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I Can See Cleerly Now. Patient Says Scan Results Were 'Eye-Opening'

by Brian Bossetta

> A patient says Cleerly's innovative technology revealed underlying heart disease that had previously gone undetected. The company's founder weighs in on the results.

Sharon Bruno wasn't concerned about her heart due to any symptoms. A registered nurse in her mid-forties, she felt fine and was by all accounts healthy.

But she was deeply concerned about the cardiovascular disease in her family; her father, who had chronic high blood pressure and cholesterol, died of a stroke at 55.

So when her calcium score came back zero, and other biomarkers were in normal ranges, she was relieved.

Until she got the results from Cleerly.

Founded in 2017 by James Min, a former cardiologist at New York-Presbyterian Hospital, Cleerly is a technology based on Min's research that utilizes coronary computed tomography angiography (CCTA) to dig deeper than standard diagnostics, offering patients like Bruno a closer look at what is really going inside their arteries.

The company's CCTA software, cleared by the FDA in 2020, relies on artificial intelligence and 3D-imaging to see exactly how much plaque has accumulated in the arteries, giving providers a leg up in preventing heart attacks and strokes.

"We didn't actually understand heart disease the way we thought we did." – James Min

In Bruno's case, her February 2021 Cleerly scan painted a much different picture than her calcium score.

"Having a zero calcium score and then finding out it wasn't really zero was eye-opening," Bruno told *Medtech Insight*.

In fact, Cleerly showed Bruno had stage 2, or moderate, plaque. The company measures plaque buildup on a four-tiered scale – 0 (no plaque), 1 mild, 2 moderate, and 3 severe. Bruno's results meant her risk for a heart attack was not zero, but moderate, with the chance to increase over time.

"When I got the results, it was definitely shocking," she said. "I had no idea I was developing plaque."

And Bruno was not alone in thinking her initial tests put her in the clear.

As Min explained to *Medtech Insight*, the majority of heart attacks strike those considered low risk, and half of heart attack patients have no prior symptoms at all. On top of that, most of the coronary lesions that cause heart attacks are missed by stress tests because the lesions do not narrow the vessels restricting blood flow.

Min furthered explained that within traditional assessments of large groups – a million patients, for example – assumptions can be made about general risks based on cholesterol and other numbers, but you cannot "pinpoint the individual" who is at risk. And diagnosing individuals, not groups, is what Min believes is the key to better treatment and prevention.

> ### Cleerly Advances CCTA Digital Pathway To Stop Heart Disease
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> By Reed Miller
>
> 06 Dec 2022
> Using artificial intelligence and coronary computed tomography angiography Cleerly is trying to shift cardiology's focus from symptoms-based interventions to prevention and treatment of the underlying vascular disease.
>
> *Read the full article here*

"That's what we recognized as one of the limitations with our current approach," he said, adding that he wants to reframe how clinicians view patients. "We want to keep a focus on people as individuals rather than as populations."

Individuals like Bruno, for instance.

JAMES K. MIN, MD

Specific to Bruno's case, Min said exhaustive research on calcium scoring led him to conclude clinicians had been asking the wrong question all along.

While acknowledging that a cohort of a million patients with zero calcium scores had a better overall prognosis than a cohort of a million with higher scores, the calcium score alone is not predictive of who in that cohort is going to have a heart attack. That's because, as Min put it, the question is population, not individual, based.

The more direct, and better, question, in Min's view, is among a million people who are going to have a future heart attack, what's the percentage of those with a zero calcium score? The answer, he said, is about a third, which is why using a zero score by itself is not a great marker to rule out risk of a heart attack.

Additionally, calcium scores cannot detect the type of plaque that is dangerous – the noncalcified, fatty cholesterol-filled plaque.

Not What We Thought

Min spent 15 years at New York Presbyterian Hospital and Cornell Medical College, where he was involved in a series of clinical trials ranging from 500 to 30,000 participants aimed at gaining a better understanding of vascular biology. He says that what he ultimately learned was "we didn't actually understand heart disease the way we thought we did."

Specifically, the conventional wisdom was all plaque was bad. But it's not.

As Min explained, while noncalcified, cholesterol-filled, and dark plaque is dangerous, once it turns bright and calcified it becomes protective, not pathologic, against disease.

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"Seeing the plaque in my arteries gave me the motivation to do more. I knew if I wanted to be healthy, I had to make changes." – Sharon Bruno

Further studies revealed that various treatments, including statins, did not destroy the dangerous plaque but transformed it into the bright, protective plaque.

And that result has been replicated, Min said, through other treatments, including low-sodium diets and increased physical activity.

"All the good things we do for patients, none of them actually regress plaque," Min said. "What they do is transform it from noncalcified into calcified plaque."

No Longer Guessing

Moreover, traditional coronary artery calcium scans, Min explained, only detect calcified but not noncalcified plaque, and do not reveal its morphology from bad to good. This means that patients are often left in the dark.

"We were truly guessing," Min said. "It turns out calcium is an age-dependent phenomenon, like developing osteoarthritis in the knee or back which happens over time. You won't see bony spurs in your knee until you're 70 years old. It's the same thing with the calcium in your heart."

And this clearer understanding of plaque is why the status quo, in Min's view, is inadequate in assessing risk.

"We want people like Sharon to understand what's going on in their heart," Min said.

Treatment and Progress

Bruno said her Cleerly scan not only pinpointed her disease but her providers were able to explain why she had developed it – family history, lifestyle, and a prior surgery that affected her hormones.

Though her doctors initially suggested statins, Bruno said she wanted to try to improve her numbers naturally.

"Seeing the plaque in my arteries gave me the motivation to do more," she said. "I exercise every day and try to eat healthier. I don't want to end up like my father. I knew if I wanted to be

healthy, I had to make changes."

And it's worked.

Bruno's follow-up scan in June 2022 showed she had reduced her total plaque from 348 to 254, eliminated her low-density noncalcified plaque, and reduced her non-calcified plaque from 211 to 159 as well as her atheroma volume from 12.5% to 7.5% with minimal stenosis.

Bruno has another follow-up scan coming up and believes her new numbers will be even better.

While initial scans are important, Min said follow ups are even more so.

"The baseline scan is really important because it gives you the information you need to properly treat a patient," he said. "But the follow-up scan tells you whether or not that therapy is actually working."