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Cardio Conversations: 'Trials, Trials, Trials!' Volta Has Big Ambitions For AI In EP

by Reed Miller

In this edition of Cardio Conversations, *Medtech Insight* editor Reed Miller talked to Théophile Mohr Durdez, the CEO and co-founder of Volta Medical, a Marseille-based company applying artificial intelligence to electrophysiology. Volta has raised over €70m and is sponsoring the TAILORED AF trial to show that its software can make atrial fibrillation ablation more effective.

Use the player below to hear the entire interview.

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Volta Medical is investing in clinical trials to show its artificial intelligence (AI) software can improve the effectiveness of *cardiac ablation* in patients with *persistent atrial fibrillation*.

"Success rates for [ablation to treat] *paroxysmal atrial fibrillation* have been very good. But if you look at the landmark studies of ablation for persistent atrial fibrillation, the success rates are stagnating around 60%," Volta CEO Theophile Mohr-Durdez told *Medtech Insight*. "This is probably one of the largest unmet needs in interventional cardiology and cardiac electrophysiology."

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> *outcomes, and follow-up. And [right now], all of this is lost to general knowledge." – Theophile Mohr-Durdez*

The French company's VX1 decision-support software helps physicians identify abnormal electrograms with real-time annotation of three-dimensional anatomical and electrical maps. It specifically identifies the *dispersed electrogram signals* associated with atrial arrhythmias. (Also see "*New AI Tech To Improve AFib Treatment Slated For 2020 Market Launch*" - Medtech Insight, 18 Jun, 2018.)

Results of a *validation study* supported a CE Mark and US Food and Drug Administration clearance in 2020. In May 2023, the FDA cleared Volta's next-generation AF-Xplorer AI system, which can be integrated with *Abbott*'s *EnSite X* mapping system and *Johnson & Johnson*/*Biosense Webster*'s *Octaray* multi-polar mapping catheter.

The company has raised over €70m from investors, including €36m from a series B round in January.

That money will allow Volta to complete *TAILORED AF*, a 374-patient, randomized trial comparing *pulmonary vein isolation* with or without guidance with Volta's AI system. The trial completed enrollment in February 2023 and the company expects the results to be available in 2024.

"[*TAILORED AF*] is one of the most ambitious randomized clinical trials in the history of [atrial fibrillation] ablation," Mohr-Durdez said. "We hope that this trial can help us penetrate the market and put a major dent in the atrial fibrillation ablation market as well."

Here are some more edited highlights from *Medtech Insight*'s interview with Theophile Mohr-Durdez.

Q ***Medtech Insight*: Can you give us a quick history of Volta and explain how you define your company's mission?**

A Theophile Mohr-Durdez: Volta Medical is a company I *co-founded in 2016 with three physicians*. Two of them are practitioners in Marseille, in the south of France, and one of them is living in the US in Providence, Rhode Island. I have a background as a data scientist and as an engineer.

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We develop software solutions to guide cardiac electrophysiologists while they are ablating patients with cardiac arrhythmias. And notably, we have the first product based on AI that is able to provide guidance during AF ablation and to help physicians better understand AF mechanisms during the procedures.

This device is *FDA-cleared*, and CE-marked since 2020. It has already undergone very extensive clinical validation with a first pilot trial. That was a multicentric trial that was published last year in the *Journal of Cardiovascular Electrophysiology*.

And we have an ongoing randomized clinical trial, *TAILORED AF*, which is one of the most ambitious, randomized clinical trials in the history of AF ablation.

Then we also are developing other algorithms to further guide and help physicians in the operating room in real time.

We are currently more than 70 people worldwide, with headquarters in France and the subsidiary in the US. We have raised more than €70m, so far, with a €36m series B funding led by *Vensana Capital* that we closed three months ago.

The mission of the company is to help physicians in the management of cardiac arrhythmias with artificial intelligence that comes on top of existing devices.

Q What is the unmet need that you are addressing? What is 'not good enough' about the current approach to ablation guidance and how is your approach different?

A From from the perspective of an engineer looking at this market, basically every procedure is 'lost experience' to the industry, to the patients and to the physicians. Each procedure generates gigabytes of data – hours and hours of experience – that translate into maps, electrograms, time series, outcomes, and follow-up. And right

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now, all of this is lost to general knowledge.

And so the idea of the company is to try to leverage these procedures to better treat the patients, to optimize treatment for the patients, and optimize outcomes in the long term.

So how can we learn from each and every single procedure that is being performed in the electrophysiology lab to optimize outcome for the patient? That is the core question that Volta is trying to at least partially answer.

If you look at the landmark studies in atrial fibrillation, pulmonary vein isolation has shown very good success rates for paroxysmal atrial fibrillation patients, especially now with new contact force catheters. If you look really at the last past 10 years, success rates for paroxysmal atrial fibrillation have been very good.

But if you look at the landmark studies of ablation for persistent atrial fibrillation, the success rates are stagnating around 60%. It means that 40% of patients essentially need another ablation – at least another ablation – to get cured from atrial fibrillation.

This is a big unmet need that we are trying to help with. This is probably one of the largest unmet needs in interventional cardiology and cardiac electrophysiology today. Our first product is aimed at providing an alternative to pulmonary vein isolation alone.

We also offer something that can be done on top of pulmonary vein isolation for patients with persistent atrial fibrillation, but also for patients that have already had pulmonary vein isolation and yet have come back for second ablation. What do you do next? When pulmonary veins are already isolated, and the patient is still in atrial fibrillation?

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Q What evidence did you have to show regulators to get *FDA clearance* and a CE Mark? What do you hope to accomplish with *TAILORED AF*?

A To obtain *clearance*, we designed the Reader Study jointly with the with the FDA. We used some of their feedback that we incorporated in our design of the study. It was more of a technical feasibility study and a validation study – to compare the performance of our AI algorithm compared to that of expert [human] annotators with unlimited time, annotating abnormal electrograms.

And the results showed, essentially, that you cannot distinguish our algorithm from an expert with unlimited time in identifying abnormal electrograms.

And then we had the metacentric study that was conducted in Europe, with eight centers and 17 operators. *We published a series of 85 patients with persistent, de novo atrial fibrillation last year in the Journal of Cardiovascular Electrophysiology.*

We managed to standardize outcomes across centers in terms of acute outcomes – termination rates – but also in terms of long-term outcomes like freedom from atrial fibrillation and freedom from any arrhythmia. And there was no difference between the [original] centers – where the technology was initially founded, developed and tested – and the 'satellite centers' where the technology was subsequently tested with physicians without any consistent experience in electrogram-based ablation. And so that was our second study that was published in 2022.

On the heels of this initial study, we design *TAILORED AF*. We just finalized enrollment three months ago and we are awaiting the results in 2024. *TAILORED AF* is a randomized clinical trial involving approximately 40 centers with more than 50 physicians in five countries – US, France, Germany, the Netherlands, and Belgium.

There are two arms of the study, with a one-to-one ratio. It is comparing pulmonary vein isolation alone versus pulmonary vein isolation plus the Volta system. And the goal is to demonstrate superiority in terms of freedom from atrial fibrillation at 12

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months.

So we are following the patients for 12 months with a very stringent follow up involving Holter monitors plus transtelephonic monitoring using cardiac devices.

And so, because it is a transatlantic trial and because there is a stringent follow up and it involves so many centers and 374 patients, this trial is really a very ambitious trial. It is probably one of the most ambitious trials in the history of atrial fibrillation ablation and we hope to demonstrate superiority of the approach using pulmonary vein isolation plus Volta versus pulmonary vein isolation alone.

That's the goal, really, of this trial. And we hope that this trial can help us penetrate the market and put a major dent in the atrial fibrillation ablation market as well.

"Trials, trials, trials – a lot of trials. The main goal of the latest funding is to finalize TAILORED AF and publish its results." – Theophile Mohr-Durdez

Q **You recently announced some big financings. What does that let you do that you would not have been able to otherwise?**

A Trials, trials, trials – a lot of trials. The main goal of the latest funding is to finalize *TAILORED AF* and publish its results.

We also got very strong feedback on the value that this device can bring for 're-do' patients. As I was telling you, the big question for physicians is what do you do next after atrial fibrillation persists even though the pulmonary veins are isolated.

We started a new trial, that will be mainly US-based, called *RESTART*. That will be specifically focused on patients with isolated pulmonary veins that come for a second

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> ablation – re-do patients.
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> And this is really one of the main goals of this series B funding. The goal is to go through enrollments and follow up.
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> Another part of the funding is allocated to commercial readiness. We are obviously heavily focused on our clinical trials, but at the same time, we need to prepare for a more consistent launch after the publication of the *TAILORED AF* results, which will probably be in the second quarter of 2024.
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> And so we are heavily invested in market research, trying to understand what the best business model for Volta would be. And then, obviously, our R&D is putting a lot of effort into developing interoperability with strategic players. We are also looking into diversification to other arrhythmias, including a project on atrial tachycardia.

Further Reading

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