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Leviticus Cardio charges towards the market

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A tiny Israeli company has beaten some of the biggest medtechs in the world to the wireless charging of heart pumps.

Left ventricular assist devices – heart pumps designed to provide circulatory support in patient with severe heart failure – are now established as a means to keep patients alive until they can be given a heart transplant. But patients must endure a power cord that exits their bodies and connects to a battery pack. A wholly implanted system is a goal towards which all LVAD developers are working.

Given that this cohort includes medtech giants like Medtronic and Abbott, it is perhaps surprising that it is a collaboration between two relatively tiny groups, Jarvik Heart and Leviticus Cardio, that has so far come closest to achieving this goal.

The Fivad device, a version of the Jarvik 2000 LVAD that is powered wirelessly through the skin using a technology called coplanar energy transfer developed by Leviticus, was implanted in a human for the first time this year (*Jarvik's heart pump goes wireless, February 8, 2019*). Now data on two patients have been presented at the annual meeting of the International Society for Heart and Lung Transplantation, and the researchers claim that the device could be "an important disruptive advance in the field".

"Wireless charging of LVADs is like the Holy Grail – people have been talking about it for years," Michael Zilbershlag, Leviticus Cardio's chief executive, tells *Vantage*. "Many attempts to do it failed because it's very difficult to get steady power transmission that can last for a long time."

Power demands

Wireless transcutaneous charging does exist for some cardiac implants, such as the Optimizer Smart device made by Impulse Dynamics (*Impulse Dynamics aims to find its niche in heart failure, May 23, 2018*). But these have much lower power demands than an LVAD, Mr Zilbershlag explains.

Leviticus's charging system works by electromagnetic inductance, transferring power from an external battery pack to an implanted coil that in turn powers the pump. A battery pack must still be worn, but with nothing breaking the skin the risk of infection is much lower, and this set-up is also more pleasant for the patient.

That said, the power cord, or driveline, connection for the Jarvik 2000 is still present as a back-up. This has an unusual design; unlike most LVADs, whose drivelines exit through the patient's abdomen, the Jarvik 2000's wires are fed up through the neck to a small titanium post screwed to the skull and coming out through the skin behind the patient's ear.

This connection is intended only to be used in emergencies, Mr Zilbershlag says, and Jarvik believes that a connection in the head offers a lower risk of infection than an abdominal driveline.

The wireless battery in the Fivad lasts for eight hours, Mr Zilbershlag says. “We tell the patient that after six hours they should connect the charger and start charging, but actually the safety alarm on the system sounds after eight hours when you have about 20% of the battery left.” But the patient can choose to ignore this and have another wireless hour.

After nine hours the patient must connect the wired battery or, if they are staying in one place such as when sleeping, they can plug into the mains.

Of the two patients implanted so far, one had no major adverse events and was discharged from the hospital at 30 days post-implantation. The other had a peri-operative ischaemic stroke and what was later determined to be pump thrombosis with obstruction of the outflow graft. This patient is in a stable condition and awaiting an urgent heart transplant.

This might seem unimpressive, but these patients are desperately sick, and with demand for heart transplants far outstripping supply these results are encouraging, though very early.

More trials

These patients were treated under compassionate use access. The next step will be more formal clinical work.

“We are going to focus this year on starting a clinical trial,” says Mr Zilbershlag. He adds that this will be similar in design to the early trials of other LVADs such as Medtronic’s HVAD and Abbott’s HeartMate. Leviticus believes that European CE mark could come in around 18 months, and US approval in three years.

Longer term, the company could develop its wireless charging tech for use with LVADs from other manufacturers.

“We do plan to be a general system. But stepwise,” says Mr Zilbershlag. “Definitely the next two years is going to be focused on Jarvik.”

The agreement with Jarvik has led to a strategic change at Leviticus, which was previously seeking a trade sale. The Jarvik collaboration has allowed Leviticus to consider an alternative path, remaining independent and bringing its technology to the market itself. This means raising money – the company has drummed up just over $10m in funding over the past decade, and is about to embark on a $20m fund-raising drive it hopes will take it to approval.

After that Leviticus will need even more money to carve out market share from its much bigger peers. If a buyer comes knocking it might take great resolution to say no.