Ultrasound expands its role in cardiac imaging with disruptive applications. Fasten your seat belt. Cardiac diagnostics is entering a zone of stunning three-dimensional (3-D) imaging, with both 2-D and 3-D systems showing promise in detecting normal blood flow and turbulence. Manufacturers of leading systems continue to mine data from the sonic signal that opens new fields for research.

Researchers are currently testing a new advance in fusion imaging developed by Toshiba for its CardioVascularFusion (CVI-Fusion) system that creates a revolutionary capability for the assessment of ischaemia. ‘At ESC we will reveal a new technique, one that is quite unique, and which no one else is doing,’ he promised. ‘We will demonstrate the feasibility of using stenosis echo in fusion imaging, which in my opinion becomes crucial. Stress echo induces ischaemia, but it is the first time we will show the ischaemia. By combining these views we can see the stenosis, the location of the stenosis, and now how the stenosis impacts on the prognosis.’

By merging the stunning three-dimensional (3-D) images with traditional X-ray, new systems are providing novel capabilities for diagnosis and navigation. ‘I believe that 3-D echo is the cornerstone for the non-invasive diagnosis of cardiac diseases,’ says Jose Zamorano MD, head of Cardiology at the University Hospital Ramón y Cajal in Madrid. ‘There can be no doubt. You can see the anatomy of the heart, and you can see the function.’ He cites as an example the turbulence created by blood flow in the cavities of the heart that is now revealed by technology called vector flow mapping developed by Hitachi-Aloka.

The heart is not a simple pump but a hard-working muscle, twisting, contracting and pushing a pulsing stream of blood. A closer look shows that this flow is not so simple either, swirling and churning in intricate patterns as it encounters resistance. ‘It’s back to physiology,’ Dr Zamorano said. ‘From the work in our lab we can now see the vectors and the vortices for normal blood flow, and we have seen the way turbulence is affected by abnormal physiology and different pathologies. What is certain is that this will help in evaluation, and it could become a prognostic indication for the patient. It opens a new area of research to correlate what we are observing with the pathologies of patients.’

Vector flow mapping is an innovative ultrasound application derived from colour Doppler velocity data that adds new mathematical methods to display flow distribution without angle dependency. This quantification tool enables researchers at the University Hospital Ramón y Cajal to visualise, measure and analyse more than a dozen parameters of blood flow distribution.

‘Most people think that Doppler ultrasound is an analysis of the blood flow itself, but we need to clarify this understanding, because Doppler only shows velocity,’ Dr Zamorano explained. ‘With vector flow mapping you truly can see how the blood behaves entering the left ventricle and how it is ejected into the system.’

In the case of an aortic stenosis, he pointed out that the turbulence which appears in the left ventricle outflow is characteristic and absolutely different from a normal patient.

Research is currently being conducted using a two-dimensional ultrasound system and while the technology is not yet ready to show the flow in 3-D, he is confident this product evolution will come.

In early September, at the European Society of Cardiology (ESC) Congress in Amsterdam, Dr Zamorano will discuss the evaluation of valvular heart disease in 3-D with echography. ‘Valve anatomy is in three dimensions and 3-D echo assesses the morphology of the valve much more accurately than other modalities,’ he explained.

Fusion imaging that combines 3-D echo images with 3-D CT scans today provides a complete picture of the heart for cardiologists. The CT view of the coronary arteries of a patient can help determine if there is a coronary disease and at which level, he pointed out, while 3-D echo displays the abnormal function that is related to that stenosis.

Jose Luis Zamorano Gomez MD is the Head of Cardiology at the University Hospital Ramón y Cajal in Madrid. A fellow of the European Society of Cardiology (ESC), currently he is the Chair of the ESC Guidelines Committee and a past-President of the European Association of Echocardiography of the ESC. Dr Zamorano is also on the editorial board of many leading journals, including the European Heart Journal and JACC Cardiowasal Imaging.
TAVI will surpass heart surgery for aortic valve replacement

Interview: John Webb

Each year the case grows stronger for transcatherter aortic valve replacement (TAVI) and it is only six years since the procedure was introduced in Europe.

The strongest clinical evidence, which has continued to fuel debate, is based on the first-generation of valves and delivery devices. It is also based on a population that was deliberately restricted to the very sickest of patients with an average age of 84 years and suffering from co-morbidities that meant they were unable to undergo traditional surgical aortic valve replacement (SAVR).

Today, a new and improved generation of valves and delivery systems is being used at clinical trial stage with greater experience among interventional cardiologists, as well as improved outcomes for patients. Increasingly in Europe the procedure is being performed on ‘intermediate risk patients,’ those who suffer from a failing heart valve but who are typically younger and better able to withstand the rigours of traditional surgery.

How far are we from a turning point where TAVI will be preferred to surgery?

The true heart team is a reality where TAVI becomes as their valve fails, TAVI becomes the indication is becoming more common. Certainly as their valve fails, TAVI becomes high risk of mortality. Some of these patients are too old, too frail to benefit.

So the clinical trial stage has been lower in terms of surgical risk for patients in Europe, driven more by the reduction in morbidity in some of the lower risk patients.

In Europe there has been a more clinically driven approach, which sometimes differs from the results of the original trials.

You have asked whether the high-risk patients enrolled in the original trials should be considered for the therapy in the first place.

That is a problem. Some patients are at high risk but could be candidates for surgery, but the morbidity in surgery would be high. There tends to be more morbidity with TAVI than with surgery intermediate to high-risk patients. In Europe, more and more the indication is becoming frailty, advanced age, without major co-morbidities that would make surgery a risk for these patients.

An open question, especially as Europe moves to younger patients, is how long do these devise last?

We know that with in-vitro testing, in the lab, the TAVI valves last as long as surgical prosthetic valves. And we know that very, very few valve failures have been seen in the clinical experience to date. We have published our outcomes beyond five years and failure of these valves is quite rare at that point. We can assume that they will fail eventually, as do surgical valves.

Concern was expressed in Europe about patients in their 70s receiving valves for which the durability is unknown.

That’s fair enough to say and a very real concern. I guess I would argue that this is not the end of the story. At least with TAVI, valve replacement is a fairly repeatable procedure in that you can place a TAVI valve inside a TAVI valve.

One of the things people were most interested in (at the Transcatheter Valve Therapeutics event in Vancouver in June, 2015) was the new information on valve-in-valve implants that transcatheter valves are placed inside failed surgical valves. It seemed that in many people’s minds this is moving rapidly to a standard of care.

All valves, surgical and TAVI, will wear out over time. However, transcatheter surgery is always a higher risk than first-time surgery. Many of these patients, of course, are elderly. There are lots of 70-year-old people who received a surgical valve and, as their valve fails, TAVI becomes an attractive option for these older patients.

What is encouraging about the newer valves produced?

There are marked improvements in deliverability, profile and sealing with the newer generation of valves. Newer valves are, in general, more easily implanted. The lower profile means they go through smaller sheaths, through smaller arteries with a lowered risk of vascular injury. They tend to be more positioned, with features incorporated into the catheter, or in the valve itself, so they tend to be deployed at the correct height and the correct angle in the aortic annulus. So positioning is improving. They tend to have features that reduce paravalvular leak with the better seals.

In addition to improvements in the valve, there are dramatic improvements in understanding the three-dimensional anatomy in the aortic root which is gathered using imaging with 3-D CT and 3-D TEE.

All the new valves need to be processed in techniques used. Early on, people had a limited idea of where to put the valve and now there are more options. There was poor understanding about how to pick the right valve size, and here there have been dramatic improvements in understanding the three-dimensional anatomy in the aortic root which is gathered using imaging with 3-D CT and 3-D TEE.

The technique is a non-invasive complement to fractional flow reserve (FFR), which is an invasive procedure, he added.

Dr Zamorano reserved his greatest enthusiasm for advancements in ultrasound for the newest arrival in the university hospital, the EchoNavigator from Philips Healthcare: ‘I just came from performing two TAVI interventions and can say this system is incredible, very innovative.

‘Usually we work with X-ray in a cath lab but now, by superimposing and looking at the conventional echo on the fluoroscopy, I can see the valves opening and closing...’

Like FFR is given the highest recommendation in ESC guidelines, the invasive nature of the procedure to assess ischaemia has slowed its adoption.

Now I can mark exactly where the valve needs to be positioned. With fluoroscopy I can guide the catheters to that precise position.

While it remains controversial, you have stated that TAVI will become a dominant approach to aortic valve disease.

Dr Webb: I believe so, yes. Because as well as bringing in a new risk patients with newer devices in experienced centres, the risk of mortality becomes quite low and is competitive with surgery in intermediate risk patients with much less morbidity. Many centres are doing this on awake patients. Early discharges are becoming more common. Certainly patients who receive bioprosthetic valves are doing better in the hospital stage. Hospital stays are shorter, ICU stays are shorter. And I think we’re going to come down and become competitive with surgery for intermediate risk patients.

Will TAVI replace open-heart valve surgery?

There will always be patients who need open-heart surgery. There are obvious advantages to that approach. But I do believe that TAVI will become more common than surgical replacement. There are patients who do not have valves that are suitable for a transcatheter approach they have other things that need to be corrected. There are advantages to surgical valves as well. There are patients who are not candidates for surgery, but just that they would be better off with TAVI. This is the direction we are moving in Canada as well.

We are asking who is better off with TAVI. The key message here is that the procedure needs to be done on patients who are going to benefit. This needs to be the focus. Cardiologists need to consider if their patient is going to have a significant improvement in quality of life; that they will live long and prosper.

Many cardiologists may scoff at the idea that TAVI should only be performed in consultation with a heart team. Many have never been invited to share in the decision.

The true heart team is a reality where TAVI becomes the indication is becoming more common. Certainly as their valve fails, TAVI becomes a risk for these patients.

There will always be patients who are not candidates for surgery, but just that they would be better off with TAVI. This is the direction we are moving in Canada as well.

We are asking who is better off with TAVI. The key message here is that the procedure needs to be done on patients who are going to benefit. This needs to be the focus. Cardiologists need to consider if their patient is going to have a significant improvement in quality of life; that they will live long and prosper.
Cardiac disease death rates fall in the EU

Report: Mark Nichols

Death rates from cardiac disease have more than halved in many EU countries since the early 1980s, according to new research published in the European Heart Journal. The majority of countries have seen on-going steady reductions in heart disease death rates in both sexes and most age groups, including among younger people – despite increases in obesity and diabetes during this period.

However, heart disease remains a leading cause of death in Europe and the study’s researchers say their analysis shows little evidence for the hypothesis that the reduction in deaths from coronary heart disease (CHD) might be beginning to plateau among younger Europeans.

There is significant variation between individual countries, with evidence of a levelling off in some countries and increases in heart disease deaths among some age groups in other countries. ‘It’s clear that there are some countries in which trends are cause for concern, where overall rates of decrease in CHD mortality do appear to have slowed, and a small number of countries in which CHD mortality rates have begun to increase significantly in recent years in younger sub-populations,’ explained Dr Melanie Nichols, a Research Associate from the British Heart Foundation Health Promotion Research Group (BHF HPRG) in Oxford.

In addition, she pointed out, ‘we should emphasise that cardiovascular disease remains the leading cause of death in Europe, and it is important that we continue to focus efforts on primary prevention, including reducing smoking, improving diets and physical activity levels.’

With her colleagues in the Oxford research group, Dr Nichols looked at trends in deaths from coronary heart disease between 1980 and 2009 in both sexes and four age groups: under 45, 45-54, 55-64 and 65 and over. They found that almost all EU countries had a large and significant decrease in death rates from CHD over the last three decades in both men and women when all ages were considered together. Denmark, Malta, The Netherlands, Sweden and the UK had the largest decreases in mortality for both sexes during this time. The exceptions to these significant decreases were among men in Hungary, Latvia, Lithuania and Poland, where the decreases were small, and in Romania where there was an increase. Among women, decreases were found in Greece, Hungary, Lithuania, Poland, Romania and Slovakia. There was some evidence that the downward trends were beginning to plateau in those aged under 45 among men and women in Italy, Latvia, Lithuania and the UK, among men in Poland and Slovakia, and among women in the Czech Republic and France.

In the 45-54 age group, there was evidence of a possible plateau in both sexes in Latvia and the UK, and also in Lithuania among women and Sweden, Austria, the Czech Republic and Slovakia among men. In Greece, women aged 45-54 showed a significant increase in death rates. Dr Nichols said: ‘Overall, across the EU, rates of death from coronary heart disease have continued to fall in most age groups in most countries. There are some exceptions, however, and there remain wide disparities across Europe in both the absolute rates of death from heart disease and the rates of improvement.’

The study authors state that the increase in risk factors for coronary heart disease, such as smoking, obesity and diabetes, could still have an impact on death rates in years to come but felt there may still be time for public health policy and action to have an impact on these risk factors.

The team also add that continuing future research is crucial to monitor trends in CHD risk factors and mortality across the EU and to examine the relationships between preventable risk factors and CHD among younger adults.

With funding from the British Heart Foundation (BHF), the study arises from the European Health Strategy II project (EuroHeart II), which has received co-funding from the European Union, in the framework of the Health Programme.

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Renal denervation

A new procedure may help people with persistent hypertension. By burning or ablating the nerves in the renal arteries, blood pressure levels can be reduced significantly. Can we hope? If true, this promising procedure would mark a breakthrough. The medical and social burden of arterial hypertension is staggering, contributing to two-thirds of all cases of stroke and half of all cases of heart disease. Or is it hype? To date there is no evidence high BP simply disappears by waving a magic wand. Here are two reports on the medical miracle called renal denervation offering the perspectives of clinicians and industry.

Clinical point of view: Rising tension in hypertension therapy

We live in three over 60-year-olds suffering arterial hypertension, this is among the commonest chronic diseases.

Drug treatment results in only 517% of those patients achieving their target levels. However, in about the same percentage of patients conventional treatment fails despite good compliance. and the administration of three, five or even more antihypertensive drugs. Their blood pressure (BP) readings often remain much above the level of 140/90 mmHg set in the current ESH/ESC guidelines – an incentive for the development, trial and evaluation of different therapies.

The two most important new developments being discussed are presented below: renal sympathetic denervation and baroreceptor stimulation. While the former is already an established procedure – particularly in Germany where almost half of all interventions are performed – the latter is frequently accompanied by negative side-effects but is nevertheless considered very promising by many cardiologists.

Renal sympathetic denervation

The debate around renal sympathetic denervation (RDN) is as hot as the procedure itself, which involves heating up the renal arteries intraoperatively to a temperature of 41°C to 43°C. Nevertheless, results ‘promising’ and have decided to start a new RDN study.

The European Society of Hypertension (ESH) calls these results promising and has decided to revise its guidelines, which has been jointly developed with the European Society of Cardiology, since numerous studies have been published over the last year proving more about the rationale, therapeutic efficacy and safety of RDN (Source: European Heart Journal, 2013; May 22/9, supplement R586-66).

Symplicity HTN-1 and HTN-2

The feasibility of the procedure was demonstrated by three Australian and two European hospitals, including the Cardiovascular Centre at the Sankt Katharinen Hospital in Krakow, under the direction of Professor Henry Krum at the Centre for Cardiovascular Research and Education in Gothenburg, Sweden, who continued with the trial. However, the patients selected for the procedure have to fulfil certain conditions, as described in the guidelines recently published by the European Society of Hypertension. According to these guidelines, RDN is indicated for truly resistant hypertensive patients, while patients with organ-related hypertension, impaired renal anatomy, e.g. due to a stenosis or impaired renal function, are excluded. The data that are available today, which were collected worldwide, are very promising. We now need further studies that corroborate the initial results,' Dr Mahfoud said. Nevertheless he recommends the procedure for the time being to be limited to medical centres with research capabilities where patients receive systematic follow-up.

The industry: Slowed by hyper-resistant doctors

As fast as the first device for renal denervation received a CE mark in 2010, the pioneering company Aedicure began to be overtaken by medical technology giant Medtronic. With great fanfare the procedure for renal denervation developed by the following year at EuroPCR, the largest gathering of interventional cardiologists in the world.

Six million people in Europe suffer from persistent hypertension, unable to bring their systolic BP below 160 millimetres of mercury. Some take three or four different antihypertensive drugs, which the condition can resist this drug-based therapy.

The potential for treating such a large population was neither lost on cardiologists nor on other medical technology companies. This year at EuroPCR, five new devices for renal denervation were presented, all with the CE Mark, ready to be sold to hospitals.

Yet market leader Medtronic has fallen far short of sales targets. Despite a large footprint covering 70 countries, the company shipped less than half the number of devices it expected to ship. It turns out that physicians are as resistant as the hypertension of their patients. Doctors want to see proof of the claim that nerve endings in the renal artery are an effective, safe and sustained treatment for this chronic condition.

Justin Roberts is arguably the point man on the bleeding edge of this innovation in medical practice. As senior director for Renal Denervation Global Market Development for Medtronic, he has been leading the company’s efforts in pushing adoption of renal denervation. He commented: ‘There are people who believe this is a billion-dollar market; that if they push a new device, the entire world will fall in line. We have learned the hard way that the largest challenges are to help build expertise in this new field to win the confidence of referring physicians. The real challenge is to build clinical evidence to convince very conservative referring physicians.

Medtronic is turning its investment in renal denervation into a multiyear clinical programme aimed at building what the company hopes will be a successful clinical-medicolegal team. Enrolment was recently completed in an ambitious pivotal clinical trial in the US of the Medtronic Symplicity renal denervation system for treatment-resistant hypertension. Data from this trial is expected to be a significant component of an unusual and rigorous parallel review by the US’s Food and Drug Administration (FDA) and the Centres for Medicare & Medicaid Services (CMS) that could lead to approval and reimbursement.

Meanwhile, Justin Roberts believes that companies need to help build expertise in this new field to win the confidence of referring physicians.

Renal denervation centres capable of appropriately screening patients need to be set up. ‘Hospitals, even with reimbursement, will continue to operate with scepticism until they decide if they want to open a service line for renal denervation. The largest and the only one by country, by local guidelines,’ St Jude is a fast-follower for both the clinical trials and market development for renal denervation. More than 5,000 patients will be studied in a robust portfolio of studies that companies need to conduct in order to win the confidence of referring physicians.

The portfolio of related studies represents a significant investment in the市场营销 of this technology that will culminate in EnligHTN. This landmark work is expected to represent a major paradigm shift in the management of resistant hypertension.

The largest denervation study ever undertaken with a primary endpoint of major adverse cardiac outcomes and secondary endpoints to include readmission in office and ambulatory BP measures, changes in renal function and cost-effectiveness measures.

Robbed down on the long road to building evidence for renal denervation, Medtronic and St Jude have lost the first-to-market advantage as more companies roll out new devices.

The technical barriers to entering the renal denervation field are relatively low. Most companies already have some kind of device in pre-clinical or clinical phase, and adapt to the renal arteries is quickly done.

All the firms will need to conduct clinical studies, but the real challenge is to focus on early small efforts focused on proving that their new device is safe and effective. Evidence of effectiveness the new players will need only point to the evidence already gathered for existing devices and St Jude to win over physicians.

While some new devices are based on follow-the-leaders technology, innovation in the pipeline may prove to be a difference for patients in the long run.

REPORT: John Brosky & Holger Zern

CARDIOLOGY
Heart failure

Remote monitoring in Lorraine reduces hospital re-admissions

Report: Brigitte Dinkloh

About 500,000 people in France people suffer heart failure (HF), and in Europe the figure is six million and the same in the USA. While traditional treatments such as ACE inhibitors, beta blockers and mineralocorticoid receptor antagonists help to decrease mortality in HF patients with reduced ejection fraction, much needs to be done, says Professor Patrick Rossignol, nephrologist and deputy physician at the Inserm Centre d’Investigation Clinique Pharmathematique Pierre Drouin (CIC-P) in Nancy, France, because the prognosis remains unfavorable.

The professor is particularly concerned about the high number of hospital re-admissions. About 20 percent of all patients with heart failure are re-admitted to a hospital within a month of the initial event and roughly one third of the patients die within a year. Poor follow-up, he emphasizes, is to blame for this dire situation.

Case in point: One year after their discharge many patients receive the same medication without dose optimization as upon their discharge. While international guidelines recommend disease management programmes (DMP) for HF patients, Patrick Rossignol points out, many patients are either not included in such a programme or it does not follow harmonized standards.

In the Lorraine region, the ‘réseau lorrain des insuffisants cardiaques’ (ICALOR - Lorraine network for cardiac insufficiency patients) was introduced in 2006, a DMP unique in France because it covers an entire region and currently includes 3,000 patients. Each patient is closely monitored at home by nurses, on top of the usual out-patient follow-up by physicians. Results are collected in a patient record that can be accessed through real-world cardiovascular challenges.

The programme results are very encouraging: the implementation of the ICALOR programme was associated with a reduction in HF hospitalisations observed in the Lorraine region, and than expected had it been similar to that observed in the whole country of -7.19% in 2010. The estimated annual hospital cost saved by ICALOR was €1,927,648 in 2010 (REF). Nevertheless, Professor Rossignol stresses, much remains to be done to ensure that the coarse of HF is less dramatic. ‘Hospital re-admission is a severe event for the heart failure patient because at that time cardiac function is already seriously compromised. The alarm signs indicating deterioration of the pump function must be recognised earlier.’

Together with Professor Faiez Zannad, who heads the Heart Failure and Hypertension Unit in the Department of Cardiology, Nancy University Hospital, Patrick Rossignol developed a new procedure for telemedical monitoring of heart failure patients. All the patients need do is introduce a drop of blood every day into a box that assesses a set of renal and cardiac biomarkers. The data are encrypted and forwarded to a telemedical monitoring centre. When the values show signs of deterioration, the primary physician is informed who can initiate a therapy adjustment, with the help of a dedicated decision support system. ‘The extremely simple procedure for patients is based on the same principle as blood sugar monitoring in diabetics. It’s a response to the problem of frequent re-hospitalisation of cardiac insufficiency patients.’

Currently being piloted, the first prototypes of the device are expected to become available later this year. Application will then be made for the CE mark.

Next year, a clinical study with several hundred patients throughout France is planned and Prof Rossignol is confident this may prove that the device helps reduce follow-up complications in HF patients. The project, which was awarded funding of €1.9 million from the Lorraine region and the European Regional Development Fund (ERDF), is carried out by a consortium headed by Cardiorenal Diagnostics, a company founded by Professors Rossignol and Zannad with Gerard Houin.

Nephrologist Patrick Rossignol MD

PhD & Professor of Therapeutics at the University of Lorraine, France. Since 2007, he has been deputy physician at Nancy University Hospital’s Inserm Clinical Investigation Centre, headed by Professor Faiez Zannad, and an Inserm UMR, 31116 researcher, as well as being a consultant at the University Hospital Heart Failure and Hypertension Unit and haemodialysis clinics. The professor’s research priorities are clinical trials and biomarker studies in the context of heart failure, chronic renal insufficiency, hypertension, and vascular diseases such as abdominal aortic aneurysms.

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Cardiovascular medical technology

If a baby’s lungs are not properly unfolded upon birth they can be supported mechanically for a few days, as Dr Robert Bartlett of Orange County Medical Centre in California (cf EH 2/13 p. 15) showed almost forty years ago. In extra-corporeal membrane oxygenation (ECMO) the blood is drained from the body and pumped into an artificial system. In a membrane carbon dioxide is removed and oxygen is added before the blood is returned to the body (Fig. 1). Dr Bartlett was aware of the poor outcomes in adult patients: A national study had been discontinued after 92 patients, due to a mortality rate of 30% in both the ECMO and the control group.

Despite those results, he continued to use ECMO after his initial successful treatment of a neonate and he achieved survival rates of 75% in neonates and infants – clinically speaking quite a success, scientifically far from a validated procedure.

The problem was less of a technical one than an ethical one. How can a study with neonates be designed in which one group receives the treatment that needs to be validated, while the control group is refused this potentially life-saving procedure? Dr Bartlett went for a unique study design: ‘Play the winner.

The first patient has a 50/50 chance to receive either ECMO or the conventional therapy. If the patient survives, the next patient receives a chance at ECMO and the rate would be 2:1. If this second patient dies the chance to receive ECMO treatment decreases to 1:2. The result was convincing: the first patient received ECMO and survived; the second patient received conventional treatment and died. The third patient now has a 3:1 chance to receive ECMO. The patient did receive ECMO and survived.

The study was halted after twelve patients: eleven neonate patients had received ECMO and survived, only one patient – the second – had not received ECMO and had died.

The success of ECMO is also evident on the international level: ELSO, which has been maintaining its register since 1990, recorded 3,545 cases. Altogether, 53,190 ECMO cases are documented in the nonmandatory register, of which 3,043 were neonates.

The ECMO system is expanding faster than it can find a market. Instead of being cost-driven, suddenly it was working in an environment that was people-driven, with a focus on developing new, cutting edge technologies of the highest quality. Before, business was just about downsizing.

Now, with Biotronik, it’s all about growth. As manufacturing director Frank Busch can certainly speak from experience: The office where he sits is only temporary, built until a more permanent one can be constructed. In other words, the firm is expanding faster than it can find space. ‘Good news for a company that can look back proudly on 50 years of excellence, quality, and innovation since 1963,’ Biotronik points out.

Back then, physicist Max Schaldach and electrical engineer Otto Franke started a biomedical engineering revolution when they developed Germany’s first implantable pacemaker. Today, Biotronik specialises in three business areas: cardiac rhythm management, electrophysiology and vascular intervention, with a focus on in-house research and development.

Continuous innovation keeps the firm at the forefront of patient care, says Frank Busch: ‘We make sure that people still understand the company’s ethos, because everyone needs to know what it means in his or her daily work to be consistently living up to the highest quality standards.’

In the last decade the firm has implemented a number of technological solutions to ease physician-patient interaction and ongoing care. For example its ProMIH technology has been used in cardiac devices and leads since 2010, enabling patients with a cardiac implant to safely undergo MR scans. Indeed, it is the world’s only company which allows ICD, IJP and heart failure patients access to those scans.

In 20 years, Biotronik has been able to grow tremendously while remaining true to its early pioneering spirit, the company points out. Today, it is represented in more than 100 countries worldwide, and has 5,600 employees.

Importantly, the focus is on patients, as Frank Busch explains: ‘I like keeping up the awareness in everybody’s mind that they are working on implants for actual people...and one of those people could be their grandmother.’
Cardiology drives innovation

A leading Austrian professor commends scanner advances

‘Cardiology is one of the most innovative medical disciplines. Many modern technologies, such as catheterisations or imaging procedures, were triggered by cardiology,’ declared Professor Gerald Maurer MD, Head of the Department of Cardiology at Allgemeines Krankenhaus Wien (Vienna’s General Hospital) and Director of the University Clinic Internal Medicine II at Medical University Vienna. In our EH interview, held during the annual meeting of the Austrian Cardiology Society in June, Prof. Maurer outlined the most recent technological developments in cardiology.

‘MRI images of heart structures are becoming increasingly precise and with increasing resolution,’ he said. This includes the late enhancement, contrast MRI technique, where the contrast agent Gadolinium-DTPA provides detailed information on the metabolism and status of heart muscle cells, supporting tissue differentiation and allows a more precise diagnosis of the cell viability. The cardiologist can see whether a sub-endocardial infarction occurred where the necrosis, due to a lack of perfusion, is limited to the inner-most layer of the heart muscle while the outer layer of the heart muscle is not involved. With myocarditis late enhancement has become the most important diagnostic indicator. Today in cardiac ultrasound, so-called strain imaging provides new functional information. In 2-D imaging the speckle tracking technology tracks several points in the heart muscle throughout the entire heart cycle and can thus look at the deformation (strain) of the myocardium.

This is particularly relevant in patients with heart failure (HF) with preserved ejection fraction (HFPEF). For a long time cardiac insufficiency was thought to be solely associated with the lack of the heart’s contraction ability. However, around 50% of cardiac failure patients show normal ejection fractions. While some of these patients show a diastolic dysfunction, systolic abnormalities can also contribute. In those patients the myocardial longitudinal shortening is inadequate – a dysfunction that can be detected in strain imaging. ‘In an aging population HFPEF is a growing public health problem,’ Prof. Maurer points out.

He believes that cardiac computed tomography (cardiac CT) will also play an increasingly important role. Cardiac CT visualises the coronary vessels well and helps determine the calcium or Agatston score, an important indicator of a coronary disease. ‘While this method does not replace the catheter, it allows the exclusion of significant coronary heart disease with high probability,’ he explains, adding that a further development is the measurement of cardiac profusion with contrast-enhanced CT.

In the area of cardiac implants, bio-absorbable stents are an important innovation. ‘One of the problems with conventional stents is the fact that in young patients they may be associated with long-term risks. In an 80-year-old patient this is not that much of an issue, but there are many patients between 20 and 40 years of age who suffer CHD and need an implant.’

While conventional stents remain intact for several decades, bio-absorbable stents, which are made from polylactide, dissolve within two to three years – with water and carbon dioxide absorbed by the body. In most cases the endothe-lium fully recovers and the patient receives a conservative therapy with cholesterol and BP medication and anticoagulants. Large long-term studies are currently being conducted but final results are not yet available.

MRI image of a patient with myocarditis; the lighter coloured lateral wall (arrow) is caused by late enhancement.

Professor Gerald Maurer MD, who has headed the cardiology department at ADH (General Hospital) in Vienna since 1983, is also Director of the University Clinic Internal Medicine II at Medical University Vienna and completed his specialist physician training in the USA (university Board of Internal Medicine; Subspecialty Board, Cardiovascular Disease). He became a professor at the University of California (UCLA), Head of Non-invasive Cardiology and Intern Head of Cardiology at Cedars-Sinai Medical Centre Los Angeles before returning to work in Austria. Prof. Maurer is Member of the Board of the Austrian Cardiology Society (ÖKG) and currently Editor-in-Chief of the European Heart Journal – Cardiovascular Imaging.

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Cardiac magnetic resonance imaging

The potential of cardiac magnetic resonance imaging (CMRI) is still largely untapped. One novel application might be ablation follow-up. The first MRI-guided cardiac interventions were performed at Herzzentrum Leipzig, but, as far as coronary imaging is concerned, MDCT remains superior to MRI. The diagnostic potential of CMRI has not yet been fully explored. Myocardial tissue differentiation – the detection of inflammation, fibrosis and scar tissue – will be further improved and objectified, "says Professor Matthias Gutberlet (Fig. 1). The Director of the Department of Diagnostic and Interventional Radiology at Herzzentrum Leipzig and professor for cardiovascular imaging at the University Leipzig expects MRI to play an increasingly important role in prognostic evaluation of patients with infection, cardiac myopathy or inflammation.

Another big issue in CMRI application will be therapy follow-up in rhythmology and the evaluation of pathological cardiovascular haemodynamics with 4D flow," he points out (Fig. 2). While MRI is already the method of choice for volumetric and functional analyses no single cardiac imaging procedure, Prof. Gutberlet has yet to become a reality. More likely, hybrid imaging procedures, such as MR/PET or PET-CT and image fusion technologies, will prevail (Fig. 3). "No single modality will be able to offer one-stop shopping capabilities," the radiologist predicts.

With regard to coronary imaging, the professor is sure that multi-detector computed tomography (MDCT) will retain its advantage (Fig. 4 a). Unlike MDCT, MRI has not advanced significantly in the past few years, he explains, and he doubts it will gain substantial ground soon. However, CMRI may still conquer image-guided cardiac interventions. "In our institution, together with the rhythmologists we quite successfully performed MRI ablations in 10 initial patients with atrial fibrillation (Fig. 5). The rhythmologists are so excited that we will definitely continue our cooperation," he confirms.

Rhythmologists consider CMRI particularly promising because the length of the ablation procedure is accompanied by high radiation exposure. Moreover, fluoroscopy does not provide sufficient anatomical detail. "MRI offers clearly enhanced visualisation of the substrate pre- and post-intervention (Fig. 4 b, c and Fig. 5 b, c). Although we are far from routine use, we are well underway and we are quite surprised how well the procedure worked – albeit in a rather simple intervention," he reflects optimistically, and underlines that the foremost aim is the reduction of radiation exposure followed by enhanced visualisation of anatomy and the arrhythmogenic substrate, as well as therapy success generally.

MRI despite a pacemaker? Patients with implants, such as a pacemaker or ICD, require particular attention prior to MRI examination. "These patients are not per se excluded," Prof. Gutberlet says. "They can well undergo MRI even if they do not have a so-called MR conditional device." While the manufacturers continue to develop MR-safe devices, most of those available are not suitable for MR. Before an MRI exam, the device has to be checked by a cardiologist and set to a certain mode, the professor explains. The patients must be informed that a certain risk remains due to the antenna effects of the ventricular electrodes. These are mostly thermal effects that might damage the device. "MRI conditional device or not – one major problem remains unsolved: artefacts created by the device or the electrodes (Fig. 6). A pacemaker that is implanted on the left side causes artefacts right where the heart sits and the lead in the right ventricle can provide misleading information in imaging (Fig. 6)."

"Reprint from 'Röko HEUTE 2013', the official publication of the German Radiology Congress

Professor Matthias Gutberlet MD has directed the Department of Diagnostic and Interventional Radiology at the Herzzentrum Leipzig (Heart Center) of Leipzig University since 2007. His research and teaching priorities are Doppler ultrasound and cardiac CT and MRI, above all in patients with congenital heart defect, cardiomyopathies, myocarditis and coronary heart disease (Figs. 6)." The professor studied medicine at Marburg and Berlin, where he submitted his habilitation thesis on diagnostic radiology on MRI in patients with congenital heart disease. In 2012 and 2013, jointly with Professor Holger Thiele, he was scientific cooperation, his "Department of Diagnostic and Interventional Radiology at Herzzentrum Leipzig".

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Fig. 1: (a) T1 mapping after CM, (b) T2 mapping with focal elevation in the lateral wall area and (c) oedema ratio (here increased at 2.5) from STIR sequence in a 29-year-old patient with suspected acute myocarditis. (T1 and T2 mapping created with CV42 using WIP sequences by Philips and Siemens).


Fig. 3: (a) Enhancement of the volumetric and functional analysis as well as vitality and inflammation diagnostics with simultaneous MR/PET with PET/PET overlay (images created with Corridor 4DM) and (b) systemic diseases with the basic implantation, such as sarcoidosis. (Images: Prof. O. Saler, Prof. T. Kahn and Prof. M. Gutberlet – Leipzig University).

Fig. 4: (a) Exclusion of CHD with MDCT (here Curved MPR of the RCA) in a 41-year-old patient with ventricular tachycardia. (b) Late Gadolinium Enhancement (LGE) (PSIR image (arrow)). In the short and (c) long axis of the same patient shows clear subepicardial to transmural LGE following myocarditis with scar tissue. In electro-anatomical mapping the vital muscle bridge (arrow) was identified as arrhythmogenic substrate and was ablated. (Images: PD C. Piorowski, Prof. G. Hindricks, PD M. Grothoff, Prof. M. Gutberlet – Leipzig University).

Fig. 5: (a) Setup of intervention-MRI (MIR) for MR-guided ablation of atrial flutter at Herzzentrum Leipzig. (b) Result of the ablation of the cavitricuspid isthmus in patient with atrial flutter in edema visualisation (STIR sequence) and (c) LGE with scars successfully visualised (arrow) (Images: Priv. Doz. Dr. C. Piorowski, Priv. Doz. Dr. M. Grothoff, Prof. G. Hindricks and Prof. Gutberlet – University Leipzig).

Fig. 6: Patient after Dore procedure and AICD implant. (a) 4-D sequence to visualise scar with LGE and RV probe (arrow) shows only few artefacts compared to the CINE-SSFp sequence (b).
Computed tomography (CT) is the modality of choice for many diagnostic issues. Whilst currently its major strength is the visualisation of anatomical detail, future technological improvements may also reduce radiation exposure.

Computed tomography (CT) will remain an imaging heavyweight

FREQUENT INDICATIONS FOR CT

- Patients for cardiac surgery not involving the coronary arteries, such as valve replacement or cardiac tumour resection
- Patients with intermediate risk who should not undergo a coronary angiography
- (Suspected) coronary anomalies
- Evaluation of bypasses (problematic calcification of the native vessels, evaluation of the anastomoses), also in case of repeat surgery to visualise existing bypasses
- Method of choice for percutaneous valve replacement
- Visualisation of cardiac veins prior to the implementation of a bi-ventricular pacemaker
- Visualisation of the pulmonary veins prior to ablation with arrhythmias
- Visualisation of the pulmonary veins post ablation (suspected stenosis)
- Anomalous pulmonary venous connection

‘Today, computed tomography is the best imaging modality to detect stenoses in patients with intermediary pre-test probability where a coronary angiography is not immediately indicated,’ according to Professor Dr Gabriele A Krombach, Department Director at the Clinic of Diagnostic and Interventional Radiology at University Hospital Giessen and Marburg (UKGM). The degree of anatomical detail, she adds, is much better in CT than in magnetic resonance imaging (MRI). ‘In malignant varia-
tions of the descending artery, where the coronary artery is compressed between aorta and pulmonary artery, CT is currently the diagnostic method of choice.’

CT is also the modality of choice for visualising coronary stenoses. With low-risk patients without suspected coronary stenoses who require cardiac surgery, e.g. to remove a cardiac tumour, a CT scan can provide valuable information on possible coronary stenoses and help predict surgical outcome.

A further important indication for CT is the visualisation of plaque to risk-stratify patients with medium pre-test probability, Dr Krombach adds. ‘With an asymptomatic patient who has a risk of 10 to 20 percent to develop coronary heart disease over the next ten years, quantification of coronary calcification with CT in indicated.’ However, with higher risks CT is not indicated and the patient has to undergo an invasive angiography right away. Similarly very low risk (below 10 percent) asymptomatic patients do not need a CT. ‘In such a cases,’ she explains, ‘we simply wait and see.’

The radiologist particularly appreciates CT in percutaneous aortic valve replacements (TAVI), recently experiencing a veritable boom. According to the Herzbericht 2010 by Dr Ernst Broekman, the number TAVI procedures increased from 93 in 2006 to more than 4,800 in 2010. ‘When planning a percutaneous aortic valve replacement the coronary artery ostia to the valve have to be determined – this is done best with CT,’ Dr Krombach explains. As a radiologist she does not expect CT to fall into obscurity any time soon, primarily because no single modality can do everything. The coronaries, for example, cannot be visualised in echocardiography. Additionally, technological progress in CT might open access to new patient groups. The alpha and omega of CT development is the reduction of radiation exposure and indeed new kinds of detectors are being designed that aim to decrease radiation to submillisievert level.

‘If we could realise dose reduction in CT by using the different spectra of X-rays, we could also examine younger patients, such as those with congenital heart defects’ – patients who today undergo MRI, she stresses.

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Counterpulsation: The Condensed Live Longer

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Counterpulsation: The condemned live longer

The technique has been considered the method of choice for short-term mechanical cardiac support following a heart attack. The principle is impressively simple: Connected to a helium pump, a cigar-shaped balloon is ECG triggered, folded and inserted into the femoral artery in the groin and pushed into the descending aorta to the point where the tip rests just under the aortic arch. After the left ventricle has ejected its blood into the aorta, the balloon is quickly inflated. The aorta is blocked, blood cannot flow out peripherally and so flows into the coronary arteries improving blood flow in the now relaxed cardiac muscle. Milliseconds before the next heartbeat the balloon is quickly deflated, reducing pressure and helping the heart to eject blood.

The C-Pulse, manufactured by Australian-American company Sunshine Heart, Inc is neither a pulsatile artificial heart nor one of the well-known non-pulsatile left heart support systems (EHJ 5/2006 p.23 and 5/2011 p.3). However, the device appears to be suitable to help slow down or even stop symptoms in patients with moderate chronic heart failure. The technology is innovative: the principle of counterpulsation (CP) is not applied intra-aortically but extra-aortically. A cuff is placed around the ascending aorta and triggered by an ECG electrode attached to the left cardiac apex epicardially (image 1, 2). When the left ventricle contracts and the blood has been ejected into the aorta, the balloon that the cuff is blown up and compresses the aorta slightly so that more blood is retained and flows into the coronary arteries, directly improving the heart’s oxygen supply. Draining the balloon just before each contraction of the ventricle temporarily also lowers resistance in the aorta and allows a second chance for blood to flow in the coronary arteries.

The device was first used in humans in May 2005 at Auckland City Hospital in New Zealand. Dr William S Peters, the system’s inventor, has been implanting the C-Pulse in Australia since 2010 (source: J Heart Lung Transplant. 2010,29:1427-32) In May 2013 he oversaw the first European implantation of the system at the German Heart Institute Berlin (DHZB). Professors Roland Hetzer, and the Cardio-Centrum Berlin, have now fitted three patients with the C-Pulse (image 5) who had not responded to prior cardiac resynchronisation therapy (CRT) in the context of a pan-European, multicentre study. Prof. Krabatsch sees two advantages: ‘The system does not come into contact with the patient’s blood circulation; therefore there is no need for permanent anticoagulation therapy. Moreover, the patient can turn the system off temporarily or even disconnect it – for example, to take a shower. Of course, this is not possible with other pumps that are fitted intra-aortically.’ The operation can be carried out without using a heart-lung
Counterpulsation: The condemned live longer

In 1839 Richard Thoma was the first to describe the idea of external counterpulsation. He identified a fundamental relationship between blood flow and arterial caliber. This important physiological mechanism currently has a renaissance in vascular medicine: Enhancing arterial flow and flow velocities rather than pressure is an important activating mechanism in the growth of biological bypasses (atheriosclerosis). This can be achieved non-invasively by externally compressing arteries after a systolic pulse wave in such a way that a diastolic augmentation is achieved.

This involves fitting cuffs around the calves, lower and upper thighs and buttocks, which are then inflated and deflated by a compressor. Whereas researchers believed that the haemodynamic changes in blood pressure would be the underlying mechanism of clinical improvement, it is now shown that this mechanism is far more complex, according to Dr Ivo Buschmann, a specialist in vascular medicine at the Charité Clinic in Berlin: ‘The effect of blood volume redistribution is probably overestimated, however blow flow is accelerated, in a similar way to what would happen during a gentle run, without a significant increase in heart rate. The objective of this personalised shear rate therapy is the induction of arteriogenesis – a rescue mechanism of the vascular system during occlusion or stenosis. We have seen patients with fully developed collateral vessels across the entire coronary circulation in such a group. In a prospective study, 23 patients aged 61±2.5 years with stable coronary artery disease and one haemodynamically relevant stenosis, were split into two groups. Sixteen patients in the therapy group received 35 one-hour treatment sessions of external counterpulsation over seven weeks; the seven patients in the control group did not. In the therapy group, the collateral flow index (CFI) increased from 0.08 ± 0.03 to 0.15 ± 0.02 and the fractional flow reserve (FFR) also increased significantly from 0.64 ± 0.03 to 0.79 ± 0.03; P = 0.001; however, no change was observed in the control group [source: Eur J Clin Invest. 2009;39:866-75].

Tailored treatment 'The extent of volume shift from the legs towards the heart is not really that important,' Dr Buschmann explained. This also might be the reason why Cochrane and the FDA do not recommend an older system such as enhanced extracorporeal counterpulsation (EECP). Potential risks, in particular due to high pressures, can be harmful. However, it is not the compression ratio in the cuffs that is decisive, but the velocity impulse which results from the inflation of the cuffs. This impulse changes the flow profile in the blood vessels. The flow not only increases, but also the shear rate across the arterial walls. This sets off morphological and biochemical processes and eventually leads to a proliferation of the vessels [source: Development 2010].

That impulse is shown graphically on a novel vascular ultrasound 'tachometer' to measure blood flow, volume and pulse rate being developed in connection with the HerzHeil® (literally translation heart pants – describing the cuffs) system. It serves as a basis of calculation for the correct setting of this personalised shear rate therapy. Each treatment is individually adapted to the patient.

Given one-hour training sessions, the heart requires three to six weeks to develop the growth of natural bypasses sufficiently. This period of time depends largely on the individual blood flow acceleration of each individual patient, Dr Buschmann explained, adding: ‘We now know that the effect lasts for around a year, so repeated training is needed – an ideal passive addition to active cardio exercise.

Health insurers in Germany have started to cover this personal shear rate treatment, but not all; it has neither NUB (new examination and treatment procedures) status nor does it qualify for an additional reimbursement. Meeting the costs is always negotiated on an individual basis.

However, there is considerable interest Apart from the Charité, another 20 clinics – in Germany, Austria and Switzerland – plan to offer this patent protected personal shear rate treatment this year.

The procedure is suitable to treat stable CHD and particularly diffuse CHD, i.e. patients who cannot be revascularised interventionaly or surgically. In addition, patients with peripheral vascular disease (PAD) also benefit from the treatment, especially if they are diabetics. Several clinical trials are currently being initiated to confirm the beneficial effects in larger patient cohorts.

The system can also be used to treat erectile dysfunction, a disease estimated to affect every other male over the age of 40 and which can frequently be a precursor of systemic vascular disease.

PD Dr Ivo Buschmann studied medicine at the University of Hamburg, where he also began his career in the cardiology department with Professor Thomas Meinertz. Awarded a Max Planck Society scholarship he moved to Prof Wolfgang Schüper’s group, where he participated in several high impact papers in the field of therapeutic arteriogenesis. With a grant from the Volkswagen Foundation’s excellence programme (2000 – 2006) Dr Buschmann continued his research at the Albert Ludwigs University of Freiburg. In 2004 his research group initiated the Richard Thoma Laboratories (RTL) for Arteriogenesis at the Charité Berlin in the Centre for Cardiovascular Research (CCR). The focus of the RTL is the generation of molecular experimental data and translation of the latter into clinical practice.

Clinically, Dr Buschmann directs the interventional angiology at the Charité Berlin (Campus Virchow) and is a building member of ESVM – the European Foundation for Vascular Medicine.

Personal shear rate therapy

Prof. Roland Hetzer (right) and Dr Holger Hetz (left) during the implantation

implanted when patients are in a state of terminal heart failure, as bridge-to-transplant devices or destination therapy. But the C-Pulse has a different approach. The implantation at an early stage either at delays or possibly completely removes the need for the implantation of a VAD. Dr Peter Göttel, Medical Director for Europe at Sunpulse, added: ‘The C-Pulse system bridges the gap between CRT-Non-Responders and the indication for an IVAD within the therapeutic range. It’s important that cardiologists who treat these types of patients mostly as out-patients are aware of the existence of new, less invasive methods of cardiac support such as extra-aortic counterpulsation. The C-Pulse alleviates patients’ symptoms with minimal impact on quality of life. In the future, we will also offer a fully implantable version. As the system does not require an implantable buffer battery, this technological advance will be possible soon.’

Studies involving 20 patients in Canada and the USA, and 50 patients in 11 hospitals across Europe, will now test the results gathered so far. These include, in Germany (alongside the DHZB), hospitals in Hannover, Düsseldorf, Erlangen and Erlangen a hospital in Glasgow, the Royal Brompton in London and Harefield Hospital, Middlesex; in Italy, hospitals in Milan, Padua and Turin.

In 1989 Thomas Krabatsch gained his medical degree at the Humboldt University of Berlin and trained as a cardiac surgeon at Berlin’s German Heart Institute. He has been Consultant for Thoracic & Vascular Surgery since 1999. In 2002 he wrote his habilitation on ‘Examinations of the clinical relevance and underlying mechanisms of transmyocardial laser revascularisation’.

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Healing hearts? Biodegradable scaffold cell cocktails

Nothing new has been invented in heart failure in the last 15 years, according to Christian Homsy, CEO of Belgian Cardio3 Bioscences. This explains the excitement surrounding an emerging treatment among cardiologists, patients and investors.

The innovative technique for turning sick heart muscle into healthy replacement tissue was developed at the celebrated Mayo Clinic in the United States.

But cardiologists who got caught up in the excitement over new treatment of heart failure patients are very much in the minority as they are caught up in the excitement over new technology. ‘Seven years! It’s like a biblical timeframe’, said Dr Erich G. Serruyts, a professor of Interventional Cardiology at Erasmus University (Rotterdam, the Netherlands), where he is also the Director of Clinical Research in the Catheterization Laboratory. Biodegradable scaffolds are revolutionary, disposable, for a coronary revascularisation market that, with the use of Amarenco’s Aroostin, could reach €10 billion annually by 2016.

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