Will software steal the heart of cardiology?

Celebrating 40 years of PCI, cardiologists fret over their future with big data, machine learning and robots, John Brosky reports

Software may replace cardiologists one day, but not the hands-on work of interventional cardiologists and their armamentum of hardware.

That was the curious consensus at the start of the 2017 EuroPCR congress, which saw the arrival of a revolution getting underway: computer-assisted diagnostic procedures and advances in computer-assisted diagnostic tools to aid guidance operators with clinical decisions, such as whether to stent or not to stent.

"Confident view among panelists at the conference came during a session dedicated to teasing out the 'next big thing in Cardiac Vascular Medicine' at the largest European gathering of interventional cardiologists.

As with this year's congress of the European Society of Cardiology (ESC), the EuroPCR meeting celebrated the 40th anniversary of the first angioplasty procedure, which opened a new specialisation for interventional cardiology.

Many of the leading members of ESC are contemporaries of the pioneer for percutaneous coronary interventions (PCI), the German radiologist Andreas Grünzig who re-opened a clogged artery using a hard wire catheter in 1977 at the University Hospital of Zurich.

Today there are almost 8,000 members of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), making this the second largest of the associations within the legal structure of the ESC, surpassed only by the Heart Failure Association.

By 2015 the worldwide market for PCI had grown to $6.5 billion according to the Dublin-based firm Research and Markets.

Grünzig's primitive tool opened what EuroPCR keynote speaker Stephan Oesterle called the vascular highway that enables interventional cardiologists to go anywhere you need to go in the body.

"The field today covers 30 procedures that can be performed over-the-wire to place stents or treat vessels with drug-eluting balloons. And this does not take into account the growing practice of structural valve repair that is also performed during PCI."

"Heart failure and mitral repair are two areas where developers are currently working to create catheter-based treatments," he said.

Yet, we are still treating end-stage disease, he told colleagues, suggesting new catheter-based procedures could be developed for preventive strategies, such as implanting sensors to monitor blood pressure or glucose levels.

A practicing cardiologist for 25 years, Oesterle worked for 15 years in intensive care medicine, Achenbach has authored around 550 publications listed in Medline. Between 2014-2016 he served as Vice President of the European Society of Cardiology (ESC) and is currently a Board Member and Chairperson of the ESC Congress Program Committee.

"We don't know how to control the monster we created"
Coronary angioplasty
is 40 years old

Coronary angioplasty is arguably the most important breakthrough in the history of cardiology. While the technique is today performed in most hospitals worldwide, its origins can be traced back to the work of Dr Andreas Grüntzig in Zurich, Switzerland, in the late 1970s.

Tragically, Grüntzig never lived to see the impact of his research, having died in a plane crash in 1985. Yet, across the world, his work has had an enduring legacy and changed the face of cardiology forever. Later this summer – on 16 September - the world of medical history will mark the 40th anniversary of the first coronary angioplasty.

Before Grüntzig embraced the concept, others had experimented in the field. The technique of angiography, for instance, was first developed in 1927 by the Portuguese physician Egan Moniz at the University of Lisbon for cerebral angiography. While, in the 1960s, American interventional radiologist Charles Dotter pioneered angioplasty catheters and the catheter-delivered stent, which were first used to dilate peripheral arteries by inserting sequential catheters with increasing diameters through the narrowing artery.

Michael Mason Sons performed the first selective coronary angiogram and a few years later, Melvin Judkins introduced catheters shaped to reach the coronary arteries to perform selective coronary angiography. It was this work that Grüntzig built on, performing the first successful percutaneous transluminal coronary angioplasty (PTCA) – or percutaneous coronary intervention (PCI) – on 26 January, 1977, at University Hospital, Zurich.

Born in 1939 in Dresden, Germany, Grüntzig was educated at Heidelberg University, graduating in 1964. He then worked with the medical device manufacturer Medtronic before joining the venture fund New Enterprise Associates, where he partnered Dr Susan Gottlieb who, in May 2017, was appointed new Commissioner of the USA’s Food & Drug Administration.

Confounding the audience
When Oesterle shifted his talk from healthcare to software, he began to confound the audience.

The next big thing in the cardiovascular studies he has heard of today room over – you must count the smart phones in everyone's pocket.

The research and development budget at Apple is $17 billion annually, and what they are working on will make the future iPhone a healthcare companion, he said.

"Google Life Sciences, now called Verily, has invested $4 billion over the past two years to create partnerships with Johnson & Johnson's surgical division and glucose monitoring specialist Dexcom, as well as several major pharmaceutical companies."

IBM has declared that healthcare is the future of the company, he said, and the Watson supercomputer is not meant to play games, having shown it can outperform radiologists.

Data analytics coupled with cognitive computing will take over healthcare, Oesterle predicted. "We have come to a point where computing power is massive, it is fast and it is incredibly cheap. Your next-generation competitor will come from software." As a venture capitalist, he noted that less than 10 percent of private equity funding goes to medical technologies, that 20 percent goes to biotechnologies and "70 percent goes into the software that is going to disrupt our practice, just as it has disrupted other industries."

"One doesn't want to back a new cent, distributed healthcare is where the money is going," he said, adding that consumer-oriented medical technologies aim to pass up the clinician in order to go directly to the patient. First Vice President for Medical Affairs at Medtronic Vascular, Martin Rothman spoke up to say "I just can't see these next big things. And he agreed the next big cardiovascular enterprise based on software would not be Medtronic. It's not our core skill. We do some software engineering but what we really do is micro-engineering and that is our skill."

"Perhaps," he suggested, "we are missing the boat, if you say, the software revolution. Untitled colleagues, we hear about an unlimited imagination in what we can do, if we change the heart from what it is at what happened with a hospital in the United Kingdom when they no longer had access to its data. We have to create a monster we don't know how to control."
Improved monitoring and raised quality of life

Intelligent shirts ‘watch’ cardiac patients

A pioneering study has certified that wearable technology produced better results in monitoring cardiac patients and improving their quality of life compared to conventional systems. European Hospital correspondent Mélisande Rouger spoke with Spanish cardiologist David Del Val MD, who led the study, before he presented his results at the European Congress of Cardiology held in Barcelona.

David Del Val: ‘Medicine, and more particularly cardiology, is experiencing a real technological revolution. Many devices have been developed to improve diagnostic therapy efficiency and patients’ quality of life. However, very few studies have actually measured the pertinence of these devices in real life. This study is a pioneering work because it compares efficiency in a new wearable device and conventional systems in clinical practice.

‘The study was designed to compare monitoring efficiency in terms of perceived life quality benefits in patients using a wearable system developed by a company called Nuubo and conventional electrocardiographic monitoring systems.

‘150 patients alternatively used intelligent shirts and a conventional ambulatory monitoring system to monitor their cardiac rhythm during 24 hours.

‘Results showed that the effective monitoring time was higher with the new system using wearable technology compared to the conventional system. Questionnaires answered by patients also revealed that quality of life indices were higher in those who used a wearable device.

‘Our cardiology department is currently working on a cutaneous patch that enables continuous medication of different haemodynamic parameters, a system that can help to follow up patients more closely and anticipate the disease progression.

‘The department also leads another project in which a toothbrush enables us, daily, to measure vital signs and various biomarkers in the saliva.’

‘Wearable technology enables us to remotely follow up different key parameters early, to detect any worsening of a given pathology. Therefore, we can anticipate and plan our actions to fight the disease, initiate early treatment, avoid hospitalisation and reduce healthcare costs.’

Are collected data then stored in the patient’s electronic health record?

‘The data generated by these devices is stored on a memory card and can be downloaded and analysed thanks to dedicated software. We write a report based on this data, which is kept in the patient’s health record. Unfortunately, in our hospital, there isn’t any system enabling connection and incorporation of this data directly into the electronic clinical history, which doubtlessly would be a great advance.’

Are you or your colleagues working on other wearable technology projects?

For the moment, I’m not involved in other projects validating wearable technology, but I consider this to be a field with major projection for patients suffering chronic diseases.

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We must protect cardiologists from cancer risk

CorPath enters the vascular highway

Shielding cardiologists from harmful radiation is the goal for two systems capable of navigating the vascular highway, John Brosky reports

'We cannot continue to accept working in conditions that put our lives in danger,' says Alain Cribier, the pioneering cardiologist from the University Hospital of Rouen, who first implanted an aortic heart valve via a catheter in 2002. 'You don’t feel anything; radiation is not painful, but there is an accumulation of dose when you do this for decades, day-in and day-out,’ he explained.

A study, published by the American Heart Association in August 2016, demonstrated a direct relation between working in a catheterisation lab and developing radiation-induced cancer, cataracts and skin lesions.

According to the study, interventional cardiologists accumulate significant lifetime radiation exposure in the range of 50 milliseverts to 200 milliseverts. This is due to the several thousand procedures each radiologist performs and the cumulative time spent in the lab.

We must embrace the potential of digital data

Cardiologists must keep up
We must embrace the potential of digital data deployed in a way that preserves the human touch. We should not be help us be better, not replace the human touch.

The research, at Bristol University, led by cardiac surgeon Professor Raimondo Ascione, alongside Professor Sarah George and Dr Jason Johnson, could revolutionise the approach to cardiac artery bypass surgery.

Presently, replacement arteries for bypass operations are limited, so surgeons use veins taken from the patient's leg to replace the blocked vessels of the heart.

**Populating veins with artery-like cells**

However, while arterial grafts can continue to work well for up to 20 years, up to half of vein grafts can become blocked within 5-10 years as the greater blood pressure of the artery environment damages the graft after implant. ‘With the bypass surgery we are taking a batch of cells from the leg which has a thin wall with blood flowing at a very low pressure,’ explained Professor Ascione, Chair of Cardiac Surgery and Translational Research at Bristol. ‘But when put into the high pressure system, so this is what leads to problems with the vein.

‘Currently, veins are used for approximately 80% of all grafts made during heart bypass surgery. They work well in the short-term, but they are not designed for the demands of working as an artery.’

This may result in the grafted vein thickening its wall and becoming blocked and, when this happens, the heart bypass operation may have to be repeated, or the patient may even suffer a heart attack.

The Bristol team aim to achieve the vein-to-artery transformation by ‘washing’ cells from the vein, stripping it back to leave a tube-like scaffold made from extracellular matrix. An artery can then be built on this framework by populating it with artery-like cells. This will be done either before surgery, in a dynamic bioreactor that mimics the arterial environment, or after the surgical implant by the host’s natural healing processes.

With the old cells stripped out of the vein we are only left with the vascular skeleton, the actual framework of the vein,’ Ascione explained. ‘The vein goes from being “pink” to like a white ghost colour. Then we can use this acellular skeleton of just vascular extracellular matrix and transform it into a high-pressure system and seed the arterial cells on this.

**Tissue-engineered arterial grafts improve long-term outcomes**

‘By stripping back a vein and using it as the framework on which to build an artery, we hope to create in the lab tissue-engineered arterial grafts that are better able to cope with the demands of carrying blood from the heart.’

The professor has already demonstrated the feasibility of these approaches in pilot studies and is now leading a new project to find the best method to re-populate the tube-like scaffolds derived from veins with cells.

Plain and pre-populated scaffolds will be implanted into pigs at the new Translational Biomedical Research Centre (TBRC) co-funded by the British Heart Foundation (BHF) and the Medical research Council (MRC) to establish if they give a better result than the grafts that are currently used. If this proves successful, it could see a new approach to the way heart bypass surgery is performed. In future, the vision is that patients would be admitted to hospital a few weeks before their operation for veins to be taken from their leg and engineered in a laboratory into arteries.

The patient would return to hospital a few weeks later for bypass surgery operation with surgeons using the vein material that has been transformed into arterial-quality conduits.

‘In terms of surgical technique, it would be pretty much the same,’ Ascione added. ‘Stitching and saturating these arterial-like grafts will be similar to those grafts surgeons are already used to, so no further training would be necessary.’

The technique could also benefit vascular surgeons who, for peripheral vascular grafting in patients with blocked arteries in their legs, can only use vein or synthetic material with poor mid-term outcome.

Around 17,000 coronary artery bypass operations are carried out in the United Kingdom each year, with many thousands more conducted internationally. This approach could improve longer-term outcomes for heart bypass patients.

‘Ultimately,’ Ascione concluded, ‘this research could mean that people receive longer-lasting grafts, improving their life expectancy while reducing their need for future surgery and use of hospital resources.’

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Cardiologist Professor Harlan Krumholz is a healthcare researcher at Yale University and Yale-New Haven Hospital, and the Harold H Hines, Jr. Professor of Medicine and Director of the Yale Center for Outcomes Research and Evaluation (CORE) – one of the America’s most productive research units dedicated to producing innovations to improve patient outcomes and promote better population health. He is also a Director of the Robert Wood Johnson Foundation Clinical Scholars Program, which prepares especially talented physicians to become future healthcare leaders.

Raimondo Ascione is Professor of Cardiac Surgery and Translational Research at the University of Bristol, UK. He is also Academic Director of the pre-clinical Translational Biomedical Research Centre (TBRC), which bridges the gap between basic science research and the NHS to boost the translation of fundamental discoveries and emerging biomedical technologies to the bedside. Ascione is also Chief Investigator of clinical trials and experimental work aimed to protect adult high-risk patients from complications during cardiac surgery.

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**An exciting new approach for heart bypass surgery**

*Report: Mark Nichols*  

Scientists in the United Kingdom are investigating the potential of a new regenerative and tissue engineering technique that could transform veins into arteries to improve the outcomes for patients undergoing heart bypass surgery.

The next generation must be deployed in a way that preserves the special nature of our profession but the advances in technology should help us be better, not replace the human touch. We should not be afraid of technology when it comes to health. It is better to embrace it - it can make us smarter than ever in looking after large populations.”
Exciting hyperpolarised MRI

Report: Mark Nicholls

A new type of scan that can detect cardiac inflammation may help tailor treatment for patients who have suffered a heart attack, according to research presented at the British Cardiovascular Society (BCS) conference in June. Developed in the UK, hyperpolarised MRI (h-MRI) enables cardiologists to see more detail of healthy and diseased hearts than conventional scans, including the level of inflammation post-myocardial infarction.

Detecting inflammation in the heart

Funded by the British Heart Foundation (BHF) the University of Oxford researchers now believe h-MRI could help scientists develop and monitor the effects of new, inflammation-targeting treatments that may improve the heart’s healing process in heart attack patients.

The discovery could have significant benefits because the hearts of patients who have suffered a myocardial infarction (MI) can undergo continued inflammation even during the healing process, and despite receiving emergency treatment. Yet research into why this may happen remains limited as conventional scans cannot detect or measure inflammation in the heart, whereas h-MRI can.

Conventional MRI measures how protons change position when exposed to a magnetic field, but h-MRI works by producing images from carbon molecules, which make up the energy sources needed to help the heart pump and can offer doctors a clearer picture of inflammation in the heart.

h-MRI as biomarker and pharmacological target

For the study, the team measured production of lactate in the damaged heart muscle after a heart attack. Lactate is released from muscle cells when the heart muscle is damaged and is then used by other body cells. The team were able to identify and localize the level of inflammation in the heart.

Monitoring how much lactate is produced in the damaged tissue, they were also able to identify and locate the myocardium and the inflammation phenotype of those cells.

The Oxford scientists – one of the first groups to use h-MRI to study the human heart – believe that h-MRI will not only detect inflammation in damaged heart tissue but also could provide a novel method for the detection of myocardial inflammation with high translational potential as both a biomarker and novel potential pharmacological target.

The Oxford University cutting edge technology, developed by Biotronik, was used in an experimental study at the European Cardiology Congress in Vienna.

Lessons gained from an EHRA 2017 Symposium

Cardiac resynchronisation therapy improvements

Which CRT patients can be ‘downgraded’ from a CRT-D device with defibrillator function to a CRT-P with just a pacemaker function?

This, with two further current CRT issues – chronotropic incompetence and telemonitoring of CRT patients – featured prominently at the European Cardiac Congress in Vienna.

For more than 20 years, cardiac resynchronisation therapy (CRT) has been a pillar in the treatment of chronic heart failure (CHF). CRT devices are either pacemakers (CRT-Ps) or implantable defibrillators (CRT-Ds), which are implanted in the patient’s chest. These are connected to the heart with three leads, the third one linking to the left ventricle, which pumps blood through the body. While both types of devices synchronise the heartbeat, CRT-Ps prevent the heart from beating too slowly and CRT-Ds prevent it from beating too quickly.

At a satellite symposium at the European Cardiac Congress (EHRA 2017) experts debated whether patients who respond well to a CRT-D and show improved heart function should receive a CRT-P in the next scheduled device replacement. The background: Many patients respond so well to CRT that their heart function markedly improves and a CRT-D might not be needed; indeed between 10-25% of patients can be ‘downgraded’. However, data presented at EHRA 2017 indicate that not all tele-monitoring systems are created equal: ‘Our work has identified several important issues in heart failure patients, the important issue is remote monitoring of ICD patients. Ever since the IN-TIME study showed Biotronik Home Monitoring reduced mortality in heart failure patients, the use of this technology has been included in the clinical guidelines. However, data presented at EHRA 2017 indicate that not all tele-monitoring systems are created equal: they do offer different clinical outcomes, TRUECOIN, a meta-analysis, showed Biotronik Home Monitoring to reduce mortality in all types of ICD patients.

Andrew Lewis MD is a Specialist Registrar in Cardiology at the Great Western Hospital in Swindon, UK, and won the Young Investigator’s Prize Competition at the British Cardiovascular Society conference in Manchester for his research into myocardial inflammation imaging.

More studies needed

‘Our work has identified several forms of heart disease where this technique could be used to improve diagnosis and treatment,’ Lewis added. ‘This is incredibly exciting, and we intend to move forward with patient studies as quickly as possible.’

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Renewing the promise of bioabsorbable implants

Electrospun materials being a spark of hope to a cardiovascular landscape darkened by setbacks for reabsorbable stents, John Broksy reports

It was famously said that implanting a device is like implanting a disease. A woman who has undergone a total body implantation may be grave/sick of it, for years to come. The AI Alliance aims to advance career opportunities for women in electrophysiology (EPIC Alliance). The EPIC Alliance engages in Electrophysiology/Arrhythmias’ scientific activity, discussing implantable devices and the latest innovations in the field.

According to Benoit Studlé, the CEO of EPIC, which has also been defined, which has created a greater number of members who have moved far beyond the initial number of members. EPIC Alliance’s mission is to bring together women in electrophysiology and cardiology, and to offer them a platform to share their knowledge. The Alliance also organises meetings and networking events for members to gather at global and local levels. The EPIC Alliance is the most successful organisation supporting women in our field, in which very few women work, said Poole, estimating that only about 10 percent of all electrophysiologists and cardiology device specialists are women.

Women, she summarises, may be put off by the two or three years of additional training and by extremely long working hours, two factors that appear to be irreconcilable with motherhood and family. However, Poole herself provides a convincing example that a satisfactory work/life balance can be achieved. ‘But’, she underlines, ‘we do need role models and we must ensure women are visible at scientific congresses.’

Male colleagues, she added, would also benefit from such a support network. ‘We are all just human beings working in a very exciting specialty.

A Swiss firm that can speak publicly about its work in cardiovascular applications is Xeltis, which, during EuroPCR 2017, renewed the hopes for bioabsorbable implants in a crowded scientific session. Xeltis presented the 24-month results for a pulmonary heart valve to correct or reconstruct right ventricular outflow tract in 10 children, as well as the first study results from the company’s preclinical aortic valve project.

The prestigous panel of key opinion leaders would have been enough to pack the room, as it included presentations by Sernys, who is a professor of Cardiology Imperial College London; Thierry Carrel, from the University Hospital Bern Clinic, who also serves on the editorial board of several international journals; the internationally renowned cardiovascular pathologist René Virmani; and, Martin Leon, the director at the Center for Interventional Vascular Therapy at Columbia University Medical Center and New York-Presbyterian Hospital.

The EPIC Alliance

‘We are now in an era where patients with implantable devices – not just pacemakers, but also cardiovascular defibrillators – can undergo MRI scanning. Although there are still open questions, we no longer have to exclude these patients from this very important imaging technology,’ said Seattle-based cardiologist Professor Jeanne E Poole, during a Cranio-Cardiac Interventional Vascular Therapy at the prestigious panel of key opinion leaders. The EPIC Alliance engages in Electrophysiology/Arrhythmias’ scientific activity, discussing implantable devices and the latest innovations in the field. The Alliance also organises meetings and networking events for members to gather at global and local levels. The EPIC Alliance is the most successful organisation supporting women in our field, in which very few women work, said Poole, estimating that only about 10 percent of all electrophysiologists and cardiology device specialists are female.

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**Early detection of cancer and cardiovascular diseases**

*Monday, 13 November 2017: Oncology – Can cancer be detected by a blood test?*

*Tuesday, 14 November 2017: Cardiology – More diagnostic confidence with myocardial infarction and heart insufficiency*

Prof. Dr. med. Stefan Holdenrieder, Deutsches Herzzentrum München

**The laboratory comes to the patient**

*Wednesday, 15 November 2017: Diabetology – From self-test to continuous glucose measurement*

Prof. Dr. med. Peter Luppa, Klinikum rechts der Isar der TU München

**Dangerous travel companions**

*Thursday, 16 November 2017: Infectiology – New multi-resistance in the age of migration*

Priv.-Doz. Dr. med. Beniam Ghebremedhin, Universität Witten/Herdecke, HELIOS Universitätsklinikum Wuppertal