HeartFlow® **Clinical Case Study**

Mobilizing Care at Cone Health

Cone Health is one of the nation's premier heart and vascular care centers due in part to its commitment to continuous improvement and investment in innovative technologies that improve patient care. The Cone Health team identified opportunities to streamline testing, achieve efficiencies in cath lab processes and improve the patient journey by reducing its reliance on stress testing for diagnosis of coronary artery disease. In seeking the most advanced solutions, the Cone Health team found HeartFlow in 2017. As an early adopter of the CCTA-first pathway coupled with the HeartFlow Analysis, their cardiovascular program continues to demonstrate leadership in advancing the quality of heart and vascular care for patients. Hear key members of the Cone Health team discuss why they adopted the HeartFlow Analysis, the impact it's had on patient care and key components of the program's success in our latest case study.

Sheryl Booth
Executive Director Heart & Vascular

Dr. Katarina Nelson
CT Program Lead, Imaging Cardiologist

Dr. Henry Smith
Interventional Cardiologist

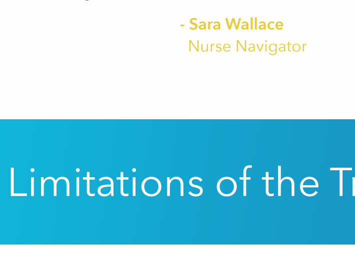
Sara Wallace
Nurse Navigator

"Looking at it from the broad overview that I have, we have a huge list of benefits that go along with having this technology."

- Sheryl Booth, RT(R), MHA
Executive Director Heart & Vascular

"The HeartFlow Analysis complements our anatomical images from Coronary CT with functional information, and it also helps procedural planning for the interventional cardiologists."

- Katarina Nelson, MD
CT Program Lead, Imaging Cardiologist

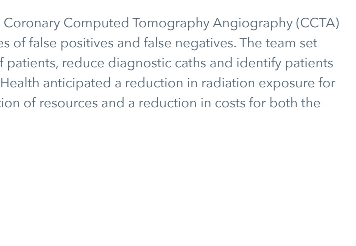


"I am impressed by the high sensitivity and specificity that the HeartFlow Analysis brings to the management of patients with coronary artery disease and stable chest pain."

- Henry Smith, MD
Interventional Cardiologist

"It's really amazed me how much I've learned in the last few months about this technology and how the HeartFlow Analysis combines anatomy and function."

- Sara Wallace
Nurse Navigator



Limitations of the Traditional Care Pathway

By initially relying on stress tests, such as SPECT and stress echo, with Coronary Computed Tomography Angiography (CCTA) alone used as backup, the Cone Health team experienced typical rates of false positives and false negatives. The team set three key improvement goals: reduce the number of tests required of patients, reduce diagnostic caths and identify patients at-risk of recurring chest pain earlier. By achieving these goals, Cone Health anticipated a reduction in radiation exposure for patients and care teams, improved cath lab efficiencies, better utilization of resources and a reduction in costs for both the health system and patients.

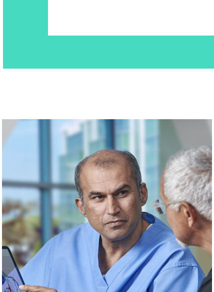
How HeartFlow Helps

Innovation

The HeartFlow Analysis is a non-invasive diagnostic test that helps physicians identify the impact that blockages have on blood flow to the heart. By leveraging a standard CT, the latest advancements in AI, cloud computing and computational physiology, physicians get both anatomic and physiologic information in one test. This powerful combination of information allows physicians to clearly identify problem areas before entering the cath lab. The results are presented as a color-coded 3D model of a patient's arteries and are available as a web application via desktop or mobile. This technology enabled the Cone Health team to better triage patients without the capital expense or investment often required when adopting new technology.

"We were early adopters of technology that enables more comprehensive evaluation of coronary artery disease by providing both anatomical and functional information and improves patients' outcomes."

- Katarina Nelson, MD
CT Program Lead, Imaging Cardiologist



Accuracy

Traditional diagnostic tests result in 20-30% false-negative rates[1] and 55% false positive rates[2]. In contrast, CT has a 98% negative predictive value[3] allowing physicians to safely defer patients without disease, and when 30-90% disease is present and more information is needed, HeartFlow helps fill in the gaps by providing functional information. The HeartFlow Analysis is proven to have the highest diagnostic performance over other non-invasive tests with long-term outcomes out to five years. For the Cone Health team this translates to appropriate use of the cath lab for interventional procedures that are more predictable, well planned, coordinated and discussed with patients and the entire care team in advance of procedures.

"This gave me a tool that I felt was more trustworthy and helped to get away from the high false positives we were getting with SPECT."

- Henry Smith, MD
Interventional Cardiologist

Patient Care

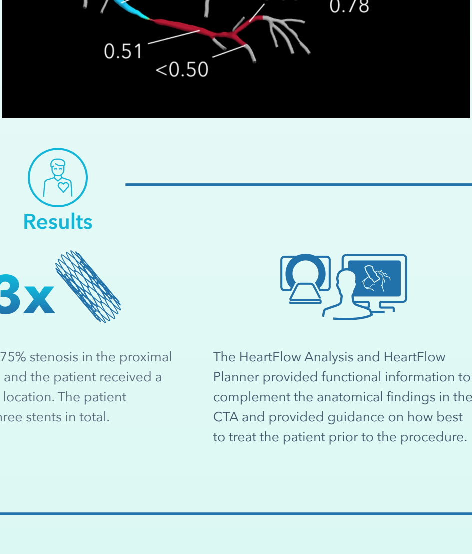
Patient satisfaction has become an integral component of a value-based healthcare system, and adoption of innovative technologies can help support meeting these goals. With the HeartFlow Analysis, patients avoid the amount of time, money and anxiety that would have resulted from using other tests and instead benefit from an accurate diagnosis and a clearer understanding of their heart health. The Cone Health team now has more engaged patient-provider conversations which helps put patients at the center of their care and build trust in the entire process.

"By having a structured program with a dedicated team, you can create a better workflow and patient experience."

- Sheryl Booth, RT(R), MHA
Executive Director Heart & Vascular

HeartFlow Analysis Patient Case

Age: 68
Sex: Male
History: Hypertension, long standing tobacco use, obesity, squamous cell lung cancer and left upper lobe resection in 2014, and obstructive sleep apnea who was referred to cardiology for progressively worsening shortness of breath after coronary calcifications were noted on follow up surveillance chest CT.



Summary: This high risk patient received a coronary CTA, which revealed diffuse coronary artery disease and coronary calcification in all three arteries. Because more information was needed, a HeartFlow Analysis was ordered; it allowed the physician to identify functionally significant disease in the mid and distal Right Coronary Artery (RCA) with a .51 FFR_{CT}, in addition to diffuse, restricted blood flow in the Left Circumflex Artery (LCX). HeartFlow Planner was also used to gauge the potential impact of restoring the coronary lumen to its normal size. The invasive coronary angiogram matched perfectly with the HeartFlow Analysis and HeartFlow Planner, which helped to identify the specific areas requiring intervention.

Results

0% Residual Stenosis

Cardiac catheterization showed 80% stenosis in the mid RCA and 90% stenosis in the distal RCA, the patient received two drug eluting stents (DES) leaving 0% residual stenosis.

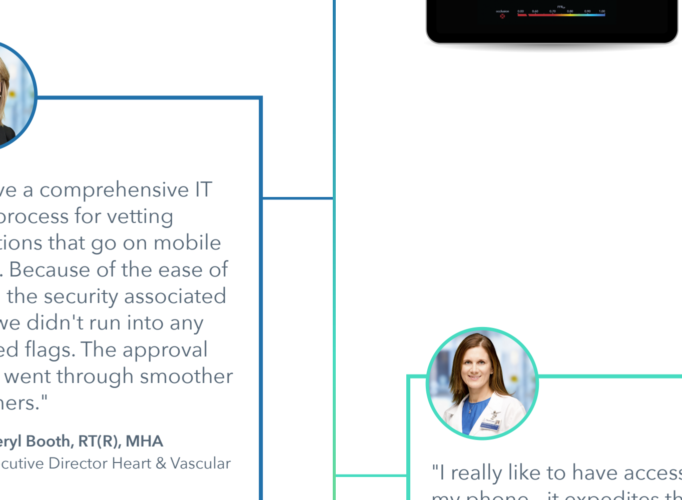
3x

There was 75% stenosis in the proximal LCX artery, and the patient received a DES in this location. The patient received three stents in total.

The HeartFlow Analysis and HeartFlow Planner provided functional information to complement the anatomical findings in the CTA and provided guidance on how best to treat the patient prior to the procedure.

* HeartFlow Planner usage at Cone Health is part of a beta program. Not commercially available.

HeartFlow is available from anywhere



"We have a comprehensive IT review process for vetting applications that go on mobile devices. Because of the ease of use and the security associated with it, we didn't run into any major red flags. The approval actually went through smoother than others."

- Sheryl Booth, RT(R), MHA
Executive Director Heart & Vascular

"I really like to have access on my phone - it expedites the process. I can quickly check on patients and text my colleagues if a patient needs to go to cath. It has nice features too - with a simple click you can see the FFR_{CT} and different parts of the vessels."

- Katarina Nelson, MD
CT Program Lead, Imaging Cardiologist

"My patients love to see their HeartFlow Analysis, and I always use my cell phone to show them."

- Henry Smith, MD
Interventional Cardiologist

"I'll read the CT interpretation and look at those photos and also log into the HeartFlow app and pull up the HeartFlow Analysis to compare the two, learn the anatomy and correlate the diagnosis with the picture."

- Sara Wallace
Nurse Navigator

Key Benefits to Cone Health

- Improves diagnosis of coronary artery disease using CT + HeartFlow Analysis pathway
- Supports continued CT program growth, plus improved CT reading and acquisition
- Reduces high false positive diagnostic rates allowing for more appropriate use of the cath lab
- Facilitates procedural and treatment planning for interventionalists
- Simplifies workflows and improves efficiency
- Enables meaningful patient interactions, education and engagement with HeartFlow mobile

"It really is a go to test, especially for the low-to-intermediate, but now also the higher risk patients, and it's very accurate. So I love it! SPECT imaging is probably going to take a big hit in our institution."

- Henry Smith, MD
Interventional Cardiologist

67% of treatment plans changed after physicians evaluated patient care using the HeartFlow Analysis[4]

Adoption of the HeartFlow Analysis at Cone Health helped the team to further enhance their cardiac program - from growing their CCTA program to achieving greater cath lab efficiencies to strengthening team collaboration. Now with a growing CCTA program with expansion plans to include three scanning locations, eleven readers, and a growing network of referring providers, their passion for adopting advanced technology paired with a well-coordinated care team is a model of success. When administrator and physician goals are aligned, optimal patient care results.

1. Arbab-Zadeh, Heart Int 2012. Yokota, et al. Neth Heart J 2018. Nakanishi, et al. J Nucl Cardiol 2016.
2. Patel, et al. N Engl J Med 2010. Patel, et al. AHJ 2014. Danad, et al. JAMA Cardiology 2017.
3. Hoffmann, et al. J Am Coll Cardiol. 2009.
4. Fairbairn, et al. Euro Heart J 2018. Patel, et al. JACC CV Imaging 2019.

The information provided by the HeartFlow Analysis and HeartFlow Planner is intended to be used in conjunction with the patient's clinical history, symptoms and other diagnostic tests, as well as the clinician's professional judgment. The HeartFlow Analysis and HeartFlow Planner may not be appropriate for all patients. See their respective indications for use and limitations for more information. The HeartFlow FFRct Analysis has received FDA Clearance, is CE-Marked, and is commercially available in the United States, Europe, Japan and Canada. The HeartFlow Planner has received FDA Clearance and is commercially available in the United States only.

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