



New Data Highlight a Significant Increase in Cardiovascular Treatment Efficiency when the Heartflow Analysis is Incorporated into the Diagnostic Pathway

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Nine-month results from FORECAST trial show statistically significant reduction in unnecessary invasive cardiac testing, increase in catheterization lab efficiency, and reduction in repeat non-invasive testing

REDWOOD CITY, Calif. – October 16, 2020 — Late-breaking results presented today confirm that incorporating the Heartflow® FFR_{CT} Analysis into a coronary computed tomography angiogram (CTA)-led diagnostic pathway significantly increases overall cardiovascular treatment efficiency. At nine months, the FORECAST trial demonstrated that a CTA-Heartflow Analysis pathway led to a statistically significant decrease in invasive diagnostic coronary angiograms (ICA), an increase in efficiency in the cardiac catheterization laboratory, and a 40% reduction in the rate of repeat non-invasive cardiac testing. These results were presented by Professor Nick Curzen, University of Southampton and principal investigator of the FORECAST trial, as a late breaking trial at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation.

“The FORECAST trial has demonstrated that selected use of FFR_{CT} in a population of patients with stable chest pain, who underwent CTA as their first line test, proved to be cost neutral and reduced the number of patients requiring invasive coronary angiography by 22%, with no difference in clinical events or coronary revascularization,” said Professor Nick Curzen, chair of interventional cardiology at the University of Southampton and president of the British Cardiovascular Intervention Society.

In the FORECAST trial, 1,400 participants from the United Kingdom with chest pain and suspected coronary artery disease (CAD) were randomized to undergo a standard of care diagnostic test (reference group) or a coronary CT angiogram (CTA), coupled as appropriate with the Heartflow Analysis (test group). The diagnostic tests utilized in the reference group included CTA, stress echo, nuclear stress, exercise ECG, stress MRI and ICA, although CTA is now considered the front-line test for diagnosing CAD in the UK per [guidance from the National Institute of Health and Care Excellence](#) (NICE).

The selective addition of the Heartflow Analysis to CTA in the test group was cost neutral over the nine-month follow up period, while demonstrating the following clinical benefits:

- A statistically significant 22% reduction in the number of patients requiring an invasive diagnostic angiogram (reference group: 175 patients vs. test group: 136 patients, p=0.01)
- A 52% reduction in ICAs not diagnosing obstructive CAD (reference group: 62 ICAs vs. test group: 30 ICAs)
- Improved revascularization efficiency, with a 36% increase in the proportion of patients who underwent ICA and also required invasive revascularization (reference group: 55% vs. test group: 75%)
- A 40% decrease in repeat non-invasive cardiac testing during the follow up period (reference group: 127 additional non-invasive tests vs. test group: 76 additional non-invasive tests)
- Safe outcomes for patients with no increase in major adverse cardiovascular and cerebrovascular events (MACCE) (reference group: 74 events vs. test group: 71 events)

The Heartflow Analysis helps doctors quickly diagnose CAD and decide the appropriate treatment for patients. In 2017, [NICE recommended the Heartflow Analysis](#) as the most cost-effective option following a coronary CTA when additional information is needed by the clinician. NICE estimated a per patient savings of £214 when compared to a CTA-only diagnostic pathway for patients whose likelihood of CAD is between 10% and 90%, as the information provided by the Heartflow Analysis enables physicians to avoid recommending invasive diagnostic procedures or requiring additional tests. With the reference group in the FORECAST trial including other types of diagnostic tests and higher risk patients in whom ICA was indicated as the initial test, no increase or decrease in cost was demonstrated.

“The FORECAST trial is the first randomized controlled study in which the Heartflow Analysis has been added to a population managed predominantly with a CTA-first approach,” said Campbell Rogers, MD, FACC, Chief Medical Officer, Heartflow. “The results are consistent with previous clinical trials in which other non-invasive or invasive tests were used as references and reinforce why more and more NHS hospitals (more than 60 at present) have adopted the coronary CTA-Heartflow pathway for diagnosing coronary heart disease.”

“The statistically significant reduction in the number of patients requiring an invasive diagnostic procedure is an important finding as it means that at least 30,000 ICAs may be avoided annually across the NHS. In addition, adoption of the CTA-Heartflow Analysis pathway has led to [reduced waiting times](#) and [improved patient care](#), which are all critical factors especially during the pandemic when physicians and hospitals are doing everything they can to minimize the number of patients who are required to be in a hospital setting,” continued Dr. Rogers. “We want to thank Prof. Curzen and the FORECAST investigators for leading this trial.

It is exciting to see the marked incremental clinical value of the Heartflow Analysis in the CTA-first diagnostic setting to which the field is quickly moving globally, and to see these benefits coming at no added cost to the NHS.”

About the Heartflow FFR_{CT} Analysis

The Heartflow Analysis is a non-invasive, cardiac test for stable symptomatic patients with CAD, the leading cause of death worldwide. Starting with a standard coronary CTA, the Heartflow Analysis leverages deep learning and highly trained analysts to create a digital, personalized 3D model of the heart. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and provides FFR_{CT} values along the coronary arteries. This information helps physicians evaluate the impact a blockage may be having on blood flow and determine the optimal course of treatment for each patient. A positive FFR_{CT} value (≤ 0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle to a degree which may warrant invasive management.

Data demonstrating the safety, efficacy and cost-effectiveness of the Heartflow Analysis have been published in more than 400 peer-reviewed publications, including long-term data out to five years. The Heartflow Analysis offers the highest diagnostic performance available from a non-invasive test.¹ To date, clinicians around the world have used the Heartflow Analysis for more than 60,000 patients to aid in the diagnosis of heart disease.

About Heartflow, Inc.

Heartflow, Inc. is a digital health company uniquely positioned at the intersection of advanced artificial intelligence and healthcare to transform how heart disease is diagnosed and treated. Our non-invasive Heartflow FFR_{CT} Analysis leverages deep learning to create a personalized 3D model of the heart. By using this model, clinicians can better evaluate the impact a blockage has on blood flow and determine the best treatment for patients. Our technology is reflective of our Silicon Valley roots and incorporates decades of scientific evidence with the latest advances in artificial intelligence. The Heartflow FFR_{CT} Analysis is commercially available in the United States, Canada, Europe and Japan. For more information, visit www.Heartflow.com.

1. Driessen, et al. J Am Coll Cardiol 2019.