

Physician Testimonial

Dr.med Sabine Fredersdorf

University Clinic, Regensburg, Germany



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Ablation for the treatment of atrial fibrillation (AF) is a promising new therapy with several known drawbacks. For interventional electrophysiologist Dr. Sabine Fredersdorf of the University Clinic at Regensburg, Germany, one of those drawbacks was the inordinate amount of time it took to safely and effectively perform a pulmonary vein (PV) ablation of atrial fibrillation.

"Ablation of atrial fibrillation is one of the most time-consuming procedures in interventional cardiology," Fredersdorf stated. Her concern was not mere clockwatching. "Increased procedure time is associated with a higher rate of complications," she explained. "At our clinic, we were looking for a way to reduce the procedure time mainly as a way to reduce the complication rate."

The University Clinic at Regensburg is a busy electrophysiology clinic but one that does not have a waiting list for AF ablation. The clinic used to ablate about two patients a week, although that schedule was variable. However, AF ablation was not only a difficult and time-consuming procedure, it had its share of complications.

With a wide variety of options for catheters and ablation techniques, Fredersdorf and colleagues used mainly cryoablation for AF until switching to the Pulmonary Vein

Ablation Catheter (PVAC™) from Ablation Frontiers in October 2007. Fredersdorf learned about this innovative technique from a colleague experienced in the technique. The PVAC catheter is a novel decapolar ablation catheter that is used with the GENius™



multi-channel, duty cycled RF generator. The system does not require three-dimensional imaging or robotic steering.

Dr. Fredersdorf then attended a Clinical Mentoring Course or CMC program which allowed her to observe ablation using the novel system and practice it in a controlled environment. "The CMC created a very safe learning environment," she said. "The CMC is a good way to see it. It's important to see the technique done by someone else before attempting it."

The first thing Dr. Fredersdorf noticed was that the PVAC system reduced procedure time by more than half. She estimated that skin-to-skin procedure times using the cryoablation method ran about three hours, but the PVAC catheter reduced that to about one hour and 20 minutes. While this has the obvious benefit of increasing patient throughput, Fredersdorf was pleased to see that it has also reduced complication rates.

“We’ve only done 16 cases to date,” she stated, “but we have had zero complications.” In a series of her first nine AF procedures using the PVAC catheter system, she found that she could isolate 97% of all four pulmonary veins with no procedural complications with an average procedure time of only 84 ± 5 minutes.

While Dr. Fredersdorf finds it is really premature to discuss cost effectiveness of the system, she has already made some observations. “It can be done in a shorter period of time, using less equipment. That will affect cost effectiveness. But for us, it is still too early to tell.”

The first group of patients who were ablated with PVAC at the Regensburg clinic are just starting to come back for their first follow-up visit, scheduled for three months following the ablation. Dr. Fredersdorf will review ECGs from these patients, typically obtained from ambulatory monitoring. Patients who show no evidence of AF may be allowed to discontinue antiarrhythmic agents.

Her biggest reservation about this innovative new system is the lack of long-term data. “I am curious about these patients,” she admitted. “I want to see how they are doing, how effective the ablation was.”



Aerial View of Regensburg Klinik



Regensburg, Germany

As an electrophysiologist, Dr. Fredersdorf has had the opportunity to work with many novel products, catheters, imaging systems, and devices.

“PVAC is fast and easy,” she said. “Cryoablation is more complicated, and it was always difficult to check to see if the ablation was successful. And, of course, the PVAC is quicker.” She is also quick to mention her requests for adding to the PVAC product portfolio. “I would like to see a larger-diameter PVAC catheter for larger veins.”

Her frontline approach for AF ablation is now the PVAC and GENius generator. It has reduced complications, streamlined the ablation, and cut procedure times in half. While the real bottom line for Dr. Fredersdorf is the dramatic reduction in procedural complications, she also admits that the novel system has drastically simplified clinical requirements for successful AF ablation.

“We don’t need to do 3D imaging. We don’t need robotic steering. There’s simply no need for it.” ■