BIOMEDICAL ENGINEERING: ADVANCING UK HEALTHCARE.

Institution of MECHANICAL ENGINEERS

Improving the world through engineering

“HEALTHCARE IS NOW BECOMING INCREASINGLY DEPENDENT ON TECHNOLOGY, AND FURTHER SAFE, EFFECTIVE ADVANCES OF THIS TECHNOLOGY DEPEND ON THE WORK OF BIOMEDICAL ENGINEERS.

DR PATRICK FINLAY CENG FIMECHE
CHAIRMAN OF THE BIOMEDICAL ENGINEERING ASSOCIATION, INSTITUTION OF MECHANICAL ENGINEERS

This report provides an overview of UK biomedical engineering. The report looks at key case studies from UK universities and industry and provides recommendations to enable the growth of this dynamic and important sector.

This report has been produced in the context of the Institution's strategic themes of Education, Energy, Environment, Manufacturing and Transport and its vision of 'Improving the world through engineering'.

Published July 2014.
Design: teamkaroshi.com

CONTENTS

INTRODUCTION

With a global population of over 7bn and a universal expectation of longer, more active lives, the technology that promotes health, fitness and wellbeing has become ubiquitous. This is the province of biomedical engineering, the discipline of engineering that interacts with the human body.

Biomedical engineering embraces devices for care of the newborn at one end of life and independent living aids for the elderly at the other. Its products range from mobile phone apps for remote diagnosis in rural Africa to medical scanners in an industrialised city hospital.

The growth of biomedical engineering is driven by familiar global trends: a growing and ageing world population, expanding healthcare coverage in emerging markets such as China and India, and ever-increasing public expectations of fitness and health well into old age. These needs inspire research and development in medical technology linked to global marketing, with sales conservatively estimated at $325bn in 2011.[1] This is growing faster than any sector in the life sciences, and its sales will soon exceed those of the pharmaceutical industry.

The UK Government's 2011 Strategy for UK Life Sciences asserts that this country "has one of the strongest and most productive life sciences industries in the world, contributing to patient well-being, improving the sustainability and the de-carbonisation of the economy and supporting growth. The industry is high-tech, innovative and highly diverse."

Engineering developments are reducing the cost and improving the performance of healthcare technology. New ways of sensing, measuring and manipulation on a micro and nano scale reduce the invasiveness of interventions. A vast range of healthcare apps for mobile phones encourages personal health tracking and allows remote diagnosis and monitoring. Other valuable enabling technologies derive from developments in biocompatible materials and very large computer processing capabilities.

Biomedical engineering, which develops and applies these innovations, is rapidly becoming an accepted branch of mainstream engineering. However, its progress is limited by a number of obstacles. In academic research, the multiple disciplines interested in the subject mean that there is a fragmented structure that results in duplication, extra costs and inconsistencies. In the UK NHS, the world's largest healthcare system, there is also no uniform recognition of biomedical engineering, which is instead subsumed into a composite engineering career pathway listed as an option under the general heading of careers in healthcare science[2]. Internationally there are still misalignments between regulatory bodies, leading to life-saving products being available in some markets but prohibited in others. Different patent legislation hinders investment by allowing varying levels of protection in different countries. Finally, in academia and industry, there is no common nomenclature to define biomedical engineers and provide a career pathway.

WHAT NEEDS TO BE DONE

Healthcare is now becoming increasingly dependent on technology, and further safe, effective advances of this technology depend on the work of biomedical engineers. To prevent this work being held back by structural inefficiencies, this new profession needs to be recognised as a distinct discipline that offers significant value to patients, hospitals and the national economy. There is a need for a consolidation of biomedical engineering within academia, health service and industry, and practical steps to encourage this should be pursued.

Specifically, the Institution of Mechanical Engineers recommends:

1. Every NHS acute trust should have a designated Chief Biomedical Engineer.
2. A single, dedicated funding programme for biomedical engineering research should be established in UK Research Councils.
3. Industrial and taxation policy should promote long-term investment in biomedical engineering to encourage domestic development and manufacturing.
4. International consensus should be pursued for global standards, a common device regulatory and approvals regime, and harmonisation of patent legislation in medical devices. Named UK leads should be agreed for these policy roles.

“”

THE UK HAS ONE OF THE STRONGEST AND MOST PRODUCTIVE LIFE SCIENCES INDUSTRIES IN THE WORLD.


ASY
67/64 (65)
6
5/3 (5)
97
169/64 121
33.3

AN OVERVIEW

This report details 14 case studies from British universities and industry, which exemplify the role of biomedical engineering. Taken together their variety illustrates the breadth of the subject. Viewed individually, each displays the academic understanding and commercial innovation, which demonstrate the activities of the UK as a world leader in biomedical engineering.

The very broad scope of biomedical engineering is illustrated in **Table 1**. The tools used by practitioners can come from mathematics, physics, anatomy, physiology, computing and many traditional branches of engineering.

Currently biomedical engineering is a fragmented discipline: often it is divided and absorbed into other departments, but even this is inconsistent. To obtain the full benefits of cross-disciplinary working, the skills of biomedical engineers need to be understood as a distinct discipline, and integrated into the healthcare interests of academia, industry, NHS and Government.

Nationally and internationally, the delivery of healthcare and wellness is increasingly dependent on technology, and the role of the biomedical engineer will become increasingly important in university research, commercial development, manufacturing and hospital practice.

Table 1: The broad scope of biomedical engineering.

The scope of biomedical engineering:

- Medical devices for diagnosis, treatment and rehabilitation
- Measurement, modelling and simulation of human physiology and anatomy
- Sports technology
- Products for wellness, and independent living

Biomedical engineering products are found in:

- Artificial organs
- Assistive technology
- Biomaterials and regenerative engineering
- Computer simulation for surgery
- Image-guided robot surgery
- Independent living
- m-health and e-health
- Mathematical modelling of human physiology
- Medical imaging
- Neurotechnology
- Orthopaedic implants
- Rehabilitation
- Sports and physiological monitoring
- Sports technology
- Telemanipulators
- Tissue engineering

> **THE UK RANKS SECOND IN THE WORLD FOR BIOMEDICAL ENGINEERING.**

ACADEMIC EDUCATION AND RESEARCH

In the UK, 18 universities offer 31 undergraduate degrees in biomedical engineering and 21 universities offer postgraduate degree courses.[3]

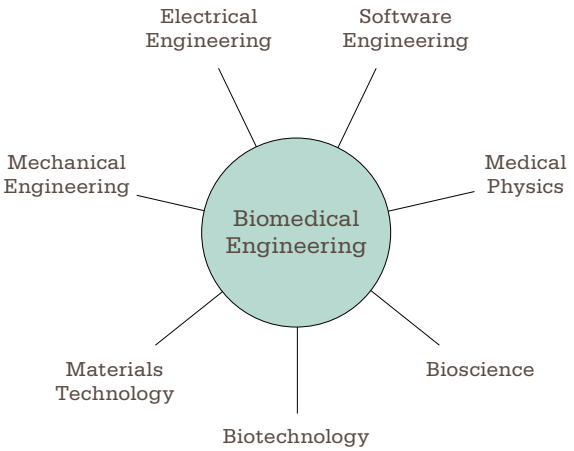
The quality of UK academic research puts British universities among the world leaders. In terms of citation in peer-reviewed academic papers for example, the UK ranks second in the world for biomedical engineering[4], as shown in **Table 2**.

Country	Citations	Documents
United States	742,911	32,596
United Kingdom	147,807	7,085
Germany	117,790	6,075
Japan	115,236	5,491
Canada	84,328	4,477
China	67,353	17,755
France	67,275	3,642
Netherlands	65,880	2,755
Italy	60,345	3,929
South Korea	44,042	3,148
Taiwan	24,441	2,625

Table 2: Documents and citations in peer reviewed academic papers by country, Scimago Journal and country rank: Biomedical Engineering 1996–2011.

At least 1,200 biomedical engineers graduate annually. Exact numbers are hard to define because of differences in course titles and overlapping syllabuses. **Figure 1** illustrates the relationship between biomedical engineering and some related disciplines.

Figure 1: Illustration of the relationship between biomedical engineering and other related disciplines.



Biomedical engineering research projects in UK universities attract Government funding of about £74m[5] from the Research Councils. Exact figures are hard to determine because biomedical engineering projects are not recognised as a separate group, but are instead distributed between various programmes. Research in biomedical engineering is mostly under the province of EPSRC (Engineering and Physical Sciences Research Council), but sometimes impinges on MRC (medical) and BBSRC (biotechnology and biological sciences). Much of biomedical engineering is included in the newly formed EPSRC healthcare technologies challenge theme, which embraces "the Healthcare and Life Sciences sector, including the pharmaceutical and medical technology industries and the NHS."[6] This broad scope includes most areas of biomedical engineering, but excludes some key areas such as sports engineering and assistive technology, aimed at improving the functional capabilities of people with disabilities. Moreover, the life science sector represents medical biotechnology, industrial biotechnology and pharmaceuticals: these are biology-based disciplines, closely related to each other but quite distinct from biomedical engineering, which is concerned with the development of devices and systems rather than biological and chemical compounds.

Academic biomedical engineering is similarly often subsumed into life sciences, a sector where it does not belong and which is directed towards biology-based technologies. Outside the university Research Councils, R&D funding is also in principle available from the National Institute for Health Research i4i budget, which had a total allocation of £20m in 2013/14 but does not have a specific biomedical engineering allocation. The Technology Strategy Board also in principle funds biomedical engineering projects from its total health budget of £55m, although this broad title also embraces innovations in medicines and cell therapy.

A major non-governmental grant awarder is the Wellcome Trust, which awards about £75m of grants for biomedical engineering projects annually.[7] Again, there is no separate recognition of the subject, and applicants have to choose between the categories of Innovation and Biomedical Science.

There is an opportunity for both the Research Councils and charitable foundations to recognise biomedical engineering as an integrating discipline that transcends traditional academic subject boundaries. A funding stream dedicated to biomedical engineering would encourage research directed to health and wellness needs that was free to draw on enabling technologies from any background.

BIOMEDICAL ENGINEERING IN INDUSTRY: THE MEDTECH MARKET

The turnover of UK medical technology companies increased by 50% in the period 2009–12, significantly ahead of the international trend, and now totals £16bn, about 5% of the global market. The sector comprises 3,000 companies employing 71,000 people.[8] About a third of these are employed in R&D and/or manufacturing.

Most UK medtech companies are small, established businesses. Three quarters have a turnover in the range of £100,000–5m, and 99% employ less than 250 people. Fewer than 500 companies in the sector have an annual turnover of over £5m.

Since 2009, although employment has risen, the number of companies has reduced, indicating some consolidation. This has been driven by the need of the larger global companies to buy in innovative products and businesses, leaving a relatively under-populated mid-size region between the very large companies and small to medium enterprises (SMEs). To capitalise on its strong research base, the UK needs more medium and large medtech companies. This is because although initial research is often best undertaken with a small technical and marketing team, development into a commercial product is more complex and requires more people and many different skills, especially in the highly regulated environment of medical devices. Again, once a product is launched, an international sales and marketing operation is required to achieve a high sales growth: UK demand represents only 5% of the global medtech market. A company needs to have a presence at least in the major markets of the USA and Europe, and increasingly in the emerging markets of China and India, in order to benefit from the scale economies offered by the global village.

Historically the UK has an excellent record in inventing and researching new medical devices, but all too often the research results are then sold to overseas corporations for development and marketing because of the lack of a domestic industrial base. This is true for example of the CT scanner invented by Sir Godfrey Hounsfield and the MRI scanner pioneered by Sir Peter Mansfield. The funding of small research-based technology companies is often from venture capital or business angels, and it is an attractive exit for these investors to complete a trade sale at an early date, as soon as a functioning prototype is available. A tax regime that encouraged investors to take a longer-term view and to grow their businesses into credible international manufacturing and marketing companies would help to counteract this trend and establish a stronger domestic medtech sector.

Medical devices are, understandably, highly regulated. Internationally there are two major schemes for approving or clearing a medical device for general sale: the CE mark system tied to the Medical Devices Directive of the European Union and the FDA clearance system for the USA. Some other countries will accept CE mark or FDA clearance, although many have their own regulatory process. A device that has achieved both FDA and CE mark regulatory clearance in practice has access to over 75% of the global market. Although the FDA and CE mark systems are broadly similar, significant differences can result in a medical device approved as safe in one jurisdiction being ruled unacceptable in the other, although the same test data is used by both. Attempts to harmonise the two systems have dragged over many years, to the detriment of manufacturers and patients.

Similar differences exist in intellectual property protection rules. Patents may be granted in one country but refused in another. Even once granted, different rules are applied to cases of alleged infringement. The IP portfolio of a young medical device company is its most important asset, particularly in the eyes of its funders, but it is also one of the most expensive overheads to acquire and maintain. If a device cannot be patented, it is risky to take it to market where a competitor can freely copy the technology. Obtaining clarity from different patent offices can take years and an international consensus on patentability would provide a major boost to innovation.

BIOMEDICAL ENGINEERING IN THE NATIONAL HEALTH SERVICE

Since its launch in 1948, the NHS has grown to become the world's largest publicly funded health service. In England, the annual expenditure for 2012/13 was £109bn. It is also one of the most efficient and most comprehensive.

The NHS employs more than 1.7m people; of those, just under half are clinically qualified. There are 15m hospital admissions and 88m outpatients every year.[9]

In England, hospitals are grouped into 162 acute trusts, of which 100 have foundation trust status. Elsewhere in the UK, hospitals are grouped and managed by health boards or trusts, with 14 in Scotland, eight in Wales and five in Northern Ireland. In total these trusts and boards are responsible for 353 hospitals.[10]

The presence and significance of biomedical engineering within NHS hospitals is often unclear, inadequately recognised and poorly understood. This is in part due to the lack of a single recognised title. Biomedical engineering is variously labelled as clinical engineering, electrical and biomechanical engineering, rehabilitation engineering, and a host of other names. More recently, the NHS has adopted the term Clinical Biomedical Engineer, as well as Medical Engineering Technician. There is no single structure at present that permits a national analysis of this workforce or the development of these roles. Staff may be managed within a medical physics or clinical engineering department, within an estates and facilities department, or even reporting directly into clinical services such as renal dialysis services or rehabilitation and enablement services. Specifically, the distinction between science and engineering is not represented well in NHS structures, with engineering often listed as a subset of science.

Where biomedical engineers exist in the NHS, under whatever name, they contribute to a wide range of clinical services providing trust-wide support. They are often responsible for the entire medical device life cycle from specification to disposal, as well as the design and development of novel and customised devices and delivering expert services directly to patients. Senior engineers support medical device clinical trials and provide a unique skill set to support the translation of industry-led product development and academic research into clinical practice. They also provide organisation-level support to clinical and financial governance of medical equipment, including analysing and reporting on incidents involving medical devices.

However many trusts do not have a recognisable biomedical engineering function. In these cases, equipment specification, supply and maintenance are contracted to commercial operators on varied terms, with a plethora of arrangements ranging from managed equipment services to grouped maintenance contracts. Usually this results in trusts with an inefficient mix of in-house, manufacturer and third-party support. Externally commissioned services are often poorly specified and provide limited incentives for development. More importantly, contracts are sometimes not managed to deliver the expected services to the quality standards specified.

The level of technological complexity within the NHS is increasing rapidly, along with the regulatory infrastructure to ensure patient safety and security of data. In such a landscape, where technology is one of the key enabling mechanisms for the NHS to meet the demands of safety, efficacy and cost-effectiveness, the role of the biomedical engineer has never been so important. Active management of the medical device asset base, its safety, functionality, maintenance and calibration, will continue to be at the core of safe and effective patient services. Achieving maximum value from investment in technology will be vital, as the scope of what equipment can achieve continues to grow, and biomedical engineers can contribute to this through health technology assessment and the monitoring of performance and use in service.

Where is the biomedical engineer?

"Acute trusts employ a large part of the NHS workforce, including nurses, doctors, pharmacists, midwives and health visitors. They also employ people doing jobs related to medicine, such as physiotherapists, radiographers, podiatrists, speech and language therapists, counsellors, occupational therapists, psychologists and healthcare scientists.

"There are many other non-medical staff employed by acute trusts, including receptionists, porters, cleaners, specialists in information technology, managers, engineers, caterers, and domestic and security staff."

About the National Health Service: NHS choices

As we move towards more personalised healthcare, the biomedical engineer will increasingly provide direct patient services through the application of new technologies and the manufacture of patient-specific devices. In such an environment, there is a growing imperative for trusts and other healthcare providers to develop a lead engineer role at an executive level to oversee these services and to develop new roles in response to changing demands and developments.

Certain positions, such as Medical Director or Chief Nurse, must be represented on the Board of a hospital trust to oversee the quality of clinical care, patient safety and clinical governance. Other positions, such as Chief Pharmacist, although not necessarily at Board level, also have organisation-wide roles with defined responsibilities for medicines management that impact directly on patient care. With the increasing importance and complexity of technology in healthcare, a need exists for a Chief Biomedical Engineer, with responsibility for a healthcare technology strategy that maximises patient safety, clinical efficacy and overall value from medical technology.

The benefits to a hospital of a biomedical function headed by a Chief Biomedical Engineer are clear from the following snapshots:

- **Efficient specification of equipment.** A guide prepared by the US Agency for Healthcare and Quality[11] states, "While technology holds much promise, the benefits of a specific technology may not be realised due to four common pitfalls:
  - — Poor technology design that does not adhere to human factors and ergonomic principles
  - — Poor technology interface with the patient or environment
  - — Inadequate plan for implementing a new technology into practice
  - — Inadequate maintenance plan
- **Timely and cost-effective maintenance and repair.** The NHS Institute for Innovation and Improvement identified "equipment failure/ unavailable" as a major reason for cancellation of operations in NHS hospitals.[12]
- **Value for money.** A National Audit Office (NAO) report[13] states, "Value for money is not being achieved across all trusts in the planning, procurement and use of high-value equipment, such as CT, MRI scanners and Linear Accelerator Machines (linacs). There are significant variations across England in levels of activity and a lack of comparable information about performance and cost of machine use."
- **Equipment management.** The same NAO report states, "Half of this high-value medical equipment is due to be replaced within the next three years. This is a challenge requiring planning by individual trusts since there is no longer a centrally funded programme. Turning to efficient management of this equipment, trusts across the NHS lack the information and benchmarking data required to secure cost-efficient procurement and sustainable maintenance of these key elements in modern diagnosis and treatment."[14]
- **Calibration and validation.** As an example of the current lack of responsibility for this function, a recent official Medical Device Equipment Alert[15] relating to the dangers of mis-calibrated patient weighing scales was addressed to "Risk Managers; Health & Safety Officers/Advisors; Estates Managers; Nurse Directors; Clinical Directors". But it is unlikely any of these people have the training or equipment to calibrate even something as simple as a set of scales. Mis-calibrations of more complex items, such as medical scanners, can result in life-threatening complications.
- **Research, development and translation**. As designers and assessors of equipment, biomedical engineers have an invaluable role working with clinicians to produce customised medical devices for individual patients. They contribute to the design, monitoring and analysis of clinical trials of new equipment, and support the translation of new products into clinical practice.

As health, independent living and wellness become more technology-dependent, biomedical engineering is becoming an ever more essential component of healthcare provision. The growth in personal health tracking using mobile phones; improvements in diagnosis through advances in imaging, sensing and measurement; developments of artificial joints and organs, minimally invasive robotic surgical procedures and computer-based aids for independent living; are all examples of current activities. The UK is already a leading player in this field, helped by a strong research base, a dynamic set of innovative companies and a cohesive internal market in the NHS. However, the future development and growth of this sector are in danger of being restricted through fragmentation, duplication and structural inefficiencies. The time has come for biomedical engineering to be recognised as a distinct discipline, with its own pathways for academic research, commercial growth, NHS integration and career development.

The Electrospinning Company's Mimetix® 96-well plate featuring electrospun 3D scaffolds.

REGENERATIVE MEDICINE

STATE OF THE ART

Regenerative medicine (or tissue engineering) is an emerging and fast-moving field of healthcare with huge potential to transform lives for the better. It covers a wide range of therapies designed to enable damaged, diseased or defective skin, bone and other tissues – and even perhaps organs – to work normally again. This area of biomedical engineering focuses on the development of novel biomaterials and engineered structures grown by seeding with cells, which can be used for replacement of organs in the body. The field spans the development of enabling technologies in cell and tissue engineering through to their translation into direct patient benefit.

The study of cellular phenomena and materials in clinical applications, such as surgical repair and treatments using the patient's own grafts, is a major focus with strong underpinning from bioengineering. Novel materials include biological and synthetic materials with new approaches in surface engineering, hybrid structures and manufacturing, for example by 'electrospinning' (a technique for drawing fine fibres) or creating structures using 3D printing. Cell-based approaches focus on the interactions between cells and their structural environment investigating stem cell behaviour, migration and function in a tissue-engineered structure.

Access to regenerative medicine products could reverse the trend of treating many chronic and life-threatening diseases by relieving suffering or delaying the progression of disease. Therapies that can cure or significantly change the course of diseases will extend and improve quality of life, while reducing the financial burden on our healthcare system. This area is a high-value science and engineering-based manufacturing industry whose products will provide economic and social impact in treating the UK's ageing population.

The relationship between materials, engineered tissues and biomechanical behaviour is fundamental to this area with strong involvement from mechanical engineering. Biomechanical conditioning of tissue-engineered constructs prior to implantation has been demonstrated to influence cell behaviour, mature biomaterials, and improve long-term biomechanical function of tissue. The mechanical performance of tissue-engineered structures in the body can be predicted using novel bioreactors to impose complex loadings across a sample. Challenges lie in integrating tissue-engineered structures with the body's own repair tissues to improve long-term clinical outcomes and functionality. Other current areas of study include manufacturing and scale-up of tissue-engineering strategies, functional assessments and quality measures for regulatory approval, and building complexity into tissue models.

> **"REGENERATIVE MEDICINE IS AN EMERGING AND FAST-MOVING FIELD OF HEALTHCARE.**

REGENERATIVE MEDICINE RESEARCH CASE STUDY

Regenerative engineering is supported nationally in a number of ways, including a recently funded Centre for Innovative Manufacturing in Regenerative Medicine with a core platform in delivery biomaterials and 3D tissue-engineered products. The Centre includes teams from Loughborough, Keele and Nottingham universities.

The delivery of cells to the patient in a clinical setting raises scientific and technological challenges. Simple injection of cells in a liquid into a disease site is inefficient, resulting in wastage of cells, compromised viability of the medicine and poor starting conditions for the regeneration of the target tissue. The Centre investigates the development of materials to aid cell delivery to the target tissue, with a particular focus on the challenges of creating reproducible 3D scaffolds – basic mechanical structures to which living cells can attach and grow. The effect of injectable solutions on cell behaviour is just one area of investigation. Other projects include:

- A new 3D delivery platform for regenerative medicine
- A novel method to develop electrospun scaffolds with customised geometries for growing different types of skin in the laboratory
- Defining and manufacturing a cell therapy product for the generation of bone in spinal surgery
- Development of a laboratory tissue-engineered 3D lymph node model
- Development of dynamic 3D models for regenerative medicine
- Evaluation of functionalised membranes that prevent the body's immune system from attacking structures in regenerative medicine and cell-based therapies
- Evaluation of injectable scaffolds for use in accelerated anterior cruciate ligament reconstruction, a common knee injury

Other major centres, including those at UCL, Imperial College and Bristol, have variously demonstrated the ability of these techniques to transplant a tissue-engineered windpipe using the patient's own stem cells, tissue engineer bone for replacing large bony defects, and even create whole organs using synthetic materials.

REGENERATIVE MEDICINE IN PRACTICE

The Electrospinning Company, based in Oxfordshire, has developed a membrane that allows human epithelium cells to be grown and transplanted for repairing a damaged cornea.

Specialist stem cells at the front of the eye keep the cornea clear and scar-free. Loss of these cells leads to blindness. For some 15 years, in a few specialist centres around the world, it has been possible to take a small piece of tissue from the unaffected eye, expand these cells in a specialist laboratory, and then transplant them to the damaged cornea on pieces of human donor amniotic membrane. Collaboration between UK-Indian consortiums, funded by the Wellcome Trust, is aiming to simplify this technique to make it available to ophthalmic surgeons worldwide. The Electrospinning Company has supplied a synthetic, sterilised, biodegradable membrane that replaces the need to harvest healthy tissue. This can be stored at -20°C for at least a year before use.

WHAT IS NEEDED

Regenerative medicine is a field in its infancy: the huge potential to revolutionise the repair of damaged body organs and structures is still being uncovered. The funding for a research centre that allows collaboration between some of the universities active in this field is welcome, and it is hoped this concept can be extended to include others. The multidisciplinary nature of regenerative medicine is typical of biomedical engineering projects, and illustrates why conventional research funding limited to traditional specialisms is ineffective. Similarly, the growing diversity of regenerative medicine applications shows the need for oversight to ensure a consistent approach in clinical practice. For these reasons, the Institution of Mechanical Engineers recommends a dedicated funding programme for biomedical engineering research should be established in the Research Councils.

“”

THE MULTIDISCIPLINARY NATURE OF REGENERATIVE MEDICINE ILLUSTRATES WHY CONVENTIONAL RESEARCH FUNDING LIMITED TO TRADITIONAL SPECIALISMS IS INEFFECTIVE.

MEDICAL IMAGING AND ROBOTICS

STATE OF THE ART

Medical imaging technology has revolutionised healthcare over the past four decades. For most patients referred to a specialist in the UK, the first investigation is likely to be a 'scan' and this scanning technology has been completely transformed in the last few years. UK physicists and engineers have led many of the most important innovations in this area. X-ray computed tomography (CT) was invented in the UK and Sir Godfrey Hounsfield was awarded the Nobel Prize in Physiology or Medicine in 1979 for his contributions. Major innovations in making magnetic resonance imaging (MRI) a clinically usable tool were developed in the UK and Sir Peter Mansfield of Nottingham University was awarded the Nobel Prize in Physiology or Medicine in 2003 for his contributions.

Significant developments in ultrasound, biophotonics and nuclear medicine have enabled doctors and medical scientists to probe the microstructure of different tissues and their molecular and biological function in health and disease. This has increased our understanding of complex diseases such as cancer, cardiovascular disease and neurodegeneration such as dementia and Alzheimer's disease. The UK has some of the world's leading laboratories developing MRI, endoscopy, photo-acoustics and robotic manipulators for minimally invasive surgical procedures. The UK also has particular strengths in computational anatomy coupled with imaging, to allow modelling of disease processes and responses to therapy. Advanced machine learning methods coupled with imaging are leading to discoveries at each end of life, from studies of healthy and abnormal foetal and neonatal development, to early disease detection in the dementias, addressing some of the most challenging healthcare problems we face with an ageing population.

Clinical translation of these discoveries and inventions provides pathways to improved healthcare. Examples include early detection of cancer through image-based screening, improved categorisation of patients through imaging allowing more specific personalised treatments, and the development of image guidance interventions, minimally invasive robotics and micro-scale manipulation to maximise the accuracy of procedures while minimising invasiveness and damage to adjacent structures.

Medical imaging is a global industry with an annual turnover of over $30bn and growth predicted at over 6% per year. Investment in the new markets in Asia, South America and Africa is increasingly significantly. Our world market share does not reflect our success at innovation. The UK is world-leading in innovation in imaging, but still needs to invest more to bring these innovations successfully to market. A vibrant community of SMEs is emerging in this sector and provides an excellent foundation for long-term growth in this sector, if nurtured appropriately. The NHS provides superb opportunities for large-scale trials in medical imaging and related technologies, but the bureaucracy of regulation needs to be significantly streamlined, without comprising patient confidentiality and safety.

> "UK PHYSICISTS AND ENGINEERS HAVE LED MANY OF THE MOST IMPORTANT INNOVATIONS IN MEDICAL IMAGING.

IMAGE GUIDED INTERVENTIONS CASE STUDY

Prostate cancer is the most commonly diagnosed cancer in UK men, with over 40,000 new cases each year, and is the second highest cause of cancer-related deaths, leading to more than 10,000 deaths per annum. The incidence of prostate cancer is increasing, predominantly due to the ageing population and the increased sensitivity of cancer detection. This has created significant healthcare challenges, as there is strong evidence that clinically insignificant disease is overtreated with the risk of significant harm and no survival benefit to the patient. On the other hand, significant, potentially life-threatening, disease continues to remain undetected in too many men.

Needle biopsy is currently the Gold Standard diagnostic test for prostate cancer. This involves extracting tissue samples from the prostate using a needle guided by an ultrasound image obtained from a probe positioned in the rectum – known as transrectal ultrasound or TRUS. Over the last seven years, a group led by Dr Dean Barratt at the UCL Centre for Medical Image Computing has been working with Professor Mark Emberton, urologist, and his team at UCLH to devise novel methods to align TRUS images with MRI images, and perform computational modelling of needle biopsy techniques. Accurate co-alignment (called registration) between MRI images and ultrasound images during biopsy enables regions suspected of being cancer to be sampled selectively leading to a less invasive, lower-cost and more efficient procedure that requires fewer tissue samples, as well as improved risk prediction. This approach is now used routinely at UCLH to aid the detection and classification of prostate cancer. The same technique also enables tissue-preserving treatment strategies to be implemented, such as focal ablation where only the dominant tumour is treated. Early studies have demonstrated that such approaches can reduce treatment-related side effects significantly.

So far, over 140 patients have had image-targeted biopsy using this novel registration of MRI and ultrasound. Furthermore, for over 50 patients electing to undergo high-intensity focused ultrasound (HIFU) therapy, the therapy has been planned using the registration software developed in this research, in collaboration with a US-based industrial partner. Discussions are currently under way to license this technology to one of the leading companies providing image-guided biopsy and focal treatments in the prostate.

In a further step, computer simulations of the needle biopsy of the prostate gland using mathematical modelling has led to a new clinical scheme for classifying patient risk. This scheme, developed by the two teams, is commonly known as the 'Traffic Light Scheme' and provides a visual way of documenting patient risk via a colour-coded system that is easily recognisable to patients. It gives an intuitive and easy-to-understand indication of the aggressiveness of disease measured by the so-called Gleason Grade. It has been particularly useful during patient consultations, as the patient can see the extent of disease and make an informed choice, together with the clinician, about which treatment option to pursue. Since its introduction, this system has determined the treatment options for over 700 prostate cancer patients, is the recommended standard of care in guidelines being updated by the Royal College of Pathology, and has been widely adopted in leading urology centres across Europe.

"MEDICAL IMAGING IS A GLOBAL INDUSTRY WITH AN ANNUAL TURNOVER OF OVER $30BN.

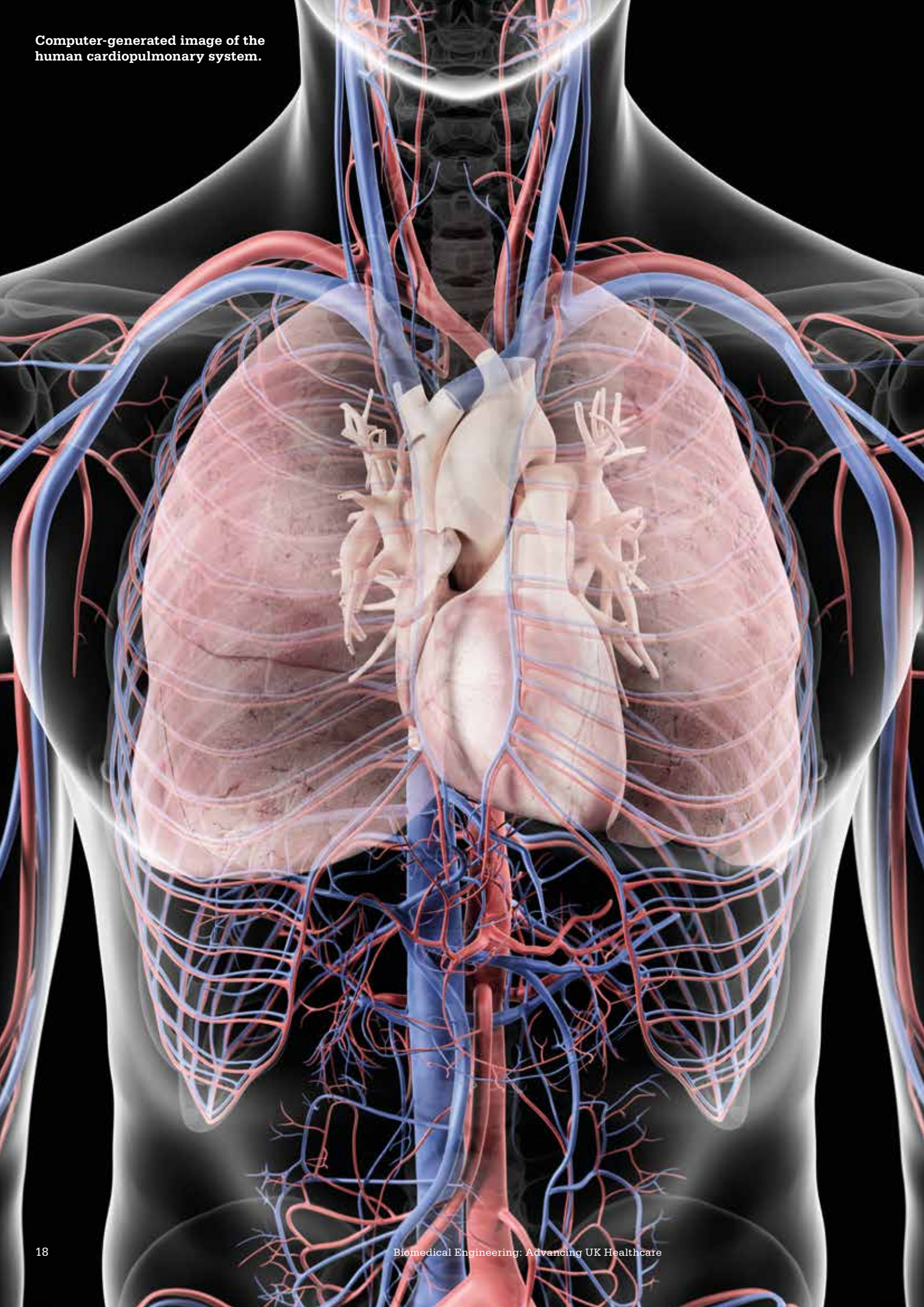
MEDICAL IMAGING AND ROBOTICS IN PRACTICE

Since medical robotics were first introduced in the 1990s, the UK has been a world leader in innovative research concepts. Some of the best research projects were developed into commercial products, and new high-technology companies were set up in the UK to manufacture, market and support these innovations. All these companies experienced difficulties in fund-raising, unable to find investors who were prepared to accept the long development cycle required for medical devices. The few companies that succeeded in raising initial funds could find only capital that was provided on a drip-feed basis, making it nearly impossible to reach the critical mass required for commercial success. This aversion to early-stage investment in medtech companies prevails generally in Europe. It contrasts with experience in the USA, where significant numbers of new medical robotic companies have raised generous capital amounts from private investors or by flotation on the Nasdaq market. Some capital-starved UK companies have been bought-out by US corporations that have subsequently sold them on at many times the acquisition cost.

One UK company that has managed to buck this trend is Surrey-based FreeHand 2010, which markets a robotic camera controller for minimally invasive surgery. This type of surgery conventionally requires two surgeons, one to perform the operation and the other to manipulate the camera and telescope assembly, which is inserted into the patient and projects the view onto a screen for the operating surgeon. FreeHand holds the camera and effectively provides the operating surgeon with a third hand, allowing camera motion to be controlled by simple head gestures. The surgeon looks towards the desired direction and the camera will track accordingly. In addition to allowing solo surgery, the FreeHand manipulator gives a tremor-free image and a natural control interface. The FreeHand system is sold internationally and used for a variety of laparoscopic, urological and cardiopulmonary procedures.

WHAT IS NEEDED

Translating innovative biomedical engineering research into commercial products requires time and finance. While the UK has an excellent reputation in biomedical engineering research, its record in producing global-scale medical device companies is poor. Too many promising UK inventions have been sold to overseas companies for commercialisation, because it proved impossible to raise venture capital domestically. Investors need incentives to commit to early stage-medtech companies. The Institution of Mechanical Engineers recommends that industrial and taxation policy should help promote long-term investment in biomedical engineering to encourage domestic development and manufacturing.



Computer-generated image of the human cardiopulmonary system.

CARDIOPULMONARY ENGINEERING

STATE OF THE ART

Assessing the heart's ability to pump blood and the changes due to disease progression within the cardiopulmonary system, are increasingly being underpinned by a number of key engineering technologies.

Numerous imaging methods have been developed within the biomedical engineering community to extract vessel volumes, wall motion, blood-flow velocity and valve function from magnetic resonance or ultrasound imaging. These parameters enable the condition of the circulatory system to be assessed and allow for critical diagnoses, such as stenoses (narrowed arteries) and aneurysms (ballooning arteries). Many of these imaging protocols are now routinely being applied in clinical practice.

In parallel with imaging technology, new medical devices under development feature improved functionality, biocompatibility and customisation. These include interventional devices such as electrical defibrillators and pacemakers, coronary and aortic stents, and mechanical pumps and ventilators. Other types of medical device are primarily diagnostic, such as catheters and blood pressure monitors. There is increasing interest in enabling vital parameters to be measured non-invasively.

In a number of cases, device and imaging technologies have been applied in tandem to aid surgical navigation during minimally invasive procedures, by creating robotic systems for the guidance of catheter-based cardiac interventions.

Computerised image processing techniques that identify anatomical structures, motion and flow can now also be combined with engineering analysis methods to understand and predict cardiopulmonary function. One example is the use of the finite element method originally developed to analyse complex engineering structures by breaking them down into tiny elements. This technique has been adapted to predict stress, strain and mechanical failure in cardiovascular tissues. Such techniques are now starting to allow the response of a whole organ to be modelled, by effectively constructing it virtually from its individual cells.

There is increasing financial and social pressure to allow patients to be monitored and assessed in local surgeries or preferably at home, rather than in specialist centres. In response, biomedical engineers have developed a number of cardiopulmonary home monitoring technologies that are starting to be deployed. These incorporate continuous tracking and extraction of multiple personalised data, for example:

1. Biosignals such as ECG, physical activity levels, blood pressure, lung function, day/night oximetry
2. Derived metrics such as chamber pressures, cardiac work, pulse wave velocity
3. Environmental factors that are closely correlated with cardiopulmonary function, such as air quality and diet

The integration of this additional patient data and clinical knowledge within models to transform information into the personalised forms, most relevant for both the patient and clinical team, represents an exciting future development.

CARDIOPULMONARY ENGINEERING RESEARCH CASE STUDY

Multi-scale techniques allow biological models to be constructed from basic building blocks. For example, the behaviour of an entire organ can be modelled based on the arrangement and interaction of its constituent cells. The integrated modelling of the complete heart is one of the most advanced current examples of the multi-scale technique and is the subject of many international and cross-disciplinary collaborations. It is one of the leading examples of an organ for which computational models have been used in clinical and industrial applications.

At the geometric level, detailed anatomically based models of the heart using techniques based on structural engineering now accurately represent cardiac anatomy, detailed microstructure and the coronary vascular system. The efficient creation of these models from medical imaging data has been underpinned by tool developments including rapid fitting techniques that allow different imaging modalities to be superimposed, interoperable data formats and web-enabled model databases.

These mathematical descriptions provide an accurate model of the heart's shape as it beats. This picture can now be enriched by adding information about the concurrent electrical activity in the heart. This information is built up cell by cell, based on knowledge of how the forces produced by electrical activity cause shape changes in the cell. These forces, added together across every cell, produce cardiac contraction and the changes in ventricular and coronary blood flow. The addition of this functional information has been made possible by novel numerical techniques for embedding cellular models into the tissue representations of the heart. Data resulting from these simulations has already produced many new scientific insights including, for example:

- New understandings of the regulation of muscle contraction
- How genetic variation is manifested functionally at the cell, whole organ and population scales

The opportunities for helping patients through these techniques are being pursued through the application of models focused on clinical outcomes. Key to this work has been the effective deployment of customisation techniques from individual patient data sets. The resulting personalised models have in turn been applied in a wide range of clinical contexts. Specific outcomes of this work that have directly benefited patients include the planning of imaging protocols, the non-invasive extraction of key measurements, and the planning of the implantation of pacemakers and cardiac assist pumps.

The next step in the development and application of this approach will be to use data collected via home monitoring and remote sensing to populate a state-of-the-art database of physiological and environmental status and its changes for individuals over an extended period. This information will be integrated within detailed and personalised computational models of heart and lung behaviour to quantify the extent to which disease is progressing in a patient, and hence to plan the timing of further therapeutic interventions and evaluate their efficacy.

CARDIOPULMONARY ENGINEERING IN PRACTICE

Medchip Solutions, based in Kent, sells a precision spirometer, SpiroConnect, which features a vertical turbine sensor and Bluetooth connectivity. SpiroConnect is the first turbine spirometer achieving the low flow sensitivity required by the latest guidelines of 0.025 litre/sec – particularly important for the diagnosis and monitoring of COPD, a condition characterised by an extended period of low flow in the spirometry manoeuvre.

The spirometer can be linked via Bluetooth to a PC-based interpretation and display package, giving real-time graphical display that provides immediate patient and operator feedback. It can be used in a GP surgery or as a portable device when connected to a laptop computer via the Bluetooth link.

WHAT IS NEEDED

The potential offered by remote sensing and monitoring is clear in the case study and the commercial example quoted. It gives an opportunity for a step change in healthcare provision: personalised monitoring delivered at home that allows constant tracking of a patient's condition and eliminates the cost and inconvenience of repeated visits to the clinic. This improves the quality of information, increases personal independence and saves money. The UK has the potential to take a leading role in this huge future market. The technology can be developed without the need for major breakthroughs, but it will take time and requires committed funding both for research and for commercial development. A committed approach to funding is required that recognises the time scales involved. For these reasons, the Institution of Mechanical Engineers recommends that a single, dedicated funding programme for biomedical engineering research should be established in the Research Councils, and industrial and taxation policy should promote long-term investment in biomedical engineering to encourage domestic development and manufacturing.

The ProSim Multi-axis Electromechanical Hip Joint Simulator.

ORTHOPAEDIC IMPLANTS

STATE OF THE ART

The first commercially and clinically successful artificial hip joint, the Charnley Hip Prosthesis[16] was designed, manufactured and clinically evaluated in the UK over 50 years ago. This technology has underpinned the subsequent development of total joint replacements across the globe. Joint replacements are now implanted in over a million patients a year worldwide, with over 90% clinical success at ten years. This makes joint replacements one of the most successful medical device interventions available today. It is predicted that the number of joint replacements being implanted every year will increase fivefold by 2030.[17] Biomedical engineers, orthopaedic surgeons and industry in the UK continue to play an internationally leading role in research, development, innovation, evaluation and adoption of technology in this field.

Early hip joint replacements were initially implanted in elderly patients, 70 years plus, to provide mobility and relief of pain. These devices consisted of a polished metal ball fastened to a stalk implanted in the femur, which articulated in a hemispherical socket fitted in the pelvis made of a tough plastic. Both components were attached to the bone with acrylic bone cement which is a fast-curing material and similar to the adhesive used in dentures. Early clinical success, with implantation lifetimes reaching ten years and more, extended the application of this technology to knee prostheses and to patients under the age of 70.

However, during the late 1980s, increasing numbers of clinical failures were seen in the second decade after implantation, with bone loss, osteolysis and loosening around the prostheses. Initially clinical research indicated this was due to breakdown of the bone cement interface.[18] This led to the development of porous bone ingrowth surfaces and bioactive hydroxyapatite surfaces for cementless fixation to bone, both in wide use today.[19] However, further research showed that the real cause of failure was minute polyethylene wear particles generated from the socket of the joint.[20] These resulted in an inflammatory reaction in which white blood cells produced bone-destroying signals leading to bone loss and loosening.[20] As a result low-wear bearing couples for hip and knee prostheses were developed, with similar technology for ankle, shoulder, elbow and spinal joint replacements.

Over the last 15 years, two different approaches have been successfully introduced into clinical practice:

1. Cross-linked and stabilised polyethylene[21] with a two to three-fold reduction in wear rate compared to historical polyethylene
2. Ceramic-on-ceramic bearings using advanced alumina zirconia composite materials[22] with extremely low wear rates

These are now showing good clinical results at ten years in young and active patients. The demand for these bearings has increased dramatically, with patients now receiving joint replacements in their 50s, with expectations of a further 50 active years of life. Long-term survivorship and reliability still needs to improve beyond current National Institute for Health and Care Excellence (NICE) guidance of less than 1% failure per year.

Pre-clinical laboratory and computational simulation will be essential to improve long-term device performance. Hip and knee joint simulation systems such as ones developed at the University of Leeds[23] now form the basis of international ISO standards[24] for testing joint prostheses under standard conditions. It has become clear more recently that a range of variables in the clinical environment and in the patient can adversely affect long-term performance and reliability.[25] To improve clinical reliability, these conditions are now being assessed more extensively during the design, development manufacture and preclinical testing of new prostheses.

ORTHOPAEDIC IMPLANTS RESEARCH CASE STUDY

Increased patient expectations and the need for longer-lasting joint replacements, aimed at '50 active years after 50', require enhanced reliability and long-term performance of joint replacements. Current international standards for joint replacements require evaluation under a single set of standard walking situations, in ideal conditions. Clinical experience over the last decade has demonstrated that failures are more commonly associated with variations in the surgical and patient conditions and activities, which are not currently evaluated through the current standards. These include variations in:

- Surgical positioning of the implant
- Patient activities, kinematics and biomechanics
- Patient anatomy and disease state
- Time-dependent variations in the bone and prosthetic material properties

The UK leads the world in the development of pre-clinical simulation methods for joint replacements. The University of Leeds, in collaboration with industrial and NHS partners, has over two decades established one of the largest and most advanced facilities in the world for simulation, functional analysis and pre-clinical evaluation of joint replacements. Working with industrial partner Simulation Solutions, it has developed some of the first commercially available hip and knee joint simulation systems,[16,17] which helped established the first international standards in 2000, where a single standard walking cycle was adopted. This standard is applied today for evaluation of implanted hip and knee joint devices.

However, it has become evident from clinical experience that high wear and failure rates in joint replacements are more frequently associated with non-standard conditions and variations in the clinical conditions listed above. Over the last decade, a range of new simulation methods have been developed and validated which start to address the variations in surgical and patient conditions that can lead to failure.

The University and industrial team has developed advanced simulation systems, which now allow functional and performance analysis and pre-clinical testing of hip and knee joints, under a wider range of clinical conditions associated with variations in surgical positioning,[18,19,20,21] different kinematic activities,[22,23,24] patient and implant sizes,[25,26] and degradation of material properties.[27,28] These systems are now being sold worldwide including to Chinese and US regulatory laboratories and are supported by licensing of know-how and training. Because clinical failure often results from adverse biological processes following deterioration in mechanical performance, these biomechanical simulations are supported by laboratory functional biological simulations and assays.[29,30,31]

Over the last ten years, these methodologies have been used to support collaborative industry developments of new prostheses such as hip joints using ceramic femoral heads with cross-linked polyethylene,[32] ceramic matrix composite hip sockets[20,33] and low-wear knee joint designs.[23,34,35] Additionally they have been used to investigate causes of failure in existing prostheses, in use before these advanced simulation methods had been developed.[26,36] These simulation methods have also been used in identifying potential clinical failure modes as part of the pre-clinical failure analysis, which have prevented products under development reaching clinical trial.[37]

ORTHOPAEDIC IMPLANTS IN PRACTICE

Simulation Solutions, based in Stockport, has worked closely with the University of Leeds to develop a range of commercially available mechanical wear simulators. The University now has one of the largest independent wear testing laboratories in the world, with a capacity of over 100 wear stations for hip, knee and spinal implants.

Simulation Solutions simulators are designed to accommodate multiple demand profile changes, to simulate the activities of daily living, and accommodate significantly wider ranges of motion and higher ranges of loading than required under current ISO standards, in order to study adverse wear.

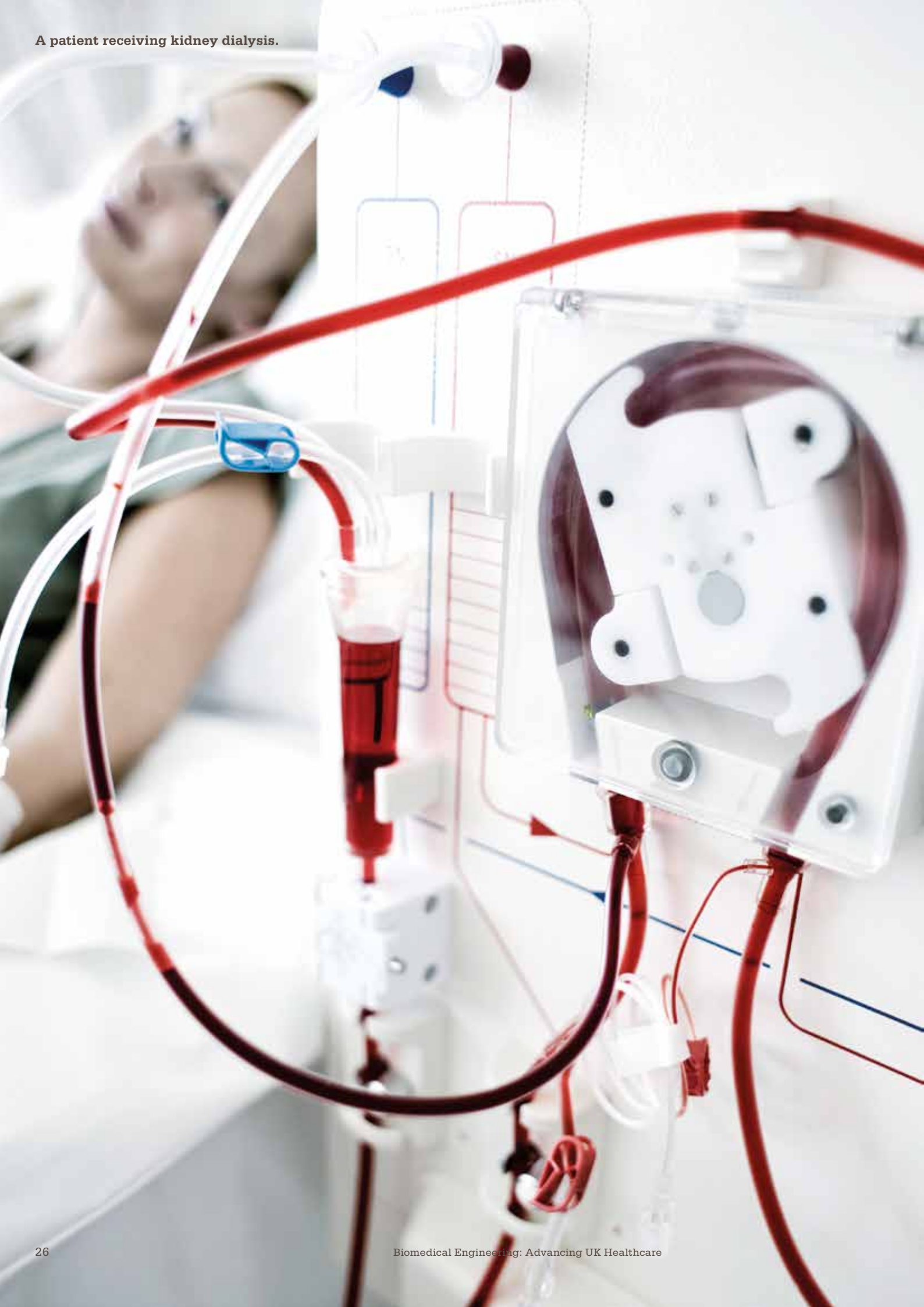
The company has a suite of mechanical wear testing simulators for the hip, knee and spinal implants, as well as other orthopaedic implants such as ankles, fingers, elbows and shoulder joints. Empirical data, generated over the last ten years, supports the assertion that the patterns of wear of implants tested on these simulators accurately mirror those of the wear of implants extracted from humans after years of use.

“”

IT IS PREDICTED THAT THE NUMBER OF JOINT REPLACEMENTS BEING IMPLANTED EVERY YEAR WILL INCREASE FIVEFOLD BY 2030.

WHAT IS NEEDED

Research in orthopaedic implants has extended the life and functionality of joint replacements, but it has also included examples of poor design and material choice, which have led to premature failure and collateral damage. This underlines the need for universally agreed methods for comparing implant performance. International standards are being planned for this, based on the research results reported in the case study. Such protection is vital for patients, and forms the basis for regulatory approval. The Institution of Mechanical Engineers recommends international consensus should be pursued for global standards, a common device regulatory and approvals regime, and harmonisation of patent legislation in medical devices.



A patient receiving kidney dialysis.

PHYSIOLOGICAL MONITORING

STATE OF THE ART

Physiological monitoring is the observation of a number of medical parameters over a period of time. This is achieved by continuous monitoring or by repeated medical tests. Engineers have been active since the early days of monitoring in developing bedside technologies such as electrocardioscopes for continuous monitoring of heart activity, and electroencephalography for displaying activity in the brain.

Physiological monitors can be classified by the target of interest, including:

- Cardiac monitoring, which generally refers to continuous electrocardiography assessing the patient's condition relative to their cardiac rhythm
- Hemodynamic monitoring, which monitors blood pressure and flow within the circulatory system
- Respiratory monitoring, such as pulse oximetry
- Neurological monitoring, such as quantifying intracranial pressure
- Body temperature monitoring

The history of the development of physiological monitoring has followed a similar path to mass-produced electronics, where miniaturisation has allowed devices to be applied more and more pervasively. Initially monitoring devices were employed at the bedside, but versions were soon developed for critical situations such as intensive care and for field use by paramedics. More recently, the development of telemetry – remote monitoring systems using wireless networks such as mobile phones – has allowed patients to be assessed using equipment in their own homes or actually worn on the body.

Biomedical engineers contribute to physiological monitoring in many ways:

- Conducting basic research on the physiological parameters that relate to patient health and developing biosensors to measure these.
- Managing data translation, where signals from the sensors are converted to a format that can be shown on a display or transferred to a recording device.
- Developing smart signal processing techniques that use surrogate non-invasive signals to monitor parameters indirectly that are otherwise hard to measure. For example, the irregular neuronal activity associated with epilepsy can be tracked non-invasively by measuring blood flow changes in the brain using functional magnetic resonance imaging (fMRI).
- Devising novel sensors using engineering and biomedical sciences for both direct and indirect physiological measurements.

In the near future, the ability to handle vast amounts of information ('big data') will allow the integration of additional patient details (imaging, functional data, lifestyle and genetic information), together with clinical knowledge and physiological monitoring, to produce powerful models that will open up new opportunities for improving personalised health and wellbeing.

PHYSIOLOGICAL MONITORING RESEARCH CASE STUDY

Recent work in physiological monitoring has focused on combining the measurements of different parameters to produce a fuller understanding of physiological processes. One such piece of pioneering work tracks the evolution of traumatic brain injury using 'multimodal' (many types of sensor) monitoring.

A person falls, hits their head violently and becomes unconscious. They are suffering from an acute traumatic brain injury (TBI). TBI is a major cause of death and disability in all age groups, and the most important cause of death and disability in working people. It is now recognised as a 'silent epidemic' in the UK and worldwide. Estimates of annual UK mortality vary considerably but it is likely that following severe TBI, some 4,000–7,000 people die (15–20% of deaths in people aged 5–30). In the USA, TBI-related healthcare costs exceed $3bn. Central to TBI's devastation is a delayed 'secondary' injury that can occur days after the initial trauma, even in patients who seem to be recovering. A mechanism in the brain, as yet not understood, causes neurons to be repeatedly disabled to the point where they begin to die. The first step to preventing this process is to characterise the mechanism and identify its source.

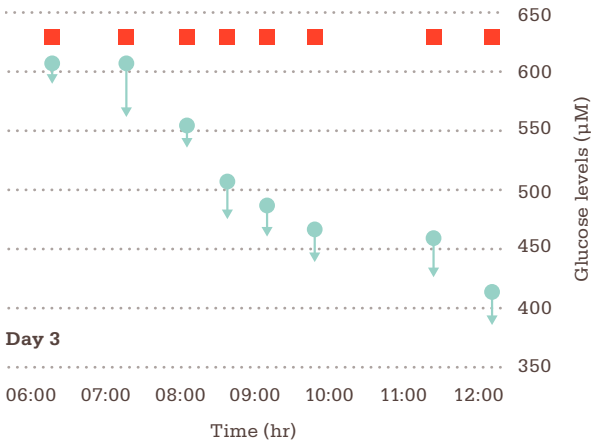
A collaboration between a biomedical engineer at Imperial College (Boutelle) and a neurosurgeon (Strong) from King's College London, has led to the development of new methods to monitor the injured human brain in real-time in the intensive care unit. These approaches are designed to detect dynamically the occurrence of transient 'secondary insults' to the injured brain, thought to be responsible for secondary brain injury. The first of these approaches is to monitor changes in brain electrical activity using electrodes placed on or into the brain surface. The second is neurochemical measurement using a combination of microdialysis and online chemical measurements from biosensors.

This work has identified an important delayed effect of TBI: a spreading depolarisation wave (SD wave). As these waves spread through the brain, they disable the brain cells they meet, rendering them unable to transmit signals.

To reactivate the brain cells so that they can continue to send signals requires very large quantities of energy. This is provided through increased delivery of glucose and oxygen by increased blood flow. Unfortunately, this at-risk tissue often has damaged or swollen blood vessels preventing this increased flow, and instead SD waves cause a prolonged decrease in brain glucose. SD waves typically repeat regularly, driving brain glucose levels down to a point where the cells die, as shown in **Figure 2**.

These measurement systems are now being engineered into a 'brain injury index' clinical instrument that uses automatic event detection algorithms to present the clinical care team in real-time with a clear view of the secondary insults affecting a patient. This is a vital first step towards being able to intercept and counteract these secondary injuries, a process that will require some years of further clinical investigation and engineering development. The eventual rewards, both clinically and commercially, from a successful solution are evident. However, to reach this goal there is a clear need for continuity and security in the development process. This illustrates the importance of access to long-term investment for biomedical engineering.

Figure 2: Red squares indicate the detection of a secondary depolarising wave; blue dots show the consequent depletion of brain glucose levels, leading eventually to cell death.



PHYSIOLOGICAL MONITORING IN PRACTICE

Hidalgo Ltd, based in Cambridge, has developed the Equivital range of mobile human monitoring solutions. Its EQ02 LifeMonitor senses, records and intelligently processes data measured from the wearer and is able to transmit this over a wireless or wired interface. Examples of health parameters that can be measured and processed include heart rate, respiration rate, body and core temperature, blood oxygen level. These can be combined with environmental measurements such as body position, fall detection and GPS co-ordinates. These datasets can be synchronised and transmitted to a remote monitoring station as well as being observable by the user at home. This provides valid and actionable information on which to make informed decisions both in real-time and retrospectively.

Equivital's products have been developed by engineers, doctors, physiologists and business professionals. Collaboration with healthcare institutions has enabled validation of equipment performance.

WHAT IS NEEDED

For a medical device, the careful translation process from basic research through to clinical verification and a saleable product is well illustrated by the early-stage research reported in the work of Boutelle and Strong: some years of continuing support is required to develop work of this sort to a commercial device. During this period, research teams and commercial partners both need to have security of funding. The Institution of Mechanical Engineers recommends a dedicated funding programme for biomedical engineering research should be established by the Research Councils.

Physiological monitoring covers a wide and expanding range of patient conditions and engineering technologies as demonstrated by the work of Hidalgo. In every hospital, there will be dozens of applications, each with multiple potential suppliers. A consistent approach to specification, introduction and continuing technical support of these systems is imperative to prevent duplication, mis-application and waste. This requires a professional central co-ordination, and is consequently one of the reasons why the Institution of Mechanical Engineers recommends every NHS acute trust should have a designated Chief Biomedical Engineer.

The NHS Health and Symptom Checker app allows users to check their symptoms when feeling unwell.

M-HEALTH AND E-HEALTH

STATE OF THE ART

m-health refers to the use of healthcare applications accessed via mobile phones. e-health, more generally, is concerned with the use of electronic information in healthcare, particularly internet-based practice. Many changes will occur in healthcare internationally in the near term, and many of them will be driven by the evolution of new technologies in mobility, internet and healthcare pathways.

The spend on healthcare varies widely between countries from 0.1–18% of total GDP. For the USA at the top end of the range, this is estimated to be three times national education spend and five times military spend. Europe is typically 9–11% of GDP. However, costs in most countries are rising as expectations increase, treatments become more widely available and we are generally living longer. Additionally diagnoses are made earlier and the total cost of drugs is rising.

New technologies such as e-health offer systems and productivity gains. We can foresee, for example, midwives able to access and update maternity records on the move; doctors in a casualty unit having instant access to the medical records of an overseas patient taken ill on holiday; a surgeon planning an operation who can inspect and combine several types of medical image of a patient, each taken in a different centre.

Data access used to be inhibited by security, reliability and data rate concerns, but these largely relate to the past. With appropriate reassurances and secure measures we can now address these issues more easily, as we see in our personal lives, for example with personal banking. Appropriate permissions can be granted by the patient for the sharing of personal medical data on a need-to-know basis, and for this data to be anonymised and made available to research studies.

However, the evolving technologies of pharmaceuticals, communications and the internet also allow new approaches and different business models. Patient-centred care may mean the individual or family can take more personal responsibility for their wellness or aftercare. This makes for a bigger pull on information and support groups, both better supported through internet delivery. Mobile devices evolving towards smartphones and tablets make this information more accessible, and can take clinicians closer to the patient. Access to and updating of patient records online, as well as support groups, all contribute to better-informed patients. Wearable measurement and remote patient management have all started to offer new pathways to care.

It is evident that both mobile communications and the internet will make a growing contribution in offering new ‘connected solutions’ for patient-centred care and better informed patient wellness. Where clinicians are remote or just not available, remote patient management is already supplementing the traditional role of the flying doctor in areas such as Australia and Africa. Mobile and wearable technologies not only help athletes, but also offer the hope of much earlier measurement, diagnosis and prevention.

The World Health Organization considers m-health as a component of e-health and defines m-health as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”. m-health solutions can be described in different ways. In general, they can be categorised into two broad areas: solutions across the patient pathway and healthcare systems strengthening.

Solutions across the patient pathway include:

- wellness
- prevention
- diagnosis
- treatment
- monitoring

These entail direct interaction with patients.

Healthcare systems-strengthening solutions include:

- emergency response
- healthcare practitioner support
- healthcare surveillance
- healthcare administration

These do not involve direct interactions with patients, but are primarily aimed at improving the efficiency of healthcare providers in delivering patient care.

Treatment needs to be supported by better prevention. Attention to wellness will increase. Access to clinicians, expertise and information will all grow with improved connectivity.

The global growth today to over 7bn mobile and 2bn internet users respectively is fostering new approaches to healthcare internationally[38,39]. However, this is no longer ‘technology push’ but ‘patient pull’. Mobile internet is not a panacea but just part of the new toolkit of e-health options. Access to information and patient support groups have become more of a right than formal provision everywhere.

M-HEALTH AND E-HEALTH RESEARCH CASE STUDIES

If people from any background are asked to list the most important needs in life, health will normally figure as one of the top five answers. This accounts for the huge number of healthcare applications available for mobile devices. The apps revolution has already touched m-health in many ways that were not expected[40]. Many of these are not just keypad-based questionnaires, for in m-health, we are already seeing methods of remote patient measurement. With over 1.8bn mobile devices being shipped every year, innovation and integration are the drivers for sensors that will help measure the five vital signs of blood pressure, heart and respiration rates, temperature and blood oxygen. Today there are plug-in accessories for mobile phones that measure these parameters individually, but integration is not far away[41,42].

These innovations take us quickly to the need for dependable solutions that ensure measurement is robust end to end. Some of the issues involved here are:

- International consensus on the safety of remote data storage and clinical assessment
- Accelerometers, cameras and plug-in accessories are already in mobile use, but their calibration needs to be consistent for accurate assessment
- The internet and Cloud storage of patient records needs to be trusted
- Confidentiality issues around patient data need to be resolved internationally

In e-health similarly, the internet has already spawned a range of experts, patient groups and new forms of innovation. This has highlighted the many differences in healthcare provision between countries, but in all of them, mobile and internet-based solutions will play a growing part. This will initially be to offer better patient access to information (whether drug availability and side effects, or early diagnosis and support), followed by productivity gains and new business models for the clinical community. Remote patient monitoring, whether in sports, wellness or long-term conditions, will add convenience as well as reduced hospital overheads. New models of care will come with better access to integrated patient record systems covering health and care, wellness and illness.

For all this to happen, the patient needs to be the driver; human factors and ease of use, e-health skills and appropriate regulation should all support this. Different countries will choose a different blend of public and private healthcare; wellness and illness boundaries will be challenged. However, whatever the mix, there is little doubt that e-health based solutions will be as important as for all other sectors of the digital economy.

M-HEALTH AND E-HEALTH IN PRACTICE

The NHS Health Apps Library was launched by NHS England in March 2013. It aims to make it simpler for people to find safe and trusted apps to help them manage their health.

A health app is a program for a mobile phone, tablet or a website that helps people manage their health. These are intended for direct use by the public rather than clinicians. Apps listed in the Health Apps Library can help improve health and reduce cost by providing information, by providing a facility to interact with health and social care services and by monitoring health and care.

All apps in the library go through an appropriate level of clinical safety and quality vetting, with users (both health professionals and the public) able to rate and comment on the usefulness of individual apps. They are checked to see whether they could potentially cause harm to a person's health or condition, for example if an app provides personalised medical recommendations or treatment options.

The NHS clinical assurance team – which is made up of doctors, nurses and safety specialists – work with the developer to make sure the app adheres to NHS safety standards. During this process, any potential safety concerns are identified and either designed out or dealt with so that any remaining risk is at an acceptable level.

"THE AREAS OF M-HEALTH AND E-HEALTH ILLUSTRATE PERHAPS MORE THAN ANY OTHERS, THE NEED FOR INTERNATIONAL HARMONISATIONS OF STANDARDS AND PRACTICES.

WHAT IS NEEDED

The areas of m-health and e-health illustrate, perhaps more than any others, the need for international harmonisation of standards and practices. Public confidence in data security, the need for systems to operate smoothly across different platforms and technology generations, transparent ability to communicate internationally, globally agreed clinical classifications – all these require international consensus and regulation to enable universal patient benefits. This is one of the reasons why the Institution of Mechanical Engineers is calling for international consensus on a common device regulatory and approvals regime, and for harmonisation of patent legislation in medical devices.

The Endolite élan foot system can detect different surfaces, walking speeds and styles and actively adapt to them.

ASSISTIVE TECHNOLOGY, REHABILITATION AND INDEPENDENT LIVING

STATE OF THE ART

Assistive technology (AT) has been defined as "any product or service designed to enable independence for disabled and older people"[43]. Early examples are artificial limbs for war-injured with the example of Ambroise Pare (1510–90) using armourers' skills to create an artificial leg. In the last 50 years, the need for independence of older people or those with disabilities has come to the attention of biomedical engineers. Their involvement has resulted in developments covering simple aids to living, aids to walking – both for amputees and those with functional impairments, and rapidly growing numbers of IT-based devices both for people with sensory impairments, and for ensuring safety in the home. At the same time, surgical and medical restorative techniques have made independent living a reality for people with either congenital or acquired impairments. A major driver over the last 30 years has been the rapidly growing numbers of older people living independently at home. A further demand has been driven by public awareness of the very serious injuries incurred by young military personnel.

The greatest demands for mechanical assistance have always been the support of mobility. Mechanical devices that can contribute to the partial or complete restoration of physical function are artificial limbs and orthoses ('orthopaedic appliances') for the lower limb. These are frequently used to substitute or correct dysfunction resulting from neurological damage or spinal cord injury. A rather smaller but important application is for the upper limb, most commonly after spinal cord injury.

Wheelchairs, in use for many hundreds of years, have reached a high level of sophistication whether attendant-propelled, user-propelled or powered. Technical advances have focused on two major groups – competitive hand-powered chairs for the highly athletic but with severe physical impairment, and sophisticated powered vehicles for people with functional and/or sensory impairments.

The maintenance of independent living at home is an economic imperative for an ageing population. While many, relatively simple, assistive devices have been developed over a long period, refinements taking advantage of new materials are still taking place.

The future state of the art is likely to involve the use of robots for a range of home tasks. This fast-developing field has the potential to provide care support to older people while maintaining a sense of independence and control. At the simplest level, these devices may be automated vacuum cleaners or even up-market dishwashers. A recent application has been that of a mobile video unit that can be remotely navigated within the home of a person with dementia. At the other end of the scale, there is considerable progress on robots to provide therapy after stroke and highly sophisticated wheelchairs for people with severe disability.

ASSISTIVE TECHNOLOGY RESEARCH CASE STUDY

The artificial lower limb has evolved from the simplest 'peg leg' design, through to sophisticated prostheses having a knee joint (where required) together with improved designs of socket to ensure comfort and positional feedback. While traditionally there has been an attempt to maximise cosmesis (ie make the artificial limb appear as a normal limb) this can conflict with the need for function. The public are now impressed rather than shocked to see a competitor in the Paralympics with a visually obvious and functionally excellent artificial limb, and this trend is likely to spread to other limb users who value function above appearance. A particular example, developed in UK is the Echelon (Charles Blatchford & Sons) artificial foot using high-technology composites with a novel geometry to achieve an impressive improvement in performance.

Biomechanically, the normal foot is a resilient and subtly controlled end effector with mechanical attributes that can change according to function – standing, walking, running, stair climbing etc. A system of complex muscles controls forces in the lower leg, ankle and foot to achieve all these activities completely naturally. However, until recently, the artificial foot has been a rigid component connected to the artificial limb by a simple spring-loaded hinge. In contrast, this new device, looking totally unlike a 'real' foot, has given fit amputees a normal walking style, and the ability to stand unaided and to climb stairs safely.

The developers have shown that, using a novel leg and ankle foot assembly, they can produce a passive foot structure that reacts against the ground in a similar way to the real foot. This produces more realistic loading on the whole limb. A particularly impressive feature is that this design allows realistic stair climbing as well as walking and running. This design has made use of both detailed biomechanical understanding of the foot and lower limb and modern composites. This is cited as an example of how the use of novel materials alongside detailed biomechanical understanding can lead to entirely novel designs that are very different from the replaced limb.

ASSISTIVE TECHNOLOGY IN PRACTICE

Blatchford Endolite is the products division of Hampshire-based Blatchford. The company's goal is to provide innovative prostheses that mimic the human form and efficiency of movement and function to enable amputees to live active and healthy lives. One example of this process can be seen in the Paralympics. Endolite uses the legacy of technology created for this type of premier performance to enhance the functionality of the knees and feet that will be used for work and play by all age and ability groups.

As one product example, the Endolite élan foot is a revolutionary new prosthetic foot/ankle system with microprocessor-controlled speed and terrain response. Sensors continuously monitor environmental feedback and the algorithm changes the foot characteristic to offer the safest, most comfortable and energy-efficient response on the flat, descending or ascending ramps and stairs. The hydraulic ankle control ensures silent operation and sinuous movement that biomimetically matches the Activity Level 3 user's body and walking style.

WHAT IS NEEDED

In the USA, government funding in excess of $50m has been provided for the Revolutionising Prosthetics programme[44]. There is no corresponding initiative in the UK, and therefore developments nationally are incremental rather than groundbreaking. However, valuable advances are possible, even with a more limited budget, provided security of funding is assured. For example, recent improvements in prosthetic design have shown the benefits of combining advanced materials with sophisticated 'biomimetic' matching of normal behaviour using smart mechanisms and software. This is an example where a targeted programme aimed at exploiting our academic and commercial expertise could initiate a new generation of devices that provide user benefits and an expansion of the national industrial base. This would be one of the key benefits to a dedicated funding programme for biomedical engineering research by the Research Councils.

CONCLUSIONS AND RECOMMENDATIONS

Biomedical engineering is a new discipline. Until now, it has been treated as an offshoot of more traditional subjects in science and engineering. It is one of the areas in which the UK excels in research, and is expanding in commercial growth and clinical applications. The increasing rate of technological change in healthcare makes it certain that the need for biomedical engineers will continue to grow. Future hospitals will increasingly rely on engineers as key members of clinical support teams. The development of new medical devices that offer clinical efficacy and financial savings will be accelerated by the expectations of improved health and wellness in a global market. The UK is well placed to benefit from these trends because of its strong research base. However, to realise these benefits requires recognition of the emergence of biomedical engineering as a distinct field. Some of the symptoms of this are now beginning to affect the development of the subject adversely and reduce its potential benefit to the UK economy.

- Academic research funding in biomedical engineering is fragmented between different programmes. For example the case study on biomaterials and tissue engineering (**page 12**) refers to research projects funded from multiple sources and based in several centres of excellence.
- Graduates in biomedical engineering are directed to well-trodden traditional career paths that do not reflect their area of competence.
- NHS hospitals have widely different approaches to biomedical engineering, leading to duplication and inefficiency. The case studies in cardiopulmonary engineering (**page 20**), medical imaging (**page 16**) and tissue engineering (**page 12**) illustrate some of the difficulties encountered in translational research – moving from laboratory experiments to patient treatment. A Chief Biomedical Engineer in every hospital would act as the champion for these programmes and ensure they were resourced and prioritised appropriately.
- The medtech industry suffers from conflicting international regimes for standardisation, regulation and intellectual property protection. One of the case studies featured in this report (**page 24**) shows how a world-class UK development in orthopaedic implant testing has the opportunity to set the benchmark for international standards, but only if agreement can be reached. Another case study (**page 33**) shows how e-health and m-health developments are vitally dependent on globally recognised standards for data management and security.
- Medical devices take longer to bring to market than conventional products due to the regulatory regime, but venture capital funders seek early exits. Several case studies describe long-term opportunities for increasing patient benefits while reducing costs, but to reach this goal they all require secure long-term funding that goes beyond university research to include commercial development and clinical validation.

Specifically, the Institution of Mechanical Engineers recommends:

1. Every NHS acute trust should have a designated Chief Biomedical Engineer.
2. A single, dedicated funding programme for biomedical engineering research should be established in UK Research Councils.
3. Industrial and taxation policy should promote long-term investment in biomedical engineering to encourage domestic development and manufacturing.
4. International consensus should be pursued for global standards, a common device regulatory and approvals regime, and harmonisation of patent legislation in medical devices. Named UK leads should be agreed for these policy roles.

AUTHORS AND CONTRIBUTORS

This report was compiled on behalf of the Institution of Mechanical Engineers by:

- **Dr Patrick Finlay CEng FIMechE**
  Managing Director, MediMaton Ltd;
  Chairman, Biomedical Engineering Association, Institution of Mechanical Engineers
- **Prof Anthony Bull PhD DIC ACGI BEng CEng FIMechE**
  Head of Department of Bioengineering, Imperial College
- **Prof Tony Unsworth BSc MSc PhD DEng CEng FREng FIMechE**
  Chair of Engineering, University of Durham

Other authors contributed significant sections:

- **Prof Alicia El Haj BSc MSc PhD**
  Director, Institute of Science & Technology in Medicine, Keele University
- **Prof John Fisher CBE BSc PhD Deng CEng FIMechE FIPEM**
  Deputy Vice-Chancellor, University of Leeds
- **Prof David Hawkes FMedSci FBIR FREng FInstP FIPEM**
  Director of the Centre for Medical Image Computing, UCL
- **Dr Peter Jarritt PhD CSci FIPEM FRCP**
  Clinical Director of Medical Physics and Clinical Engineering, Cambridge University Hospitals NHS Foundation Trust
- **Emeritus Prof Garth Johnson FREng CEng FIMechE**
  School of Mechanical and Systems Engineering, Newcastle University
- **Dr Mike Short CBE BA FREng FIET**
  Vice President, Telefonica Europe;
  Past President Institution of Engineering and Technology
- **Prof Nicolas Smith MA Oxf., BE(Hons) PhD, MIEEE**
  Dean of Engineering, University of Auckland, previously Head of Dept of Biomedical Engineering, King's College London

Additional input was provided by:

- **Richard Campbell**
  Institution of Mechanical Engineers
- **Matthew Chapman**
  National Institute for Health Research
- **Erica Herrero-Martinez**
  Institution of Mechanical Engineers
- **Keith Ison OBE MA MSc PhD MBA FIPEM CSci**
  Head of Medical Physics,
  Guy's and St Thomas' NHS Foundation Trust
- **Prof Stephen Keevil MA MSc PhD FIPEM**
  President, Institute of Physics in Engineering and Medicine; Professor of Medical Physics, King's College London
- **Dr Helen Meese CEng MIMechE**
  Head of Engineering in Society, Institution of Mechanical Engineers
- **Dr Oliver Wells PhD**
  Commercial Director Devices for Dignity Ltd

REFERENCES

1 Strength and Opportunity 2012: The landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK. HM Government December 2012. NOTE: This sales figure does not include non-clinical areas such as sports technology. Other estimates for biomedical engineering sales range up to $500bn

2 www.nhscareers.nhs.uk/explore-by-career/healthcare-science/careers-in-healthcare-science/careers-in-clinical-engineering-and-medical-physics/clinical-engineer/

3 UCAS undergraduate and postgraduate search tool www.ucas.com

4 Scimago Journal and country rank: Biomedical Engineering 1996–2011

5 Figure computed from EPSRC research grant awards

6 www.epsrc.ac.uk/research/ourportfolio/themes/Pages/themes.aspx

7 Figure computed from published research grants

8 Strength and Opportunity 2012: The landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK. HM Government December 2012

9 www.nhsconfed.org

10 www.drfosterhealth.co.uk/hospital-guide/full-hospital-list/

11 Hughes RG (ed). Patient safety and quality: An evidence-based handbook for nurses. (Prepared with support from the Robert Wood Johnson Foundation.) AHRQ Publication No 08-0043. Rockville, MD: Agency for Healthcare Research and Quality; March 2008

12 www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/cancelled_operations.html

13 Managing high-value capital equipment in the NHS in England. National Audit Office 2011

14 Amyas Morse, head of the National Audit Office, 30 March 2011, quoted in NAO report above op cit

15 www.dhsspsni.gov.uk/mdea_ni_2008-036.pdf

16 Barbour et al, Proceedings Institution of Mechanical Engineers, 214H, 569–576 (2000)

17 Barnett et al, J Materials Science: Materials in Medicine, 12, 1039–1042 (2001)

18 Williams et al, J Biomechanics, 39, 2274–2281 (2006)

19 Leslie et al, Clin Orthop Relat Res, 467–9, 2259–2265 (2009)

20 Al-Hajjar M et al, J Biomedical Materials Research, B Appl Biomaterials, 95, 263–268 (2010)

21 Fisher J, Bone J, Joint Surg Br, 93,1001–1004 (2011)

22 Barbour et al, Proceedings Institution of Mechanical Engineers, 213H, 455–467 (1999)

23 McEwen et al, J Biomechanics, 38, 357–365, 2005

24 Jennings LM, Proceedings Institution of Mechanical Engineers, 221H, 305–314 (2007)

25. Fisher et al, Clinical Orthopaedics & Related Research, 453:25–34 (2006)

26 Leslie et al, J Biomedical Materials Research, B Appl Biomater, 87,163–172 (2008)

27 Endo et al, Proceedings Institution of Mechanical Engineers, 216H, 111–122 (2002)

28 Fisher et al, The Knee, 11, 173–176 (2004)

29 Green et al, Biomaterials, 19, 2297–2302 (1998)

30 Germain et al, Biomaterials, 24, 469–479 (2003)

31 Hatton et al, Biomaterials, 24, 1193–1204 (2003)

32 Galvin et al, Proceedings Institution of Mechanical Engineers, 224H, 1175–1183 (2010)

33 Stewart et al, J Biomedical Materials Research, 66B, 567–573 (2003)

34 Galvin et al, J Biomechanics, 42, 1898–1902 (2009)

35 Brockett CL et al, Proceedings Institution of Mechanical Engineers, 225H:511–519 (2011)

36 Williams et al, Bone J, Joint Surg Am, 90, 3, 111–117 (2008)

37 Leslie et al, Proceedings Institution of Mechanical Engineers, 227H, 345–349 (2013)

38 February 2013 Mobile Economy www.gsma.com/newsroom/gsma-outlines-state-of-mobile-industry-in-new-report

39 February 2013 GSMA/PWC report www.gsma.com/newsroom/gsma-the-adoption

40 October 2012, the first European Directory of Health Apps available in the public domain on the PatientView website www.patient-view.com/-bull-directories.html http://patientview.createsend3.com/t/j-l-wkukdy-jlukllliti-s/

41 August 2013 www.mobileworldlive.com/m-health-tracker

42 September 2013 mDiabetes and m-health endurance bike ride www.gsma.com/newsroom/gsma-m-health-grand

43 User group consultation at the King's Fund, 2001

44 www.neurotechreports.com/pages/darpaprosthetics.html

Institution of Mechanical Engineers

1 Birdcage Walk
Westminster
London SW1H 9JJ

T +44 (0)20 7304 6862
F +44 (0)20 7222 8553

media@imeche.org
www.imeche.org