VOL 23 ISSUE 1/14 • FEBRUARY/MARCH 2014

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Promising substitutes for human hearts

Marcello Conviti, CEO of Carmat, the company that developed and now manufactures the total artifical heart

Fully implantable mechanical hearts bring hope to 121,000 heart failure patients who will never receive a heart transplant

Report: John Brosky

It is a world-first. In December 2013, a fully artificial heart was implanted in a 75-year-old French man, who is continues to be doing 'very, very well,' according to surgeons.

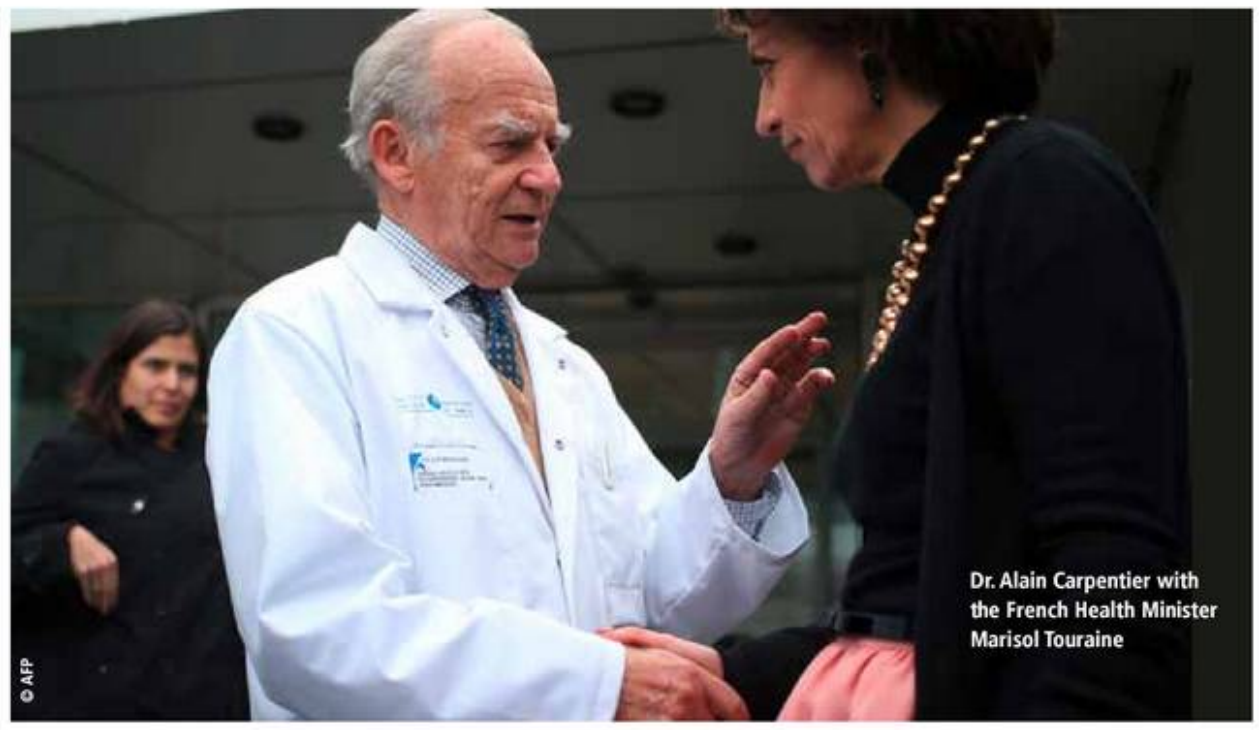
This year three more French patients with end-stage heart failure are expected to receive mechanical heart replacements as part of this first-in-man trial for safety and feasibility. If all goes well, a second group of 20 patients from Germany, Belgium, Poland, Slovenia, and Saudi Arabia will receive hearts in an expanded clinical trial that could lead to CE approval in 2015.

It is estimated that each year 125,000 end-stage patients in the United States and Europe are awaiting a heart transplant, where only 4,000 transplants will be performed.

We have heard about heart failure patients receiving heart-assist devices that serve as a bridge-to-transplantation, keeping them in life while waiting for a human heart to become available. Yet this was the first patient to have his heart completely replaced by a mechanical device that is a destination therapy. If all goes well, that is first French patient will leave the hospital wearing only a lithium-ion battery in a shoulder harness.

'This is completely new, a fully implantable artificial heart and not a ventricle assist device,' explained Marcello Conviti, CEO of Carmat, the company that developed and manufactures the device.

'Ventricle assist devices are used as a bridge-to-transplant, and they work well. However, these devices need an external air compressor that drives the membrane to push the blood. There are also tubes exiting the patient. With the Carmat heart only a wire exits the body to supply electricity and give information about device performance. All the other parts are inside the patient,' he explained in an interview with European Hospital.



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Dr. Alain Carpentier with the French Health Minister Marisol Touraine

A heart from outer space

Developed by a team of engineers from EADS, the Carmat heart weighs 900 grams, nearly three times more than an average healthy human heart. 'What is significant is the level of innovation in our approach.

All the parts that are in contact with the blood are made of biocompatible materials, the same as have been used in artificial heart valves. This should reduce dramatically the level of anti-thrombotic drugs required because the risk of thrombosis is extremely low, compared to ventricle assist devices.

'Our device is also auto-regulating with embedded electronics, so it's going to deliver output in line with a patient's needs, from two to nine litres per minute. There are sensors to optimise the machine's performance for cardiac output according to the patient position and activities.

'The other devices in the market have pumps that deliver a fixed level of output. This makes a very big difference because it affects not only the quality of life of the patient but the level of precision will maintain a level of health for the patient. 'The Carmat heart is also silent so the patient does not have noise around him,' Marcello Conviti added. 'With heart-assist devices, the patient has a big compressor pumping air in and out with mechanical valves that you can hear clicking.'

The service life of the device is estimated to be five years. 'We have done bench testing that shows device performance goes well beyond five years,' he explained. 'But time will tell. In bench testing it was very difficult to simulate beyond 10 years.'

Exceeding all expectations: valves run beyond 10 years

Carpentier heart valves, invented by Alain Carpentier MD, a founder of Carmat and the driving force behind the artificial heart, were expected to fail after two years, 'because all the previous generations of artificial heart valves had failed due to calcification; but, after five years, the Carpentier valve was still going, performing very well,' Marcello Conviti pointed out. 'Then these valves performed beyond 10 years. Currently there is a large series of Carpentier biological valves, and they are still performing after 30 years.'The cost for the heart device cost and implantation procedure is between €140,000 to €180,000, roughly equivalent to reimbursement levels for a heart transplant, a key to the design requirements set down by Dr Carpentier. 'What good is there in developing a device if it is too costly to be used for everybody,' he told the French Sunday newspaper, Le Journal du Dimanche.

Carmat's CEO said he is prudent in his estimations of the value of the business potential for providing hearts off an assembly line. 'We do not provide any guidance at this point, except to say that we hope to start commercial activities in 2015, to be in the USA in 2018, and to reach full capacity with revenues of $1.5 billion in 2020 – something like that. We are talking about a company that has only one product for the moment, and which has not yet sold anything, yet.'

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First results of the global Quantitative Imaging Biomarkers Alliance (QIBA) initiative

Liver fibrosis emerges as a breakthrough for elastography

Clinicians agree elastography is an essential functionality in ultrasound, though they are divided on how to use it

Report: John Brosky

'Elastography is in a position much like Doppler 20 years ago,' according to David Cosgrove, BMBCh, MA, FRCR, FRCP, Professor of Clinical Ultrasound at Imperial College School of Medicine in London. 'Back then Doppler was new and people were excited about it. They wouldn't buy a high-end machine without the capability. Yet they didn't a quite know what they would do with it. That's now the situation with elastography.'

A renowned expert in ultrasound, Prof. Cosgrove has authored numerous publications and is a key contributor to the 'Guidelines and Recommendations on the Clinical Use of Ultrasound Elastography' from the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) that spells out the basic principles and technology as well as the clinical applications of ultrasound elastography. In a similar effort, he helped compile guidelines for the World Federation for *Ultrasound* in Medicine and Biology (WFUMB), with publication expected later this year.

'The guidelines have been effective in getting people launched in the right direction, suggesting where to put their efforts, as well as helping to know what has been found wanting,' he explained, adding that they also provide a good meta-analysis, with the writers of each section summarising the available literature and adding their own experience.

According to the professor, the reason for the uneven adoption of elastography is that the quality is extremely variable: 'There are so many technologies, some good, some very good, whilst in others the results seem random, in some cases regrettably rather poor.'

The turning point in the wide adoption of colour Doppler came with deep vein thrombosis (DVT) when it became clear that it was a much easier diagnostic technique and gave greater confidence. Once clinicians found it indispensible for this application, they were more assured in applying it elsewhere, Prof. Cosgrove pointed out.

He believes the breakthrough for greater adoption of elastography will come with investigations of liver fibrosis. 'Classifying this disease is difficult,' he said. 'Biopsies are not nearly as easy as in the breast, and take just a tiny sample of a rather large organ, whereas elastography can sample much, much more. There are a lot of reasons why liver elastography is probably going to be the most important and widely used application.'

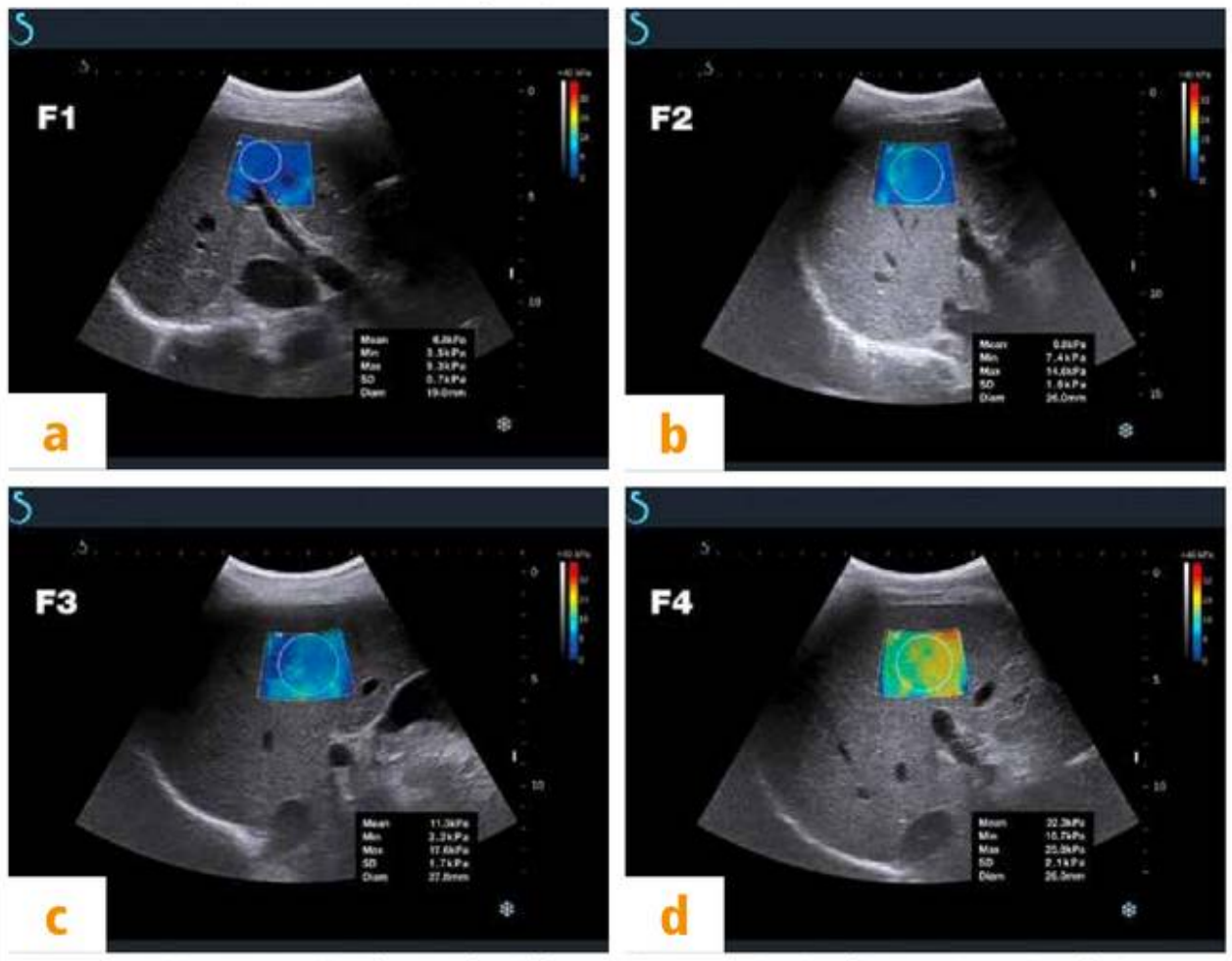
The United Kingdom's National Health Service Technology Adoption Centre (NTAC) found ultrasound elastography, using the shear-wave speed technique, 'enables a non-invasive, and therefore safer, diagnosis and subsequent monitoring of liver fibrosis when compared to the traditional gold standard procedure of liver biopsy.'

NTAC concluded: 'the findings suggest that for a cohort of 27,620 patients, the estimated number of patients diagnosed with liver disease in England and Wales, implementing ultrasound elastography is predicted to save a total of £14 million, or £520 per patient'.

Benefits to patients included a low risk of complications for the non-invasive procedure, no pain, and an outpatient exam of 15 minutes against a hospital stay of up to three days for biopsy procedures.

'It is a small study with three centres, not as thorough as NICE (National Institute for Health and Clinical Excellence) would have done, but it is quite a strong recommendation,' Prof. Cosgrove notes.

For the ultrasound component of the Quantitative Imaging Biomarkers Alliance (QIBA) project sponsored by the Radiological Society of North America (RSNA), the work group also narrowed its focus to liver fibrosis, and also selected the shear wave speed elastography technology.



Four patients with hepatitis C and liver fibrosis in four different stages.
Metavir scores (F1 to F4) were obtained from liver biopsy.
Elasticity charts of each case were acquired with a single pulse.
a) Patient with F1 liver fibrosis and SWE values of approx. 6.8 kPa, standard deviation 0.7 kPa
b) Patient with F2 liver fibrosis and SWE values of 9.8 kPa, standard deviation 1.6 kPa
c) Patient with F3 liver fibrosis and SWE values of 11.3 kPa, standard deviation 1.7 kPa
d) Patient with F4 liver fibrosis and SWE values of approx. 22.3 kPa, standard deviation 2.1 kPa

David Cosgrove, Professor of Clinical Ultrasound, Imperial College School of Medicine, London

Ultrasound based platforms in this class include the Fibroscan from Echosens, the Siemens S2000, S3000, Philips iU22, and the Aixplorer from SuperSonic Imagine. All systems are capable of quantifying tissue stiffness, but only two produce an ultrasound image.

'Siemens' Acuson S3000 produces a still image on which you can take measurements, whereas SuperSonic's Imagine's shear wave elastography technology produces a real-time, moving image, which is a significant improvement and is probably the pre-eminent of the technologies,' the professor pointed out. The first results of the global QIBA initiative, presented at the RSNA congress in December 2013, showed very low inter-observer variation on phantoms, 'a reassuring result,' according to Prof. Cosgrove. Currently a study of so-called confounders, like inflammation and liver congestion, is underway with the Harvard Medical School at the Massachusetts General Hospital. A second generation of phantoms featuring a viscous component that simulates fat content, or steatosis, will now make the rounds of QIBA participating centres worldwide.

Prof. Cosgrove: 'The overall point is to establish an undisputable clinical application for elastography. Adoption will ripple out from that.'

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The flexible 6-megapixel 30-inch LED backlit colour display

Recently launched, Totuku's new six megapixel colour display CCL650i2 has a 30-inch screen and brightness of 800cd/m², making it highly suitable for all diagnostic conventional X-ray applications, the manufacturer reports, adding that the model is equipped with a new LED backlight.

The successor of the CCFL technology is based on semiconductors and is known from a variety of consumer products. 'The benefits are both ecological as well as financial and qualitative nature,' said Marcel Herrmann, Totoku Medical's Marketing Manager for displays. 'Compared to CCFL monitors, LED displays save up to 20 percent of electricity and have a longer life span of about 30 percent – a positive effect on the user's budget. Furthermore, the CO2 emission decreases due to reduced energy production. Specifically, those displays will use 15 percent less power than their predecessor.' He also mentioned environmental benefits because LEDs 'do not contain critical elements such as mercury'.

Additionally, the standby power consumption has been reduced by 80% due to a newly developed power supply.

The CCL650i2 also offers a newly developed flexible input concept, with a dual DVI and Dual DisplayPort Input. 'In this way users can decide to connect two signals from one workstation or to connect two workstations,' Totoku adds. 'With Display Port, all recent AMD or NVIDIA cards can be connected. For older Matrox MED or RAD cards the CCL650i2 support a 3MP simulation mode, this ensures full compatibility here [in Europe].'