



Big Data, automation, and artificial intelligence – no doubt, all these developments will have an impact on surgery. During our interview, Professor Hubertus Feußner, Head of the interdisciplinary research group 'Minimally invasive interdisciplinary therapy intervention' at the Technical University Munich, Germany, and Professor Christoph Thümmeler, Professor for eHealth at Edinburgh Napier University, Edinburgh, Scotland, spoke of the role of Big Data and cloud computing in surgery, and intelligent devices that will fundamentally change surgery. They also explain why, despite technological progress, robots will not make the human surgeon obsolete.

Asked what role big data will play in the operating room (OR), Professor Hubertus Feußner said that, at this point, 'Big Data simply means we will have to deal with data volumes that do not grow in a linear manner, but will reach entirely new dimensions.'

'We are increasingly faced with the fact that we need more and more – and above all reliable – data in ever shorter time frames. Case in point: teleconsultation. The external expert assesses the site via a video camera and offers advice and maybe also physically intervenes and can thus significantly influence the procedure. In such a scenario, there must not be the slightest delay in data transmission, as the surgeon needs the required data instantaneously, and reliably.'

'The next data processing level is telesurgery – a still controversial idea. It's not new; 15 years ago Professor Jacques Marescaux performed the so-called Lindbergh operation. However, due to prohibitive costs and unreliability telesurgery has not yet conquered surgical routine; but this might change with reliable and affordable 5G solutions and this might indeed enhance surgery in certain cases.'

Thümmeler: 'Let's not forget Industry 4.0, which is making inroads in healthcare. The degree of personalisation that Industry 4.0 will bring will not only enhance surgery but also my own discipline – internal medicine. With regard to catheter exams this means that we don't have to use previously acquired images, but that specific algorithms allow us to analyse images immediately on site.'

'With algorithms that detect more detail than the human eye, we can



A graduate from Philipps University, Marburg, Germany, **Professor Hubertus Feußner MD** has pioneered minimally invasive surgery, with the focus on visceral medicine. In 1999 he founded the interdisciplinary research group 'Minimally invasive interdisciplinary therapy Intervention' (MITI Institute), which he heads today. He has also published ground-breaking work on medical technology, as well as laparoscopic and scar-less operations.

compare real-time images with previously acquired images. That's a quantum leap. However, enormous data volumes will have to be processed which requires next generation network technology, such as 5G.'

Is that where the cloud comes in?

Thümmeler: There is no such thing as "the" cloud but many different kinds of clouds. Public clouds, such as those we know from Amazon or Google; private clouds that we install at home, or hybrid clouds that are a mixture of both. We have to clearly differentiate here.

For healthcare, the public cloud is utterly unsuitable because the privacy of the patients and the hospital staff as well as the hospital's business secrets cannot be sufficiently protected. On the other hand, the idea that we feed all data in one huge platform that can be accessed by everybody is unfeasible, as is the idea that we exchange data without the patient's explicit consent. Software-to-data is a strategy that is worthwhile considering. It means that algorithms and software elements process data on site.'

In the OR the surgeon receives many radiology and lab data. Are data also sent from the OR straight to the cloud?

Feußner: 'Basically, only for teaching purposes or to obtain an outside opinion. The majority of the data volumes are created during intra-surgery tissue differentiation. In cancer surgery, particularly, it's very difficult

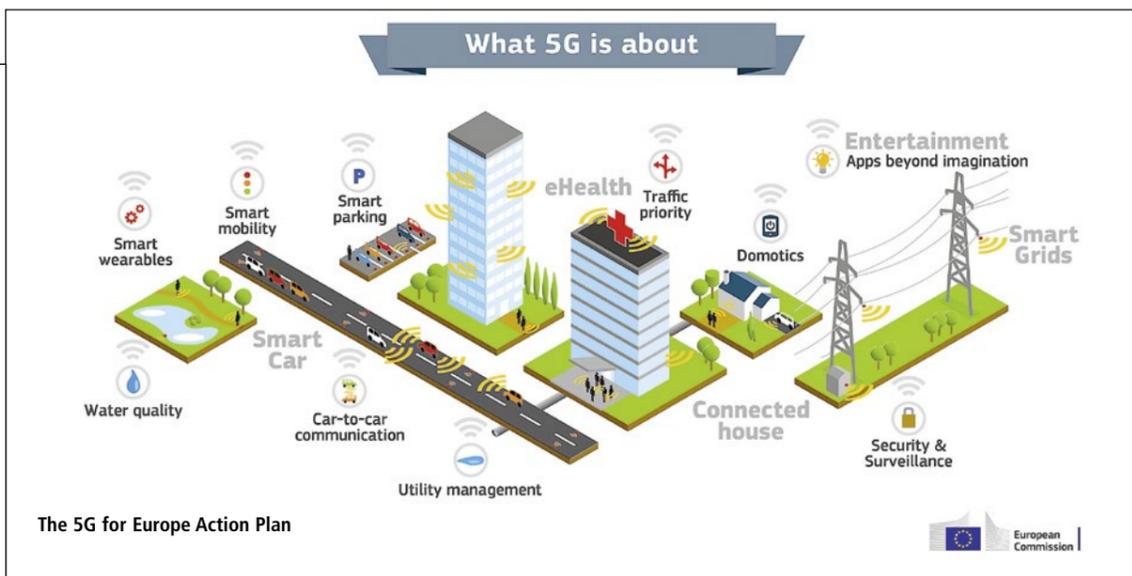


Professor Christoph Thümmeler MD is a specialist in general and internal medicine and professor of eHealth at Edinburgh Napier University. In the 1990s he was already specialising in electronic healthcare systems and, for a number of years, has been expert at a European level for the internet of things and healthcare information and communication technology.

Continued on page 3

Robots will not kill off human specialists

An autonomous 'surgeon' will not be developed for at least another 20-25 years



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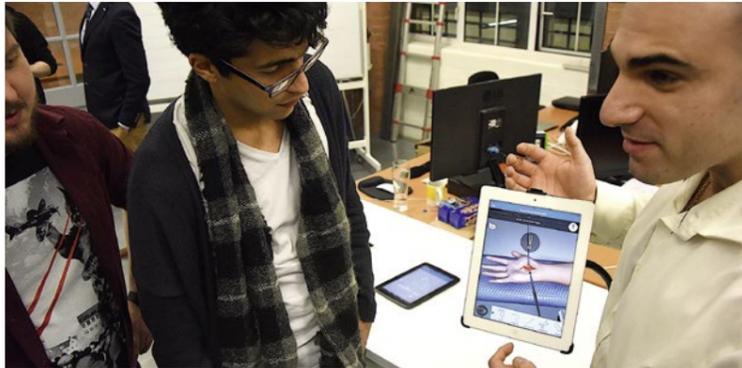
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HIV Ab/Ag combi		
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Surgeons adopt mini mobile technology asset

Pulling an operating theatre out of a pocket

The reprocessing of medical devices in Europe is very inconsistent, according to a European Commission survey carried out in the 27 EU member states among politicians, medical devices manufacturers and reprocessing companies, as well as doctors, hospitals and related parties.



Touch Surgery has been developed on the basis of cognitive task analysis, breaking down a portfolio of operations into a series of steps and decision points

Report: Cornelia Wels-Maug

Dr Jean Nehme, a London-based trainee plastic surgeon, reflects on his own training – a decade spent attending lectures, revising textbooks, passing examinations – but did he actually practise a surgical operation? 'In training, you spend many months learning how to operate, without performing any operations. It took me a long time to learn to do it the right way and there are very few rehearsal and foundation tools accessible,' he explains. With a shortage of surgeons, trainee surgeons cannot get the valuable experience they need.

That's why Nehme, and three other surgeons, decided to tackle the problem. In 2013 the team created 'Touch Surgery', a mobile surgery simulator that runs on iOS and Android mobile devices. This provides a cognitive map

for operations, allowing users to learn and rehearse a surgical procedure step by step on a virtual patient in 3-D in an interactive way.

Nehme believes a successful surgery relies about 75% on cognitive skills e.g. visual and pattern recognition and 25% on technical skills. Therefore, Touch Surgery has been developed on the basis of cognitive task analysis, breaking down a portfolio of operations into a series of steps and decision points. Users are guided with a few swipes and pinches as to where to make incisions, how to remove organs and then sew patients up again.

They can also test themselves at each step against a choice of tools and parts of the body. A 'gamification' element allows users to upload their scores and compare them against the top and average score.

The free app currently has a portfolio of more than 40 virtual surgical simulations, co-authored by expert surgeons at leading international associations and medical institutions. In this way, Touch Surgery wants to facilitate the dissemination of surgical best practices and novel procedures and to improve patient outcomes. With more than one million users in over 225 countries in the three years since its launch, the company clearly meets a universal need for this tool. It appeals not only to trainee surgeons but also to established surgeons to help them keep abreast of advances in medical technology.

Patients also find it a useful tool because it assists them to better understand the procedures they are about to receive. The app has been fully endorsed by surgical societies such as the Royal College of Surgeons of Edinburgh and the American Society for Surgery of the Hand (AASH), and is also integrated into leading residency programmes in the USA, for example by the Stanford School of Medicine, Harvard Medical School, Penn Medicine, NYU School of Medicine.

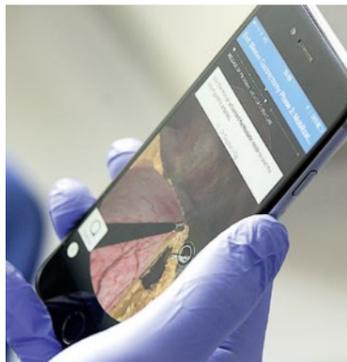
More recently, the company applied the technology in the virtual reality space, allowing multiple teams across different locations to collaborate on establishing a knowledge base of surgical techniques and best practices.

What's next? Touch Surgery is keen to put this technology on wearable hardware to make it part of the operating room to provide a decision system to assist surgery. The firm also looks into applying cognitive mapping in robotics. With a background in



Dr Jean Nehme is a London-based trainee plastic surgeon. In 2013 he and some colleagues created 'Touch Surgery', a mobile surgery simulator that runs on iOS and Android mobile devices.

medical engineering, gaming, simulation and animation design – with animators who worked on films like Avatar, Finding Nemo, Gravity and Skyfall – the team looks set to come up with more innovation for the operating theatre. This certainly appears to be a firm to watch.



The free app currently has a portfolio of more than 40 virtual surgical simulations

to determine whether all malignant cells were removed and the remaining tissue is healthy. Thus, today, we tend to remove more tissue than necessary. To be able to follow the principle "as much as necessary and as little as possible" we have to be able to differentiate tissue during surgery. Currently, the only way we can do this is via an intra-operative frozen section. Our vision is to have sufficient information on hand to be able to answer questions on tissue malignancy during the intervention.'

How could this vision become reality?

Feußner: 'One option might be a probe that we insert into the tissue and which sends us information. Another option might be automatic differentiation with a scope. We envision a machine, an intelligent device that tells us with what kind of cells we are dealing.'

'This is a tall order for any knowledge-based system and conventional technology cannot yet fulfil it.'

Thümmler: 'When you want to examine tissue locally and compare it to entries in an existing data base with similar tissue structures, or certain patterns, this is where Big Data comes on stage: We need existing data for comparative purposes, we want to use algorithms to fuse historical data with new data in real-time.'

Feußner: Here data mining, the extraction of knowledge, plays a crucial role. In the future I want to make evidence-based decisions by accessing thousands of similar cases which point in a certain direction and which tell me what I have to expect. To make a decision based on past experience, learned knowledge, that would be a fantastic step forward.

Are we therefore moving towards computer-based and cognitive surgery?

Feußner: 'Exactly. Cognitive surgery is the combination of experience and learned knowledge, actively support-

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Mobile devices that support patient monitoring, data transfer and wireless transmission are increasingly common to streamline patient care in hospitals, the firm points out.

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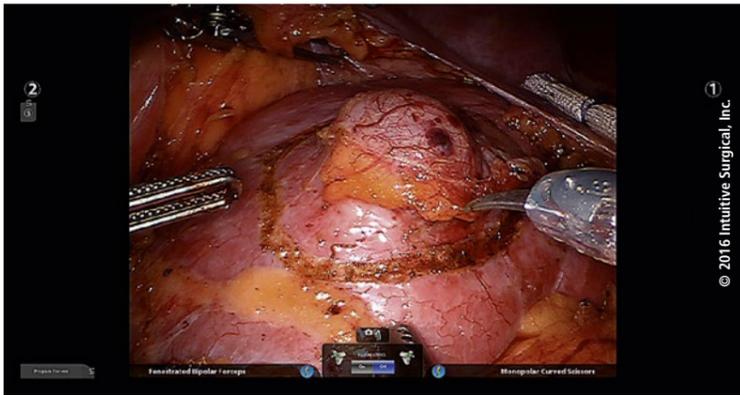
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Robots will not see off human specialists

continued from page 1



Normal 3-D HD illumination mode (view of renal hilum) during da Vinci partial nephrectomy

ed by intelligent systems or cooperative devices.'

Thümmler: 'We are talking about cyberphysical systems that link the real and virtual world and communicate with each other in real-time. In the virtual world, we are dealing with algorithms and databases, in the real world we are dealing with the surgeon in the OR. If we can construct systems that activate knowledge in real-time, we are coming pretty close to surgery 4.0.'

We have Big Data and the cloud; very soon we may have learning software and algorithms. Do we still need a surgeon if we can programme a robot with the necessary knowledge – and a robot that could learn from our experience?

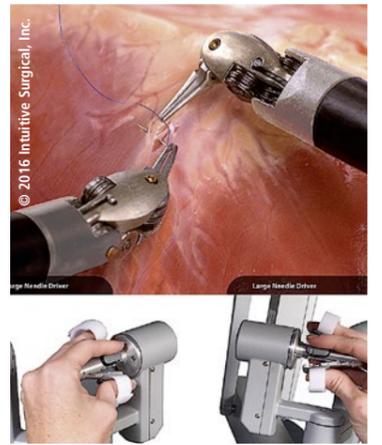
Thümmler: 'Current surgical robots are more or less the surgeon's extended arm, who still has to treat the patient one to one. That's an important aspect in the current debate. At the end of the day the surgeon is not superfluous. Indeed, sometimes it is more tiresome to work with the Da Vinci robot.'

Feußner: 'The term robotics is difficult as it conjures up images of metal and plastic. We should rather call it support or assistance systems or, to use robotics terminology, mechatron-

ic assistance systems. Their role is not to passively perform commands, as with the current master-slave systems, but to work autonomously or semi-autonomously to a certain degree. The system should be able to do the surgical drudgery – tasks that are tiresome, boring or time-consuming, such as tying a surgical knot. With the current systems I basically have to tie my fingers into a knot first in order to tie the suture into a knot. It takes forever. If I could ask a future system to tie a knot, that would be a major help. These things are conceiv-

able. Such skills can be learned with the help of deep learning procedures in robotics.

'Having said this, the "driving" surgical robot – the robot that acts autonomously, will not be developed in the immediate future, at least not for another 20 to 25 years. After all, surgery is a biological process that is often performed under highly dynamic and unpredictable circumstances and will continue to need human intervention for many years to come.'



Hands on the master controls of the surgeon's console and operative screen

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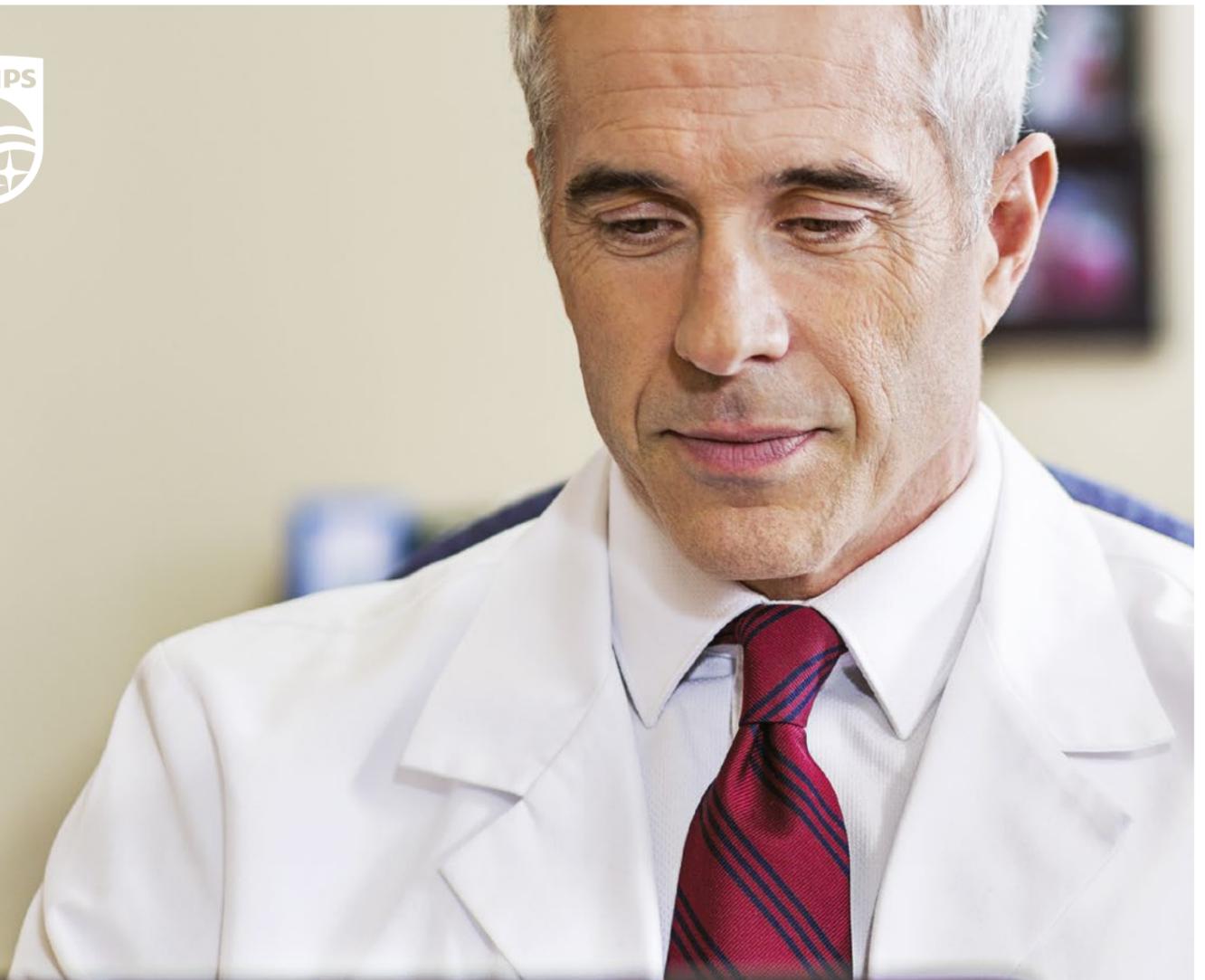


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Navigation systems sometimes reach limits

CAS is a fine aid but not a threat to surgeons

Computer Assisted Surgery (CAS) has entered various surgical disciplines. The term includes concepts that support surgical interventions with the use of computer technology from the pre-operative to post-operative phase. This includes image-guided surgery as well as surgical navigation systems or the more critically viewed robot-assisted surgery, Melanie Günther reports

The basic prerequisite for CAS is an accurate model of the patient. To gain this, various image formats – whether CT, MRI or PET/MRI scans – are prepared and combined via software during the pre-operative planning phase.

Professor Markus Kleemann, Division Chief of Vascular and Endovascular Surgery at the University Medical Centre, Schleswig-Holstein, explains: 'High-resolution data sets in the millimetre range can be reconstructed

three-dimensionally. This image is subsequently transferred to the patient. The reconstruction conveys a more intuitive view of the findings, for instance, regarding the location of a tumour or vascular disease.

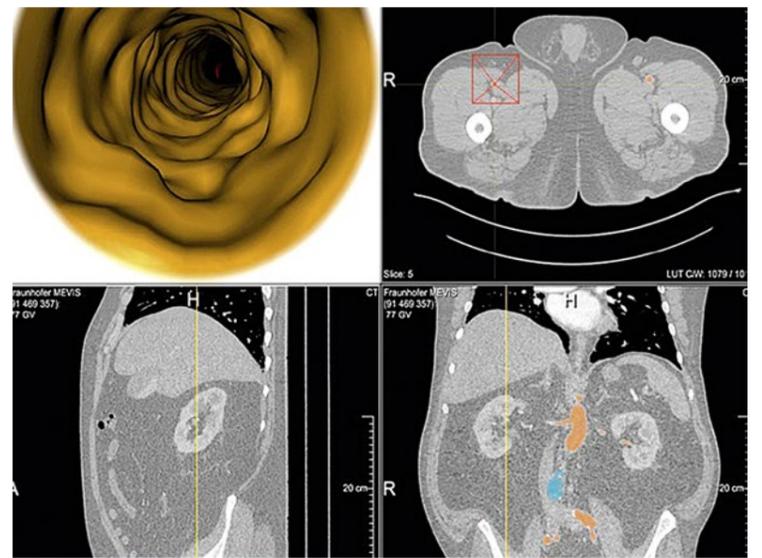
'Thanks to this visualisation technique, today we can calculate distances, diameters or volumes prior to the intervention and accurately specify the surgical strategy. The implementation during surgery assumes that the information collected from the image data can be transferred to the surgical settings.

'In some cases, a 3-D model of the operable organ or bone is produced after the image reconstruction. In doing so, stents or implants can be positioned on a trial basis, or accesses simulated to be able to operate as minimally invasively as possible. Based on these types of custom-made models, implants can also be custom-fit, in some instances.

'CAS is primarily used in specialised clinics since the technique only lends itself to more complex cases. The generated CAS data can be transferred between individual clinics and hospitals. This is important in patient transfers or teleradiology consulting when the goal is to save time and gain information.'

From preoperative planning to navigation

'Minimally invasive surgical procedures have considerably increased in recent years and have also become gentler and more accurate. That's why it is certainly no coincidence that the development of CAS as a navigation



Distances, diameters or volumes can be calculated prior to an intervention and specify a surgical strategy

aid went along with the refinement of minimally invasive procedures. Surgical navigation systems give surgeons access to structures that would not be accessible without navigation. And they also enable them to work with more precision – all of this benefitting the patient.'

Navigation systems are based on optical or electromagnetic tracking systems. Professor Michael Nerlich, Director of the Department of Trauma Surgery at the University Medical Centre in Regensburg, works with 3-D stereo cameras in his specialty area. 'The sensors of the camera system facilitate a precise spatial presentation that is directly transferred onto the screen. As a surgeon, I can see exactly where I am presently at with the respective instrument. This is especially helpful with spine surgeries where every millimetre is crucial. Thanks to the navigation aid, screws, wires or implants can be put in place by using minimally invasive techniques.'

Today's commercially available navigation systems often use optical and electromagnetic tracking and combine the benefits of both techniques. The differences between interventions can be the mathematical model data set by which the tracking data is synchro-

nised, i.e. 'registered'. The University Medical Centre, Schleswig-Holstein, currently studies the use of fiberglass navigation systems for vascular surgery. 'Within the scope of further developing minimally invasive endovascular procedures, we try to subject patients to less radiation and contrast agents. Thanks to the integrated fiberglass in the catheter system, we can control the position based on intra-operative imaging and know exactly where our catheter is located in the vascular system,' Kleemann adds.

Navigation as a self-learning system

Yet even navigation systems sometimes reach their limits, namely when complex procedures are necessary that the software does not contain in its programming. 'The systems are often geared towards standard procedures and cannot be used for complex malpositioned knee or hip prostheses. This is why it would obviously be desirable if these systems could act in a self-learning manner in the future based on artificial intelligence,' Nerlich suggests. He could also imagine systems customised to the weaknesses and strengths of a surgeon to triumph. They could warn surgeons if movement fluctuates. 'Currently, there are studies on knowledge-based systems that adapt to the individual surgeon and allow for a customised surgical technique. There is still a wide, expandable potential for development in the CAS sector.'

Man vs. machine

Besides surgical navigation systems, robot-assisted surgery is another field that's not new. Kleemann explains: 'The misconception about robotic surgery is that the robot automatically performs surgery. That's not quite the case. These are actually so-called master-slave robot systems with a surgical console and a patient-side cart with three or four robotic arms that ultimately perform the movement.'

The best-known system is the Da Vinci tele-robotic surgical system, though there is no conclusive scientific data that proves an explicit benefit of the device for the patient, according to Kleemann. The high costs call for a clear marketing strategy. Nerlich also agrees with that statement.

The 'granddaddy' among systems should have actually been revised and updated some time ago. According to Kleemann, newer developments are actually headed for haptic feedback, as is the case with the MiroSurge robotic system, a research project by the German Aerospace Centre; yet this does not solve the cost-benefit issue. 'Although patients are very attracted to this technology, I don't believe that the surgical profession will someday be replaced by robots.'

An evidence-based data analysis and facts that prove an actual benefit are still missing, he adds.

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Lighting up the operating theatre

43 LEDs shadow-less lamps

The Italian firm
Acem Medical Company produces an impressive range of medical lighting, sharing the firm's special LED optics to generate a shadow-less, clear and homogeneous light. The model StarLED5 NX is no exception, generating an IR-free light, excellent colour temperature and a practically endless life cycle at low consumptions, the manufacturer reports. 'The 43 LEDs that make the StarLED5 NX are circularly positioned and divided into five reflectors (with seven LEDs each) and other eight LEDs are radially placed around the handle. In this way, the lamp produces a high illumination level of 130,000 lux (160,000 lux optional) for a steady life cycle of about 50,000 hours.'

ACRIS ensures, by the use of a microprocessor, control of electrical curves typical of LEDs remain unaltered over time but maintain a long life cycle. The colour rendering index of this lighting is 95 and colour temperature 4,500°K. These two values allow the exact chromatic scale of the colours of the human body to be reproduced, the firm points out.

Focused and ambient light

To achieve the right illumination to meet different needs this model can produce either focused or ambient light: 'The light field focusing system adjusts the light spot diameter accurately, assuring an excellent sharpness of details in the operating area,' Acem adds. Ambient light is managed by the Endo function. This technology allows

visual comfort as well as a correct vision of the surrounding environment thanks to its particular light beam coming from the upper part of the lamp. StarLED5 NX is particularly suitable for minimal invasive surgery and is ideal for preparation and treatment during the operation, monitoring the patient and microscope operations.'

Practical and functional design

Acem adds that the model's removable, sterilisable central handle can house a video camera for on demand shooting the surgical operations accurately (the video camera can be placed on a separate arm alternatively). 'The lamp shape assures visual comfort and is particularly suitable for laminar flows in the operating room. All the functions of StarLED5 NX are managed by the handy, digital and easy-to-read I-Sense control panel positioned on the cardanic structure.'

www.acem.it

Acem is at Medica
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NEW: The medical grade 4K-native UHD Camera

A full 4K-ultra-high-definition camera designed to capture video of surgical operations is making its debut at Medica. Ikegami, its manufacturer, points out that the model is also ideal for attachment to microscopes or endoscopes.

This 4K-native camera incorporates a 4K-native 3840 x 2160 pixel CMOS optical sensor achieving a very high horizontal resolution

of 1800 TV lines, very much higher than that of 1920 x 1080 pixel HD cameras, the firm adds.

'Sensitivity is 2000 lux (at an aperture of f/5.6 and 3.2 K colour temperature), allowing effective image capture in a wide range of lighting conditions. UHD TV output can be provided as Quad3G to match customer requirements, including optional HDMI 2.0, 12G or IP output, pending confirmation of an established standard for UHD equipment connectivity.'

Images can be UHD and full HD, allowing use with existing HD monitors as well as UHD displays.

'An integral image correction function enables the camera to express high image resolution in detail,' Ikegami continues.

'Also included is a gradation correction function which delivers high contrast without over-exposure or black-crushing.'

'Structurally, the 4K-native camera consists of miniature head with integral optics. The head connects via cable to an Ikegami mains-powered camera control unit (CCU). The camera and CCU have an antibiotic coating to assist infection control. All major camera functions, plus the ability to record video and capture still images, can be controlled from the front panel of the CCU.'

'The CCU itself is based on the same control board as the established MKC-750UHD pixel-offset 3-CMOS medical grade camera, providing essentially a universal platform for future cameras in this product range,' the manufacturer explains.

* The new camera will be available in 2017.

www.ikegami.de/medical.html



Ikegami is at Medica
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Information is everywhere - Intelligence is another story

Inspired by management practices in the pharma industry and influenced by increasing concentration (mergers & acquisitions), managers at all levels in med-tech companies are heavily relying on robust data and insights for planning and decision-making, writes Natalie Christie, representing the Business Development section of TforG Group, which provides business intelligence (BI) and decision support to international med-tech businesses. 'Its unique focus is the medical devices and medical technology markets within a hospital context,' the company explains. 'In a world where information is readily and publicly available,' she writes, 'marketing directors, as well as product managers, develop their own business intelligence (BI) activity, enhanced by commercial platforms, reports and customised market research.'

'Market information is everywhere: Exhaustive healthcare mar-



Natalie Christie
ket information on almost everything (care providers, specialisms, products and innovations, companies, legislation and regulation, reimbursement, etc.) and is easily retrieved by search engines from articles, publicly available databanks, company websites and other sources.

'However, professionals heavily depend on the reliability and effectiveness of the information collected for the quality of their decisions. This is time consuming and most of the data found is irrelevant, or useless, or the value is hard to qualify; colleagues can end up with different data and

argue over which to use or, finally, the information retrieved is lost after use and invisible to the rest of the company. New market research med-tech solutions surface,' she points out. The good news is that new BI platforms are being developed and brought to the market, which assist these emerging BI needs and avoid the challenges mentioned above.

'They typically provide a single access point or a department, or firm; integration of proprietary data and better use of available data (internal/external) by modelling, algorithms, etc.; a selection of data relevant for a specific business segment and that supports typical decision processes, and finally, a format allowing an easy comparison of data between countries, segments, etc.' Med-tech firms can compile their personal 'MedTech BI dashboard' at tforG.com/mytools.

Natalie Christie is available at Medica: Phone: +32 3 201 64 25

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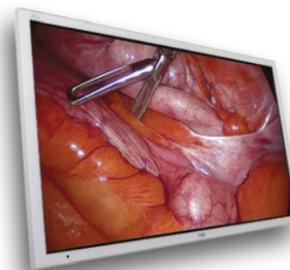
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The sustainable pathogen killer

Professor Peter Guggenbichler is only too aware of infection prevention and control issues in hospitals. Prior to his retirement in 2013, from the Children's Hospital at Erlangen

University Hospital, in Germany, he led the Infectiology and Preventive Medicine Department, for 25 years. 'After countless nights on the intensive care ward I realised that the staff

does not adhere to infection prevention and control guidelines because, realistically, these cannot be adhered to,' Guggenbichler explains.

According to the guidelines, nurses and doctors are supposed to disinfect their hands between 50 to 80 times during just one shift. After each fifth to sixth application of a disinfection agent they should also wash their hands because otherwise the hand disinfection agent merely spreads the dirt. According to the infection specialist this is not achievable: 'Staff would spend more than an hour per shift on hand disinfection, and in case of emergencies there is no time for this, anyway. This prompted me to think about alternatives and to precisely analyse the workflows in the hospital and on the intensive care ward.'

Every year around 5% of inpatients in Europe develop hospital acquired infections (HAIs). Of the 1.75 million patients affected, at least 10%, i.e. around 175,000 people, do not survive this (source: www.ESCMID 2015). The risk of nosocomial infections is therefore higher than the risk of being involved in a road traffic accident.

The staff's hands are contami-

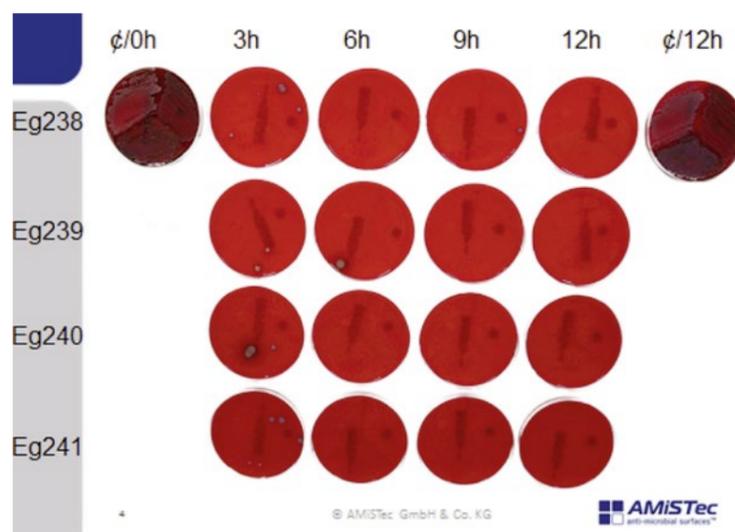


Figure 1: Results of effectiveness testing of *Staphylococcus aureus* (Sa), *Escherichia coli* (Ec) and *Pseudomonas aeruginosa* on hospital furniture with different additives and concentrations. The method used in the study was droplet application: application of 10^8 CFU/ml in 100 μ l. 238: zinc molybdate one percent, 239: molybdenum trioxide one percent, 240: zinc molybdate 0.5 %, 241: molybdenum trioxide 0.5 %. All microorganisms were destroyed within three hours.

nated but so are hospital surfaces, and pathogens and multi-resistant organisms are transmitted with every touch. Be it hospital furniture, touchpads, control knobs, cables, floors, computer keyboards or telephone receivers – as soon as something is touched it is no longer germ-free, even if previously disinfected. Surfaces that can kill pathogens would therefore be ideal – and this is exactly what Guggenbichler has worked on for years, initially with antibiotics and disinfection agents and, since the 1990s, also silver.

'In 1999 we developed an outstanding silver technology, which is still effective for external ventricle drainages for intracranial pressure, and is therefore still successful on the market. However, the most silver technologies do not work for the impregnation of surfaces because the pathogen-killing silver ions are used up after 3-5 weeks. As with disinfection agents and antibiotics, silver ions are incorporated into the metabolism of microorganisms, so they must be dissolved out of a hydrophilic surface and are then lost. This means that a number of silver technologies on sale is basically ineffective, and this is not being questioned enough.'

Guggenbichler and his team have now developed a technology which, with the help of various transition metal acids (mostly zinc molybdate in situ, i.e. the polymer itself), can generate H_3O^+ ions, reactive oxygen species and photocatalytic activ-

ity from tiny amounts of water, and this has a strong antibacterial effect on the surface. 'The basic assumption about the effective mode of action is that hydrating oxonium ions (H_3O^+)(OH) $_n$ ($n=1.3$) in contact with micro-organisms initially remove the hydration water and finally also the remaining water molecule. The now naked protons can attack the cell walls of bacteria in an unspecific way by permanently denaturing their protein shells and fimbriae. Additionally, the protons can block the effect of essential enzyme systems inside the cell. The entire process is known as proteolysis (coagulation necrosis),' the scientist explains.

The result is a slightly acidic surface, similar to the acid mantle of the skin, which, with a pH value of 4.2 – 4.5, quickly kills germs. Additionally, there is the positive zeta potential, i.e. a positively charged surface that attracts negatively charged micro-organisms, so that overall there is a synergistic effect. Zinc molybdate is neither water nor alcohol soluble, so cannot be removed by disinfectants. It is thermally stable and non-toxic. Both elements, molybdate and zinc, are essential trace elements in the body, which even if they should become dissolved, remain below the permitted threshold level for 24 hours by factor 250.

'Obviously nurses will have to continue washing and disinfecting their hands, but if they forget to do so once in a while the consequences will



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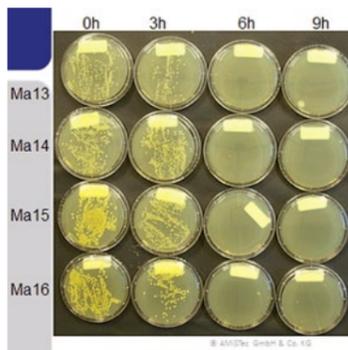


Figure 2: Results of effectiveness testing of lacquer sample with zinc molybdate 0.25 % using different technologies (Ma13 – Ma 15), contact plate method. Application of 10^7 CFU/ml in 10 μ l. Determination of bioburden with Rodac plates after 0, 3, 6, 9 hours. All microorganisms were destroyed within three hours

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The changing face of colposcopy

Simpler cervical intraepithelial neoplasia detection

ZedScan, a pioneering diagnostic system that is significantly impacting on the changing clinical pathway for cervical cancer, is being demonstrated at Medica by multi-award winning firm Zilico Ltd from the United Kingdom (UK).

This device is a handheld portable system that uses patented Electrical Impedance Spectroscopy (EIS) to detect the development of pre-cancerous cervical abnormalities, otherwise known as cervical intraepithelial neoplasia (CIN).

'The innovative system not only removes subjectivity and increases accuracy,' the manufacturer reports, 'it's also helping clinicians manage growing colposcopy referrals generated by the introduction of primary HPV testing.'

In a recent review of over 1,500 women referred to an NHS colposcopy clinic, adoption of ZedScan resulted in a significant increase in disease detection, equating to an additional 10,000 women being diagnosed across the UK annually.

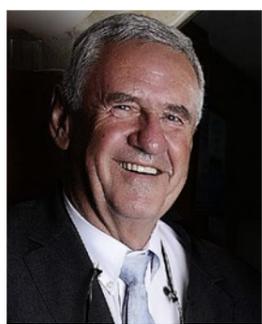
Performance was not impacted by hrHPV genotype with increased detection in both HPV16 and non 16 hr HPV positive women. The system is now used in several National Health



Zilico is at Medica
Hall 16 / Stand F18-5



Delivering greater care control over immobile, bariatric and ulcer patients



Professor Josef-Peter Guggenbichler studied medicine at the University of Innsbruck and qualified as a paediatrician at the Mayo Clinic, Rochester, Minnesota, USA. After his return to Austria he became a professor at the University of Innsbruck (1980-90) and then he worked as an extraordinary professor at the Department for Infectiology and Preventative Medicine at the Children's Hospital, University Hospital Erlangen, Germany (1990-2009). Guggenbichler holds more than 30 patents for the antimicrobial impregnation of surfaces and is cofounder and managing director of the start-up company AMISTec (www.amistec.at) founded in 2011.

be less dramatic. The new technology is a kind of safety valve: instead of disinfecting hands 60 times a day it can be done every 20-30 minutes instead, because the surfaces will remain self-disinfecting for many years.' To achieve this, there is no need to refurbish the entire hospital because the zinc molybdate can be applied retrospectively as a transparent film to telephone receivers, furniture and fittings etc. like any normal lacquer.

Guggenbichler already discovered this mode of action around ten years ago. But his discoveries really gathered pace since his retirement from the hospital and the foundation of the start-up company AMISTec, and patients will soon benefit from this.

Paints and lacquers for large medical devices are now ready for use. However, the possibilities go way beyond this; airline seats, car air conditioning systems, shower trays and even underwater power cables will soon be self-disinfecting. We can only hope that hospitals will not miss the boat. With the rapid increase of multi-resistant pathogens and talk of the post-antibiotic era, there is an urgent need for action in the prevention of infection.

Details: www.krankenhaushygiene.de/informationen/hygiene-tipp/hygienetipp2015/557

Lessening nurses' physical work and patients' potential bed sores

UK's pioneering pressure mattress solutions

The bed – such a vital part of patient care and a nurse's tasks. Good sleep hastens recovery. Bedsores do not; they also add significantly the healthcare costs, not to mention patients' despair. Rober, a company in the United

Kingdom, is pioneering the development and manufacture of mattresses with 'zero pressure' technology, having invested heavily in R&D in the last few years. The result is a complete range of pressure ulcer mattresses that cater

for various needs, including those of patients who are immobile, bariatric or have existing pressure injuries.

'Developed in conjunction with clinicians, the mattresses feature clinically proven technology that prevents pressure injuries from developing. They also have therapeutic properties that promote the healing of established ulcers,' Rober reports. The fully automatic mattresses mean that patients nursed upon them need less frequent

manual repositioning, thus relieving nurses' physical strain.

'Rober's mattresses, overlays and cushions have been developed to replicate the body's natural movements by responding to a patient's weight, spontaneous movement pattern and body position,' explained Mike Hutson, Chief Executive of Rober. 'They provide enhanced comfort and complete pressure elimination at regular intervals.'

Details: www.roberlimited.com.

Rober is at Medica Hall 16 / Stand G20-2



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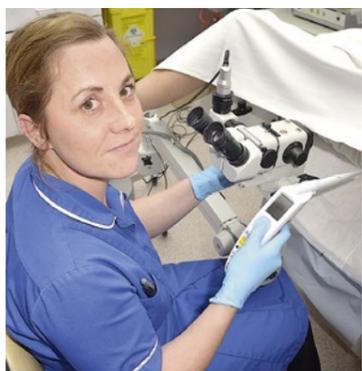
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Conjugation technology improves signal intensity

Lateral flow immunoassays

BBI Solutions has developed a novel conjugation technology, Morffi, with the potential to enhance – up to 10 times – the sensitivity of lateral flow immunoassays

Lateral flow immunoassays (LFIs) rely on the specific interaction between the analyte of interest and an immobilised binding partner (antibody, antigen or enzyme). To improve performance, an agent (most commonly used: BSA) is bound to unoccupied conjugation sites on the reporter label, preventing non-specific binding. BSA causes cross-reaction issues

with human, bovine and other animal-origin targets and also exhibits significant lot-to-lot variability. Its large size can also lead to steric hindrance, further affecting the detection of the target molecule.

BBI Solutions, manufacturer of biological reagents and finished test platforms for the in vitro diagnostics, recently launched Morffi technology,



**BBI is at Medica
Hall 01 / Stand F26**

which can overcome these issues without further adjustments to conjugate manufacturing parameters. This proprietary technology can be used to improve the availability of analyte-specific binding partners on the surface of the label. This increases signal intensity for LFIs by reducing non-specific binding and steric hindrance, enhancing sensitivity by an order of magnitude compared to traditional techniques.

Morffi technology has been successfully tested with over 30 conjugates to date, and its benefits are highlighted in the BBI Solutions whitepaper 'Morffi: Enhanced performance of a lateral flow assay' (Morgan West, Ffion Walters, Shaun Phillips and Darren Rowles; Enhanced performance of a lateral flow assay. Use of a novel conjugate blocking technology to improve performance of a gold nanoparticle-based lateral flow assay).

This paper uses a 40 nm gold nanoparticle reporter label in a model assay system to detect brain natriuretic peptide (BNP), and the results clearly demonstrate the performance of the patent pending Morffi technology. It offers a significant improvement in signal intensity over the BSA conjugate for the BNP assay system, visually discernible at high antigen concentrations, which leads to a 10-fold enhancement in the limit of detection.

These findings support the potential of this technology to dramatically improve the performance of a wide range of LFIs, and the company is already working with a number of partners to introduce Morffi assays to the market.

BBI is currently scheduling feasibility studies for January 2017.

Details: www.bbisolutions.com



The fully automated formalin mixing station

Histo-paths gain a new

It's the second day of MEDICA 2016 and thousands of visitors have visited the World Forum for Medicine. Not to miss is the newly launched fully automated formalin mixing station AFDS-100, from German firm Kugel medical, a leading supplier of histo-pathology equipment.

The reclassification of formaldehyde is frequently discussed within all industries. In this connection, not only maximum concentration values at the workplace for work involving formalin, but also sustainable reduction of formalin concentration in working environments, play an important role.

The formalin mixing station AFDS-100 is designed for easy and reliable preparation of formalin solutions in laboratories with the aim to reduce formalin concentration in pathologies, since employees do not come into contact with 37% formalin stock solution. Thanks to its compact design, the mixing station is also suitable for small laboratories. All operations, such as preparing a 3.7% standard formalin solution or a customised solution with variable quantities of formalin, water and a buffer solution, are controlled through one single surface with a LCD display at the device. After entering the desired mixing ratio according to the menu, the liquids are pumped into the tank. Subsequently these liquids are mixed for 15 minutes. The prepared mixture can be drained directly from a tap at the device, or transferred to a multiple remote station that can be up to 200 metres away. Additionally,



**Kugel Medical is at
Hall 03 / Stand E5**

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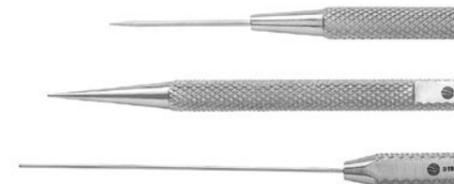
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Sterile simulators and dilators are



Over in Hall 16, leading single-use instrument manufacturer DTR Medical is demonstrating its latest innovations such as the double-ended Punctum Dilator in its ophthalmic range, which is designed with a round knurled handle for better grip. 'Its 17mm and 21mm tapered ends allow for increased range of dilation to offer added flexibility,' the firm adds.

In addition, the new Punctum Seeker features a sharp tip to ensure high performance when locating the Lacrimal Punctum. 'Expanding this product line are double-ended Lacrimal Probes, available with two size options for adaptability during procedures,' DTR reports. 'Their thin



**DTR Medical is at
Hall 16 / Stand F4**

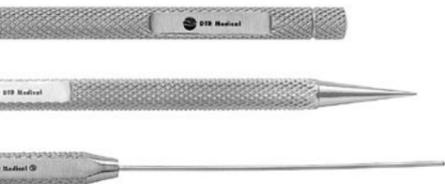
Pathologists New tool



the remaining solution is blended automatically six times a day, for 15 minutes. Electronic and mechanical safety precautions keep liquids from overflowing within the tank to guarantee the utmost safety for laboratory staff. 'On the technical side, exhaust and ventilation technology has never been more important than now, especially energy recovery and filtration of pollutants play a main role, which is why we always design our products from our customers point of view,' explains Robert Karl, Kugel medical's CEO.

The company is at Medica demonstrating that the fully automated formalin mixing station AFDS-100 has a lot more to offer. www.kugel-medical.de

Single-use and probes



wire, with rounded ends, allows the surgeon to effectively clear the passageway to the tear duct.'

Established for over a decade ago, the firm adds that its collaboration with clinicians and academics at leading hospitals worldwide has enabled it to develop innovative sterile single-use alternatives to re-usable instruments. The benefits include time saving, plus reduction in patient risk and cost reduction.

A full range of new products is on show for ENT/MAXFAX, general surgery, gynaecology, neurosurgical, ophthalmic and orthopaedic instruments.

Details: www.dtrmedical.com

Call to re-evaluate sepsis screening tool

Expert declares updated criteria for sepsis identification is not early enough. **Mélanie Rouger reports**

New criteria used as an initial screening tool in the emergency department need to be re-evaluated, a specialised surgeon will highlight in a dedicated talk during the Spanish national congress of surgery this November.

In Spain sepsis affects 50,000 people and is responsible for 17,000 deaths each year (The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016 Feb 23;315(8):801-10).

Early detection of infection, before patients must be admitted to intensive care, is essential to trigger appropriate treatment and improve outcome.

A commonly used strategy among doctors to identify a suspected infection and evaluate severity has been to use criteria defined by experts. The Systemic inflammatory response syndrome (SIRS) criteria, which rely on the degree of hypoperfusion and inflammatory response to determine the presence and degree of the infection, have long served as a reference in clinical practice and research. However, many practitioners have insisted the SIRS are not sensitive and specific enough. In fact, the controversy over these old criteria pushed the international consensus responsible for setting sepsis criteria to issue new measures earlier this year.

These experts updated the definitions by putting the focus on low blood pressure, high respiratory rate and altered mentation as means to recognise sepsis and septic shock for patients inside and outside the ICU.

The new criteria have been named the qSOFA (Quick SOFA Score), and many thought they would help gain time in patient management.

However, the authors of a more recent study have concluded that the qSOFA does not help to evaluate patients in the Emergency Department who are not yet in need of critical care (qSOFA, SIRS, and Early Warning Scores for Detecting Clinical Deterioration in Infected Patients Outside the ICU. Churpek, Snyder, Han, Sokol, Pettit, Howell, Edelson).

Thus things are back to square one and there hasn't been much progress in speeding the identification of effective criteria for early diagnosis, Dr Ines Rubio-Perez from La Paz Hospital in Madrid, explained. 'The change of parameters was meant to improve everything. But, according to the new study, the qSOFA are not that good in diagnosing patients on time; actually if you have to monitor altered mentation it means it's a little late already,' she said. 'qSOFA detect mortality very well but they are not early criteria. So

there's not much difference between the old and the new, and many people are discussing the utility of these criteria in the emergency setting.'

Rubio-Perez, a colorectal surgeon with special interest in surgical infections, will join a symposium on intra abdominal infection diagnosis and treatment update during the meeting. In her opinion the absence of a gold standard in sepsis management is due to the complexity of the disease. 'What happened again with the Sepsis 3 consensus is that things don't work as well in practice as in theory. Sepsis is a complex process and it's complicated to define uniform standards. We still need to revise our criteria, or make a combination between the SIRS, the qSOFA or other scores.'

To speed things up, Madrid hospitals started the Code Sepsis initiative, similar to Code Stroke, and in which healthcare members are put on alert in case of suspected sepsis to trigger the appropriate chain of action.

'Initiatives like the Surviving Sepsis campaign and Code Sepsis can offer simple pathways and identification systems to diagnose patients with sepsis early. This must be an institutional and multidisciplinary effort. A few other regions in Spain have done the same with successful results,' Rubio-Perez pointed out. Sepsis is a common scenario in abdominal emergencies, for instance in peritonitis or appendicitis, and treatment relies on antibiotic and surgical therapy.

Besides finding the appropriate diagnostic criteria, the other challenge in sepsis management is antibiotic resistance. 'A patient presenting with an infection due to multi-resistant bacteria may not respond to usual treatment, as the initial antibiotic may not cover appropriately. This significantly increases morbimortality.'

Rubio-Perez, PhD was on the topic, suggests looking at risk factors, such as previous antibiotic intake, or recent hospitalisation, prolonged stay in long-term care, or residential home, a daily hospital visit for dialysis, and other clinical factors, including diabetes, immune suppression, repeated urinary tract infection, etc. 'Having suffered a previous super resistant bacterial infection, i.e. being a carrier, augments risk for a patient to present with a clinical infection,' she added.

Complications increase in post-surgery patients who develop a nosocomial infection. Treatment may be only one or two antibiotics, because of resistance, and this may also substantially augment morbidity.



After completing her residency in general surgery in 2012 at Princesa Hospital in Madrid, **Ines Rubio-Perez MD** became

a staff surgeon in the colorectal surgery unit at La Paz University Hospital. Her research activities include the study of clinical profiles and risk factors of multi-resistant infections in surgical patients – the subject of her PhD thesis in 2015. She is a member of the board of the Surgical Infections Section in the Spanish Surgical Association (AEC), and Councillor and Educational Committee member of the Surgical Infection Society - Europe (SIS-E), where she strives to involve surgeons in the knowledge and importance of infections.

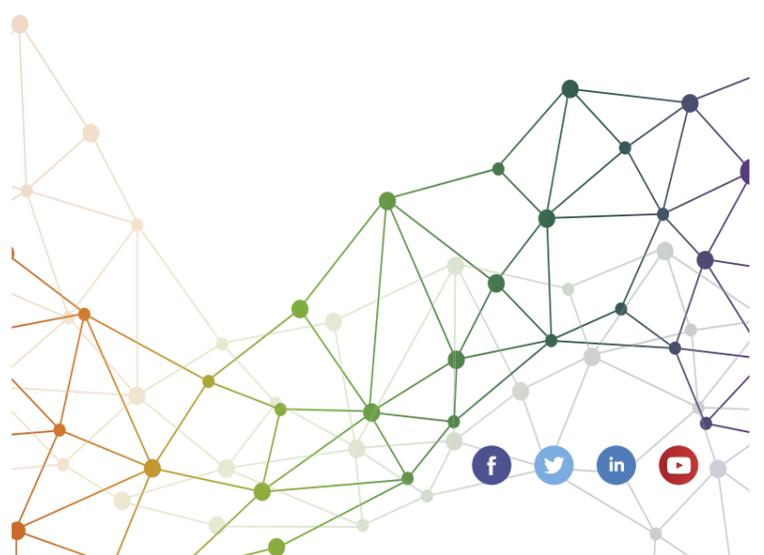


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Heraeus Medical: Understanding biofilms

Anti-biofilm strategies

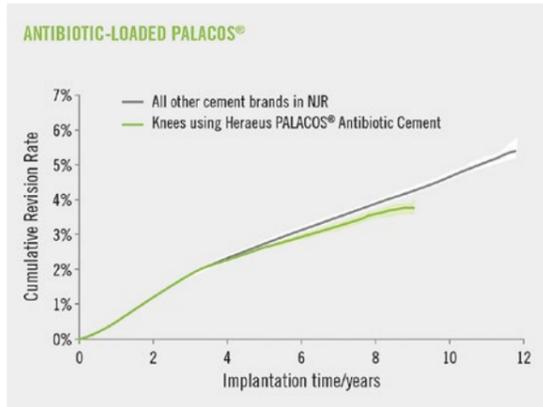
The association of biofilms with multi-drug resistance has highlighted the need for further understanding of biofilms and for anti-biofilm strategies. This September, in a satellite symposium sponsored by Heraeus Medical, manufacturer of products for orthopaedic surgery and traumatology, at the 35th Annual meeting of the European Bone and Joint Infection Society, in Oxford, the latest knowledge of biofilms and local methods of overcoming the challenge of infection was discussed.

Biofilm-related implant malfunction

In orthopaedics, bacteria may colonise a surface for months or years but remain undetected until they trigger an immune response and signs of infection. During this time, there may be low-grade infection, and symptoms such as persistent pain, stiffness, lack of range-of-movement, fibrosis, 'aseptic' implant loosening and non-union of fractures.

Biofilms and multi-drug resistance

A mature biofilm can form within



Among all cement brands in the NJR Palacos R+G is superior

24 hours of contact with an implant and can even penetrate the surface of titanium. As the biofilm matrix is more abundant than the bacteria themselves, the biofilm must be disrupted in order to expose the bacteria to antimicrobial agents.

Multi-drug resistance may also be related to biofilm formation, for example, methicillin-resistant *Staphylococcus aureus* (MRSA) produces more biofilm than methicillin-susceptible *S. aureus* (MSSA), and

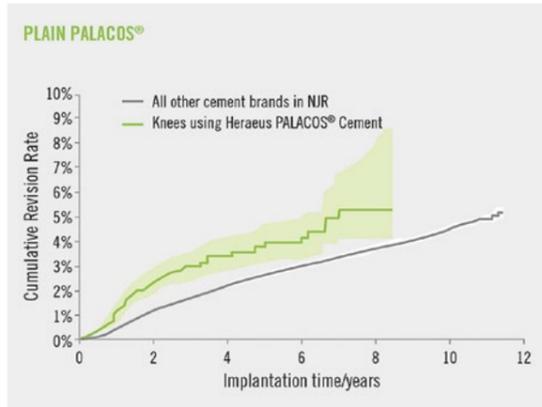
therefore biofilms may magnify the cost, suffering and mortality associated with antibiotic resistance.

Superior outcome in hip and knee arthroplasty

In addition to the well-documented benefit of bone cements such as Palacos R+G in total hip replacement (THR), registry data was presented showing that significantly fewer revisions are required when that bone cement was used in total knee replacement surgery, compared to all other bone cements (Data on file. National Joint Registry (NJR, www.njrcentre.org.uk) data licensed to Heraeus Medical GmbH, Wehrheim). Palacos R+G with gentamicin also significantly outperforms plain Palacos.

Significant reduction of surgical site infections (SSIs)

It is particularly important to optimise strategies for reducing peri-prosthetic joint infections (PJIs) in high risk patients, but which bone cement best overcomes the current challenges in PJI prevention? A quasi-randomised, double blind study was carried out, comparing the two bone cements, Palacos R+G and Copal G+C, in



patients requiring haemi-arthroplasty for a fractured neck of femur. There was a significant reduction in both deep and superficial SSIs with Copal G+C compared with Palacos R+G (Tyas B, Marsh M, Molyneux C. et al. Abstract 59 presented at the Oxford meeting) explained by the previously-observed high antibiotic concentrations in wound fluid.

Extrapolating the reduction in infection rates to the entire UK hip haemi-arthroplasty population would lead to healthcare savings of over £4 million.

Dual antibiotic-loaded cement does not affect antibiotic resistance profiles

A concern regarding the use of antibiotic loaded bone cements is whether they cause antibiotic resistance. The study reported no significant differences in resistance between Palacos R+G and Copal G+C. The only cases of resistance with Copal G+C were to gentamicin and clindamycin, which is as expected.

Resistance to other standard antibiotics remained low. Furthermore, Copal G+C completely eradicated infection caused by *Corynebacterium* species and *S. aureus*.
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Strapless vaginal v

Over in Hall 16, Pelican Feminine Healthcare, a leading UK manufacturer of single-use medical devices for women's health, is demonstrating the FETOfit, a strapless foetal monitoring solution and PELIspec Pro-Wall, a vaginal speculum designed to offer added vaginal wall support.

'Simple, secure and strapless, the FETOfit is a disposable device specifically designed to secure TOCO and CTG transducers quickly and easily for foetal monitoring,' the firm explains. 'Both products offer cost effective but high quality, single-use solutions. Developed in conjunction with specialist clinicians, Pelican's market-leading innovations are manufactured to the highest quality standards. This is reinforced by stringent monitoring processes, with over 15,000 quality control checks performed annually and across our product range.'

Export Manager, Michael Denver, commented the firm's single-use products are becoming the choice for health services and professionals worldwide. 'We are keen to build on this success, especially in Latin America, and Medica is the perfect platform to appoint new partners and develop existing relationships.'

Details: www.pelicanfh.co.uk

Pelican Feminine
Hall 16 / Stand F4

Augmenting diabetics' POC

Point-of-care HbA1c analysers at Medica 2016

Today at Medica: EKF Diagnostics is previewing the new connectivity solution for the firm's range of Point-of-care HbA1c analysers. 'Quo-Test and Quo-Lab now come with a connectivity package including a connector interface box, cables and a software upgrade, allowing the analysers to transmit patient data to the majority of Lab Information Management Systems (LIMS) or Hospital Information Systems (HIS) in use today,' the company reports.

'The connectivity package uses the POCT1-A2 communication protocol and the in-house designed Connector Interface Box to create bidirectional communication between a multitude of Lab

Information Management Systems and the Quo systems. Unlike many closed proprietary data management systems, the EKF Diagnostics connectivity solution is open, allowing for easy and simple connection to whatever system the clinic is currently using.'

As well as using the industry standard POCT1-A2 communication protocol, the connectivity solution also unlocks a host of new features aimed at improving security and quality control.

For the first time, an increased amount of demographic information can be recorded, including full patient name, date of birth, patient ID numbers and additional results

commentary, using either the standard product barcode scanner, or new keyboard accessory. This additional demographic information enables the patient and his/her results to be linked and traced throughout the whole healthcare system.

'Operator IDs can now be added to each test result, significantly improving the traceability and security applied to every HbA1c reading. A controlled list of trained operators assures that only those with sufficient competency have access to the system to start taking measurements,' the company points out. 'This new feature takes away the risk that an untrained operator can access the system, or even review patient results, unless they have the proper and correct security level.

Enhanced quality control is now also possible with multiple user-defined QC lockout options available to POCT coordinators, ensuring that tests can only be run according to whatever quality assurance procedure is needed. EKF:

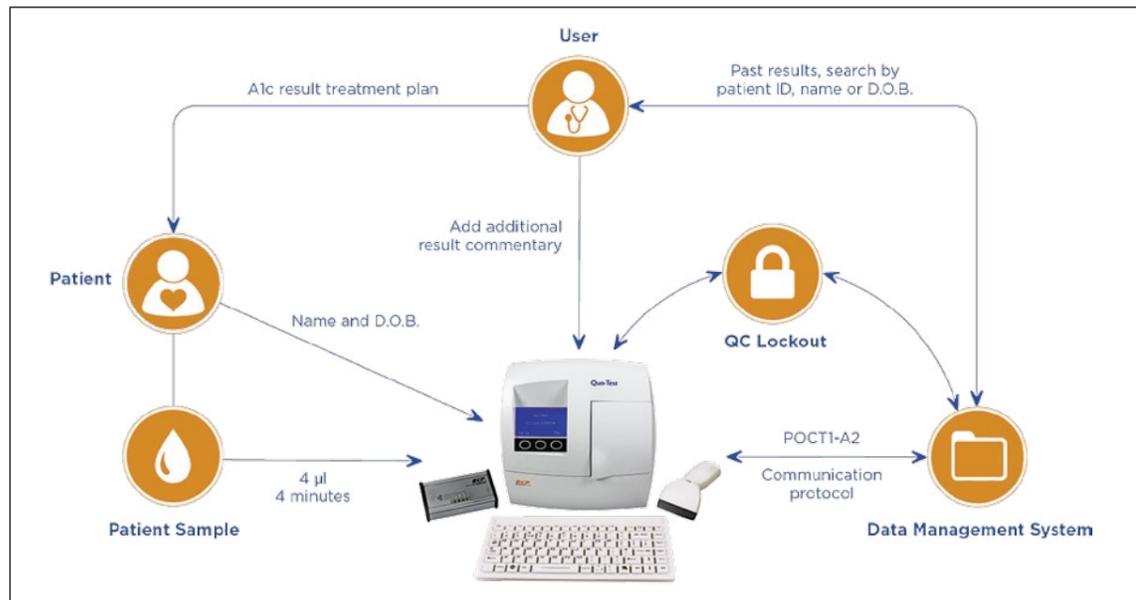
'Even more traceability is possible because consumables and quality controls can now be added to an

approval list, meaning only those products that have passed incoming inspection are used.'

These new connectivity solutions take Quo-Test and Quo-Lab to the next level in POC patient management and the firm reports 'It will help EKF to further its aim of making POC diabetes patient management more accessible and also more robust.'

Details: www.hba1c-test.com

EKF Diagnostics is at Medica Hall 03 / Stand C70



Make the connection



Connectivity now available on Quo-Test and Quo-Lab A1c analysers.

The world's easiest to use HbA1c analysers just got even better.

Quo-Test and Quo-Lab from EKF Diagnostics now come with POCT1-A2 connectivity, QC and user ID lockout as standard.

Make your connection today:

hba1c-test.com
 +44 (0)2920 710 570
connect@ekfdiagnostics.com

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