van' t Veer, V. Klauss, G. Manoharan, T. Engstrom, K.G. Oldroyd, P.N. Ver Lee, P.A. MacCarthy, and W.F. Fearon, Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. *N Engl J Med*, 2009. 360 (3): p. 213-24.
4. Jung, P.H., J. Rieber, S. Stork, C. Hoyer, I. Erhardt, A. Nowotny, W. Voelker, F. Weidemann, G. Ertl, V. Klauss, and C.E. Angermann, Effect of contrast application on interpretability and diagnostic value of dobutamine stress echocardiography in patients with intermediate coronary lesions: comparison with myocardial fractional flow reserve. *Eur Heart J*, 2008. 29 (20): p. 2536-43.
5. Meijboom, W.B., C.A. Van Mieghem, N. van Pelt, A. Weustink, F. Pugliese, N.R. Mollet, E. Boersma, E. Regar, R.J. van Geuns, P.J. de Jaegere, P.W. Serruys, G.P. Krestin, and P.J. de Feyter, Comprehensive assessment of coronary artery stenoses: computed tomography coronary angiography versus conventional coronary angiography and correlation with fractional flow reserve in patients with stable angina. *J Am Coll Cardiol*, 2008. 52 (8): p. 636-43.
6. Melikian, N., P. De Bondt, P. Tonino, O. De Winter, E. Wyffels, J. Bartunek, G.R. Heyndrickx, W.F. Fearon, N.H. Pijls, W. Wijns, and B. De Bruyne, Fractional flow reserve and myocardial perfusion imaging in patients with angiographic multivessel coronary artery disease. *JACC Cardiovasc Interv*, 2010. 3 (3): p. 307-14.
7. Taylor, C.A., T.A. Fonte, and J.K. Min, Computational fluid dynamics applied to cardiac computed tomography for noninvasive quantification of fractional flow reserve: scientific basis. *J Am Coll Cardiol*, 2013. 61 (22): p. 2233-41.
8. Hlatky, M.A., A. Saxena, B.K. Koo, A. Erglis, C.K. Zarins, and J.K. Min, Projected Costs and Consequences of Computed Tomography-Determined Fractional Flow Reserve. *Clin Cardiol*, 2013.