## A Clinical SICCESS

Bringing cutting-edge medicine to our community

By Robert A. Poarch

harles Franks, a 69-year-old retired factory worker and auto body technician living in Pisgah Forest, tries to go fishing and bow hunting as often as he can. He had to limit these activities about a year ago, because his legs were giving him a lot of pain when he walked.

Franks was referred to John Henretta, MD, a vascular surgeon with Mission Hospital and Carolina Vascular. "We determined that Franks had a reduction of circulation in his left leg and foot," said Dr. Henretta, "which probably accounted for some of the pain he described when he walks or tries to exercise."

Dr. Henretta was able to determine that Franks's pain stemmed from disease in the superficial femoral artery of his left thigh. Based on the condition of the artery, the doctor recommended treating Franks with balloon angioplasty to restore blood flow in his leg. Franks also happened to be an excellent match for a medical trial being performed at Mission.

## The Mission Research Institute

The Mission Research Institute collaborates with Mission Health doctors, like Dr. Henretta, to perform clinical trials of new drugs, devices and techniques. Research staff help identify and screen possible patients, like Franks, for ongoing studies. Most importantly, they make sure that Mission's doctors adhere to research study and regulatory protocols, and ensure the collection and communication of clinical data to the trial researchers.

"We've been fortunate to have a lot of different device trials and, more recently, some drug trials," said Dr. Henretta. "In doing so, we will provide different companies in trials with information about how things progress. Mission Health is supportive of the endeavors of research here by having a research staff that can assist us in collating all the data, putting everything together and making sure patient following ups are done."

Each patient is fully supported by the Mission Research Institute throughout the clinical trial. "We have a research nurse here, which is nice for me because patients have a phone number they can call to reach a research coordinator who is directly responsible for their information and can quickly answer questions. Without that person, I don't think research in a community is nearly that successful," said Dr. Henretta.

## Participating in a Trial

The Mission Research Institute reached out to Franks. "I read the information, and saw what the pros and cons were. Then I talked to the nurse, and she explained it to me more in depth," Franks said. "Then, me and my wife talked about it and prayed about it. We decided if I can help somebody, I'd go ahead and do it."

This trial was looking for candidates like Franks who had narrowing of an artery treatable with balloon angioplasty. Basically, with the help of X-ray, a tiny drug-coated balloon catheter was guided through the blood vessel in Franks's leg to the location of the narrowing. The balloon catheter was inflated for about two minutes to expand the artery and release the medication, and then the balloon is deflated and removed.

"The trial was for a medicated balloon that would ideally reduce the risk of the artery renarrowing in the future," said Dr. Henretta. "They're trying to improve the delivery of the medicine to the treatment area. This was an advancement on something that's already been out."

According to Dr. Henretta, Franks's procedure went well. "We were able to treat the area with the balloon with very nice angiographic result and, more importantly, a good clinical result. Charles is doing exceedingly well," said Dr. Henretta.

As part of the trial, Franks follows up with Dr. Henretta after one month, three months, six months, one year and two years to evaluate the artery. "So far it seems to be working very well," said Franks, after his one-year checkup. "I can walk around the yard and up any steep hills. I can do my weed eating.



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I've got a bank in the yard, and I don't have any trouble now. So that's a good thing."

## Staying in Our Comfort Zone

Though Franks admits he was a little nervous about participating in a clinical trial at first, talking to the Mission Research Institute nurse and Dr. Henretta made him comfortable with the study procedure. "We didn't know what was going to happen," he said. "In the end, I didn't think the possibility of any dangers was very high. That was the main reason that I did it. I would advise someone else to try it."

"Fortunately in the US, and most developed countries, research trials are very carefully vetted and looked at by the FDA," said Dr. Henretta, about patient safety. "And often

times, like with this study, we're not breaking new ground and trying experimental stuff on patients. We're trying to improve what's currently available and FDA approved."

Ultimately, research trials like these are good for our patients and community. "With heart research for example, it allows patients to receive certain treatments without having to go to a different center. It gives patients access to newer and advancing options," said Dr. Henretta. "Having these trials in our community allows our patients to receive advanced care without having to travel beyond their comfort zone."

"That's the way medicine has been throughout history. Someone has to use it before they know whether it will work or not," Franks said, philosophically summing up is his clinical trial experience. "It gave me a better way of life." ©



John Henretta, MD, is a vascular surgeon with Mission Hospital and Carolina Vascular.

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