EUROPEAN HOSPITAL @ MEDICA

SPECIAL NEWS ISSUE: MEDICAL | TECHNICAL | PHARMACEUTICAL | INDUSTRIAL

13-16 NOVEMBER 2023

State of the art and latest advances in technology

Robotics in the operating theatre

Modern surgery has come a long way in the past decades, thanks to improved techniques, tools and medical equipment. However, traditional surgery still has some limitations, including accuracy as well as fatigue and hand tremors in surgeons, which can impact the quality of procedures.

These limitations have led to the emergence of robot-assisted surgery, which has dramatically increased the accuracy of surgical procedures while reducing hospitalisation times and postoperative complications. Surgical robots have been designed for use in a wide variety of surgical procedures across multiple fields, including cardiology, gynaecology, and urology.

The latter has seen an especially pronounced surge in robotic use; while in 2008, only 1.5% of urology surgery was performed with robot assistance, this has skyrocketed to over 43% today, according to various hospital sources. In total, some 1.5 million surgical procedures are performed worldwide using surgical robots. The advantages of this are manifold, including access to difficult areas through the use of slender, flexible robotic arms and on-board cameras, stable navigation of surgical instruments, significant reductions in operating times and hospital stays, as well as a reduction in postoperative complications (bleeding, infections, etc.).

The procedures that have benefited most from surgical robotics include prostate removal and renal ureter repair, gastrectomy, cholecystectomy and colectomy, plus heart valve surgery and coronary bypass surgery, along with total hip and knee replacements. This is a burgeoning market expected to be worth $14.9 billion by 2028.

Top five manufacturers

The top five surgical robot manufacturers by market share in 2020 were Intuitive Surgical, Stryker, Medtronic, Zimmer Biomet, and Smith & Nephew. Intuitive Surgical supplies four robots for urology, ENT, abdominal and gynaecology surgery – the Da Vinci and Ion platforms. These have a market share of more than 69% between them. Stryker has the Malo platform, with a motorised arm holding cutting instruments (oscillating saw, acetabular burr) linked to an infrared stereoscopic system for partial knee replacement surgery. Medtronic has developed two systems: a semi-automatic navigation assistant named the Mazor X Stealth Station, for rectifying spinal deformity, and the Hugo RAS multi-port remote guidance system. Zimmer Biomet markets a semi-automatic navigation assistant for partial and total knee replacement, its Rosa Knee robot. Finally, Smith & Nephew has the Navio FPS platform, a manual navigation assistant using a handpiece combined with an optical navigation system designed for partial and total knee arthroplasty.

Guide for automation options

Faced with the emergence of numerous surgical robots, the biomedical and equipment department at Geneva University Hospitals in Switzerland, together with the Swiss Foundation for Innovation and Training, have published a guide listing and classifying all automation and assistance technology options for surgical gestures. 'The process of choosing and introducing these high-tech systems into the complex environment of the hospital must be subject to a structured and complete methodological approach,' explains Hervé Jacquemoud. His team distinguishes between guidance assistants, laparoscopy devices and telesurgery systems. The number of knee replacement procedures in OECD countries is expected to increase from 2.4 million procedures today to 5.7 million by 2030. 'Currently, 95% of procedures are performed with no robotic assistance and with a very high patient dissatisfaction rate of more than 20%,' observes Sophie Cahen, co-founder and CEO of Ganymed robotics. Her med-tech company, based in Paris, France, has been selected by the EU for inclusion in a project which hopes to develop a compact robot to make joint replacement surgery more precise and less invasive. The initial focus is on total knee replacement, though Ganymed is looking to expand this to other joints including the shoulder, ankle and hip. 'We aim to offer the first compact, ergonomic, intuitive and cost-effective robotic device,' says Cahen. This next generation of robot introduces computer vision-driven intelligence and perception into the operating theatre, allowing contactless localisation of the patient's anatomy and opening the way to data-driven operating theatres.

Microsure, based in Eindhoven, the Netherlands, is a spin-off from Eindhoven University of Technology (TU/e), and has developed the world's first clinically available CE-marked microsurgery robot. The Meet MUSA project, funded by the EU to the tune of more than €2.6 million, will tackle the obstacles to successful product roll-out, including scaling up and optimising manufacture. Mechanics, electronics engineers, software developers and control engineers at Microsure have designed a system where surgeons look through 3D glasses at a large screen connected to a digital microscope positioned above the patient. The movements made by the surgeon using joysticks are detected and transformed into highly accurate movement of the small, lightweight robot attached to a platform fitted with arms able to hold and manipulate microsurgical instruments. 'Given this large unmet need in microsurgery, we are convinced that the time is right to launch MUSA on the market,' said Sjaak Deckers, CEO of Microsure. The company will introduce MUSA across Europe by 2029, confident that it will achieve major social and economic impact. ■

MUSA, the world's first clinically available CE marked microsurgery robot.
© Microsure BV

Report: Bernard Banga

When *Sterility* is Indicated...

There's Only *One* Choice:

Sterile Aquasonic® 100 Ultrasound Transmission Gel.

The World Standard for sterile ultrasound transmission.

- **Easy-to-open *Tyvek® overwrap**
  Guarantees sterility of the inner foil pouch and the gel within
- **Consistent quality**
  Aqueous, non-staining
- **Acoustically correct**
- **Non-injurious to transducers**
- **Available in 20 gram overwrapped foil pouches, 48 sterile pouches per box**

Visit booth #9D41 Medica 2023

*Trademark of Dupont®

ISO 13485:2016

PARKER Parker Laboratories, Inc.

The sound choice in patient care.™ 973.276.9500 parkerlabs.com

© 2018 Parker Laboratories, Inc. The sound choice in patient care is a trademark of Parker Laboratories, Inc. MKT-0101-2 REV 3

Experts outline European infrastructure

AI in health imaging: computational power isn't everything

What will the future structure for artificial intelligence in health imaging across Europe look like? While the algorithms show great promise in collecting, storing, analysing, and using data to advance healthcare, delegates to a session on the topic at ECR 2023 in Vienna also heard that it was important for the use of AI to move from research and more toward practical applications for patients.

Dr Nikolaos Papanikolaou from the Champalimaud Research Foundation in Lisbon, Portugal, looked at the basic concepts of AI and radiomics, the challenges in a multi-centric setting, and on best practices to increase translation from research to clinic. He discussed the ProCancer-I project, an AI platform integrating imaging data and models, supporting precision care for prostate cancer. The major challenges in AI/radiomics include a lack of standardisation in image representation in the data and that radiomics features are highly sensitive to variations in image acquisition, he said.

While access to increased computational power is crucial, he also stressed the importance of the availability and accessibility to well curated high-quality data. He pointed out that medical images often non-harmonized, inconsistent, and heavily dependent on the way they have been acquired.

Intent on clinical translation

Papanikolaou said inconsistencies in feature extraction may deliver unreliable and non-reproducible results. This challenge should be addressed by applying harmonization methods, with AI models exposed to real world big data to learn invariant features. 'But at the end of the day, the AI should not be only a research exercise – it should be developed towards an intention to be applied in the clinics,' he said.

Areas of validity, usability and utility need to be 'seriously addressed' to convince people to start translating the technology into the clinic, he urged. 'We need to prospectively, and consecutively, validate AI models into the clinical environment and organise randomised controlled clinical trials to document the impact on the clinical outcomes and to assess cost effectiveness.'

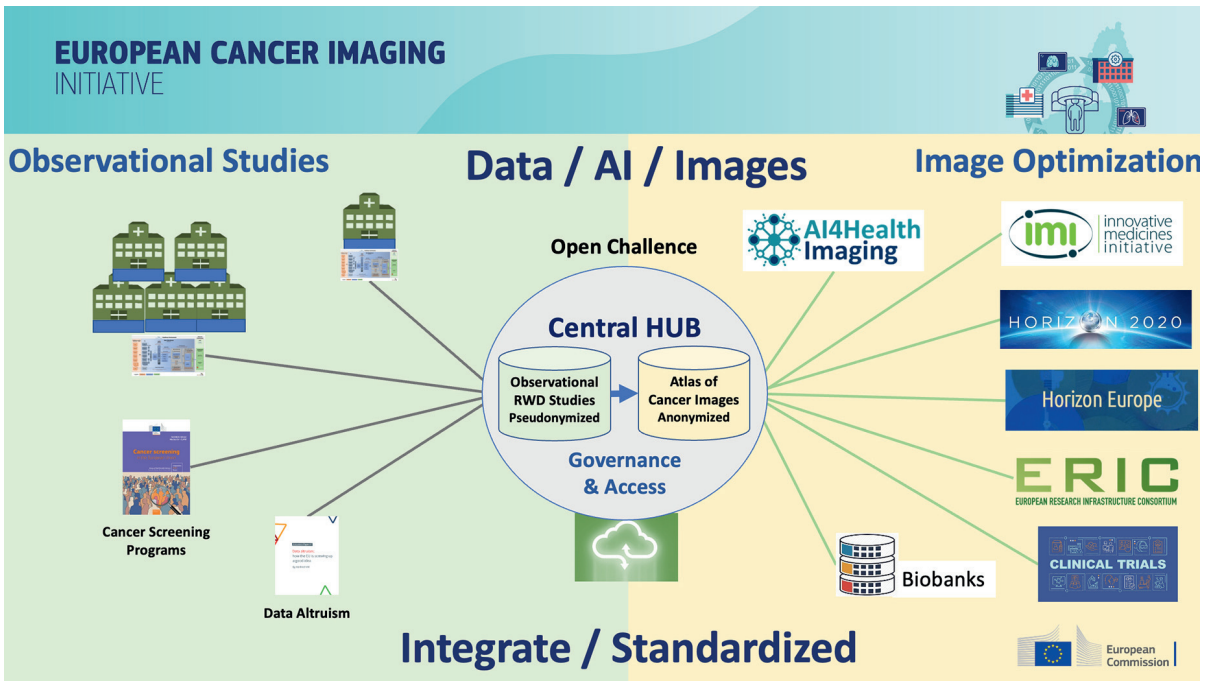
From fragmented to harmonized and structured data

Professor Luis Martí-Bonmatí, who co-chaired the session with Gabriel Krestin from Rotterdam, presented details and the goals of the EUCAIM (EUropean federation for CAncer IMages) project, which supports researchers to perform research on data. He looked at how fragmented health data silos can be linked and efforts made towards distributed big data harmonization and structure, while offering an appreciation of how federated learning can be used to construct clinical prediction models. While there are opportunities for precision imaging and cancer, he also addressed the challenges: 'Images are highly variable and data from Electronic Health Records is mainly non-structured and difficult to extract,' said Martí-Bonmatí, who is EUCAIM's Scientific Director.

Addressing the "innovation chasm"

'We need a state-of-the-art platform for AI imaging to beat cancer but there is an innovation chasm,' he said. To address this, EUCAIM aims to deploy a pan-European federated infrastructure to power up AI imaging to beat cancer; provide a research platform to develop and benchmark AI tools toward precision medicine; address the fragmentation of existing cancer imaging repositories; create a federated data warehouse approach to allow the construction of observational studies and populate a central repository; and allow the construction of observational studies. There is also the need to develop and foster standardization and harmonization tool via AI, the expert concluded.

Several other projects were also discussed during the session. Martin Starmans from the University Medical Center in Rotterdam, the Netherlands, discussed the "EuCanImage" project and looked at the role of the platform for streamlining European AI research in cancer imaging from data to deployment, with a focus on liver, colorectal and breast cancers 'to address real-world unmet clinical needs.'



With the CHAIMELEON project, Professor Ignacio Blanquer from the Technical University of Valencia, Spain, talked about the concept of in-situ access to data and examined the pros and cons of centralised repository models on harmonized images from patients with breast, lung, colorectal and prostate tumours.

Delegates also were presented details on the INCISIVE project, which looks at ongoing research efforts for developing AI services for decision-support of clinical experts. Senior analyst and INCISIVE co-ordinator Gianna Tsakou underlined the importance of imaging and clinical data sharing, while acknowledging the benefits and hurdles of health data sharing and the role of clinical experts in this process.

In a further presentation, Angel Alberich-Bayarri from Quibim, Valencia, outlined the PRIMAGE project with a specific focus on the architecture of an imaging platform for a paediatric cancer imaging biobank. ■

Report: Mark Nicholls

DON'T MISS!

Connected Healthcare Forum

MONDAY

Connected Medical Things
- Advancing future healthcare with IoT technologies

15th Healthcare Innovation World Cup
- pitch and award ceremony

Alternative Care Delivery Models
- Balancing at-home technology, outpatient and clinical healthcare

Mobile Health
- Improving healthcare at home and at the point of care

TUESDAY

Robotics
- Advancing surgeries, rehabilitation and processes to the next level

Healthcare Accelerators
- Scaling up future health innovations

AI, Big Data & Machine Learning
- Thriving, surviving and discovery in the data age

12th MEDICA Start-Up Competition
- pitch and award ceremony

WEDNESDAY

Sustainability in Healthcare
- Creating green healthcare initiatives for a positive impact on the environment

Brain, Mental Health and Neuroscience
- Understanding the brain and mental health

Health Metaverse
- Creating the future of immersive healthcare through AR/VR, digital twins and more

Future of Therapy
- Managing diseases with therapeuticals and new treatment approaches

THURSDAY

Diagnostics and Health Monitoring
- Pushing the frontiers of diagnostics

Future Hospitals and Care Centers
- Advancing outpatient and clinical processes and experiences

Health Start-Up Innovation Hubs I
- 15 Start-ups from Taiwan

Health Start-Up Innovation Hubs II
- Digital health hubs in Germany

MEDICA Start-Up Park
- Accelerating the future of digital health

Hall 12 / E37

How to bring about better patient outcomes with health data

Propelling innovation in healthcare with the help of health data spaces

Every year on January 28, "Data Protection Day," as it is called in Europe, or "Privacy Day," as it is called outside Europe, is celebrated. It marks the date on which the Council of Europe's data protection convention, known as "Convention 108" was opened for signature back in 1981. According to the Council of Europe, it is the 'only international, multilateral and legally binding instrument to protect privacy and personal data'.

The protection of personal data is a particularly sensitive issue in the healthcare field and has impeded to some extent the process of digitisation as well as the more widespread use of the generated healthcare data. Nevertheless, digitisation has been beneficial in streamlining workflows and facilitating the emergence of new processes to cure and prevent illnesses as well as in engaging with patients. The Covid-19 pandemic has only accelerated digitisation efforts, with especially telemedicine seeing a significant increase in acceptance.

Health data as a source for better patient outcomes

The generated health data is used for various purposes that ultimately serve to improve patient outcomes, ranging from patient management, product development, patient safety measures, quality control to research and innovation. However, there needs to be an understanding regarding the management of the healthcare data and which principles should be guiding its primary and secondary usage. Primary use includes patients having access to and control over their electronic health record (EHR) data along with health professionals being able to access their patients' data. Secondary data usage entails the reuse of patient data for regulatory, policy-making and statistical purposes as well as research.

The use of healthcare data also entails the challenge of how to protect individuals' data. The major legal framework for the protection of personal data, including healthcare data of natural persons in Europe, is the General Data Protection Regulation (GDPR). It safeguards the processing of natural persons' personal data as well as its free movement.

Driving innovation whilst striking a balance between data privacy and the overall health of a population

Overall, patients look for innovation to maximise patient outcome. This can be in the form of increased safety, a stronger relationship with care givers, enhanced self-care strategies or better adherence to therapeutic treatments, amongst others. The analysis of health data, especially with the use of artificial intelligence (AI), is central to achieve this. However, striking the balance between driving health outcomes via research based on the analysis of heath data and at the same time avoiding associated data protection risks can often be heavily skewed toward avoiding risks in the first place and, therefore decreasing the chances of gaining new insights. To enable this balancing act, the idea of a European Health Data Space (EHDS) was born.

The European Health Data Space

First presented in March 2022, the European Health Data Space is designed to leverage the potential of health data by supporting the use of primary and secondary health data. To achieve this, a newly created access organisation is to decide upon the eligibility of third parties to use the data.

The EHDS will provide a trustworthy setting for secure access to and processing of a wide range of health data and builds further on the GDPR, the proposed Data Governance Act and the Network and Information Systems Directive. At the core lies the exchange of health data between patients and health professionals across member states of the European Union (EU). It establishes a common governance framework across EU states that combines rules, standards, practices, and infrastructures. However, it will also need the definition of strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.

Some of its services are already operational in some places and the rest will be implemented progressively across member states until the end of 2025.

Benefits of the European Health Data Space

The EHDS comes with a list of benefits for the various stakeholders involved. They range from ensuring that health data follows people to promoting a genuine single market for digital health services and products.

Individuals can immediately access their health data from their EHR and share it with healthcare professionals nationally and internationally. Researchers, industry or public institutions will have access to large amounts of health data of higher quality and only for specific purposes that benefit individuals and society. They may only access data that does not reveal the identity of the individual, whereby the data may only be accessed and processed in closed, secure environments. The EHDS will benefit the healthcare professionals as they have faster access to patients' EHRs and easier access to health records from different systems, which significantly reduces the administrative burden.

Regulators and policymakers will also have easier, more transparent and less costly access to non-identifiable health data for the benefit of public health, the overall functioning of healthcare systems and to ensure patient safety. The data will be held in a common European format.

One example of an EHDS is the newly created Health Outcome Observatory (H2O). It is the first European network that aims to create a 'robust data governance and infrastructure model to collect and incorporate patient outcomes at scale into healthcare decision making at an individual and population level'. Its concept is firmly built on the coexistence of primary and secondary usage of health data. H2O brings together 24 partners – 13 academic institutions, small and medium enterprises and 14 pharmaceutical companies. It incorporates EHR data from providers, patient-generated-data, and those from disease registries from Spain, the Netherlands, Austria and Germany. The data can only be analysed with the patients' consent. Initially, the initiative will collect outcome data for diabetes, inflammatory bowel disease (IBD) and cancer.

The data can be used by patients to better communicate with their clinicians, by health authorities for more informed decision making and researchers to drive new insights. It is planned to extend the H2O concept to additional data sources and other settings in the future. 'Health data has the potential to inform and facilitate a richer dialogue between patients and their healthcare providers as well as improve self-management, thus resulting in better care for individuals and more efficient and sustainable health care systems for the entire community,' says Angèle Bénard-Sankaran, who, until recently, was Project Manager at H2O. ■

Report: Cornelia Wels-Maug

An overview

DON'T MISS:

Hot issues, current trends and innovations at the Labmed Forum

Cancer and coronary diseases, infections and new anti-bacterial active substances, digitalisation and artificial intelligence – these are some of the top issues discussed this year at the MEDICA Labmed Forum.

Laboratory medicine forms a bridge between clinical practice, research and patient care. Together with the life sciences, it is therefore an essential driver for a progressive healthcare system.

Over the last years, the forum has developed into an especially noted part of the programme at the internationally leading trade fair for the health and medical technology industry, and will be held on all four days of the event in the trade fair Hall 1 from 10.30 a.m. to 4.00 p.m.

Though the topics are complex, it is a hallmark of the MEDICA Labmed Forum that all presentations are short, to the point and easy to understand, and can be addressed in further depth in panel discussions.

Like last year, the sophisticated programme was organised by Prof. Stefan Holdenrieder and Prof. Georg Hoffmann (German Heart Centre at the Technical University of Munich). During each lunch break, exhibiting companies are given the opportunity to introduce themselves with short presentations about their company.

MONDAY:
IVDR and AI in Laboratory Management

On Monday, MEDICA starts with two "scandalous" issues which currently cause heated debates throughout the field of laboratory medicine: the potential threat to the existence of small IVD companies and specialised labs posed by the "In-Vitro Diagnostics Regulation" (IVDR) and the use of artificial intelligence (AI) with new possibilities and also risks.

Led by Prof. Astrid Petersmann (University of Oldenburg), in the morning there will be a professional discussion concerning the challenges posed by the new EU directive for the quality assurance of diagnostic tests, and how these can be overcome.

In the afternoon, an equally exciting discussion will follow, concerning how artificial intelligence and machine learning are about to change the way we work in laboratories.

One of the most advanced application areas currently is the automatic evaluation of microscopic images and complex data sets, for example in the diagnosis of leukaemia.

TUESDAY:
Advances in Lab Diagnostics in Oncology and Cardiology

On the second day, led by Prof. Stefan Holdenrieder, German Heart Centre Munich, there will be a discussion of new developments in laboratory medicine within the fields of oncology and cardiology. Over the last years, research has revealed the enormous potential of blood examinations for the diagnosis, prognostication and therapy management of different types of cancer. For example, circulating tumour cells and nucleic acids are becoming established as a second methodological pillar, which opens up new perspectives beyond the classic examination of tissue for the field of oncology.

A change of perspective is visible in cardiology as well: Molecular diagnostic tests allow for the increasing improvement of risk assessment for arteriosclerotic cardiovascular diseases, and thanks to advances in heart surgery, the importance of genetic examinations in the case of congenital heart defects is also on the rise. Other than that, thromboinflammation presents a new pathophysiological concept for understanding thrombogenesis.

WEDNESDAY:
The Young Scientists' Perspectives

The third day of the Forum traditionally belongs to the next scientific generation within laboratory medicine. PD Dr Verena Haselmann, senior physician at the University Hospital Mannheim, invites young colleagues every year to report on their current research and thus give an outlook on the future of the scientific field.

The leitmotif for 2023 is taken from the "data sciences", which naturally exert a special attraction for young people due to the intelligent evaluation of large amounts of lab data. The presentation subjects in the morning run the gamut from AI-supported image evaluation to the analysis of complex lab data to the automated generation of reports on diagnostic findings. In the afternoon, there will be a discussion of practical applications in hospitals, in doctor's offices and within the diagnostics industry, among other subjects.

THURSDAY:
Innovation from an Industry Perspective

The last day of the event at the MEDICA Labmed Forum starts with an overview of diagnostic solutions that noticeably shorten the time it takes to identify a pathogen, thus allowing physicians to make the most effective therapeutic response at an early stage instead of turning in risky diagnostic circles and losing time. Special attention is given to managing septicaemia through quick identification of the pathogen and the targeted use of antibiotics.

More thorough research into scientific basics and possible applications yields a perspective for future options beyond classic antibiotic therapy, with the goal of countering the problematic development of resistances through innovative approaches. The spectrum of possible approaches under discussion ranges from the use of small molecules against bacterial toxins or specific transporters in the bacterial wall to phage therapy.

A look inside the world of "Next Generation Sequencing" (NGS) and bioinformatics rounds out the event. The focus here is on characterising the microbiome of newborns, a very vulnerable patient group. Another established tradition at MEDICA is the presentation of future trends from the point of view of the diagnostics and life science industry – a part of the forum programme that has for years been realised by Dr Peter Quick, member of the board of the Diagnostics Industry Association (Verband der Diagnostica-Industrie, VDGH). Present for the first time as a co-chairman this year is his colleague in the association, Dr Jan Gorka. Both have chosen infectious diseases as a focus for 2023, because 'bacterial resistances to antibiotics are a serious and growing health problem that is accepted as the new normal in some health systems, among them Germany, and which will therefore cost the lives of thousands of people in future,' according to Quick. ■

» Hall 1 / G37

Latest advances in lab-on-a-chip systems in 2023

The micro-lab revolution

Integrating multiple laboratory functions on a single small device, "lab-on-a-chip" micro-total analysis systems are revolutionizing the field of in vitro diagnostics. Experts outline the beginnings and evolution of this technology, and its benefits, including faster, more accurate and cost-effective testing, for advanced and next-generation operational platforms.

'Lab-on-a-chip is a novel technology that reveals a mini lab onto a small coin size chip,' explains Cansu Ilke Kur, research biochemist from the Department of Biochemistry, Faculty of Science, Ege University in Izmir, Turkey. This concept for this technology – termed at the time as "total chemical analysis system" – emerged during the 1980s in analytical chemistry to propose the process of automation in analytical systems. Ten years later, central analytical researchers from Ciba-Geigy AG, Switzerland, presented the concept of using planar fluidic devices to handle small volumes of liquid and established the field of "miniaturized total chemical analysis systems" (µTAS). The high-speed electrophoretic separation of fluorescent DNA and amino acids which are fluorescently labelled were the first examples of microchip analysis developed in the 1990s.

Materials and microfabrication methods in biochip technology

Today, advances in microelectronics have made it possible to use integrated circuits to perform lab-on-a-chip actuation and sensing. Now, three categories of material can be used to manufacture bio-micromechanical systems:

- conventional silicon glass and quartz
- polycarbonate then flexible, biocompatible and wearable plastic and polymers such as polydimethylsiloxane (PDMS) or polymethylmethacrylate (PMMA) proteins
- cells and tissues

These materials are used to better integrate electrophysiology techniques on biochips. 'Over the years, paper and plastic substrates have shown unique properties such as durability, flexibility, mobility, cost-effective and simple manufacturing procedure owing to their compatibility with a wide range of printing equipment,' observes Pranjal Chandra, Associate Professor in the Laboratory of Bio-Physio Sensors & Nanobioengineering at the Indian Institute of Technology (BHU). Today's research teams use various types of microfabrication methods of micrometre scale channels able to manipulate and process low volumes (10–9 to 10–18L). This includes soft lithography, direct laser micromachining and additive manufacturing methods for extensively designing lab-on-a-chip sensing devices. 'Lab-on-a-chip technologies are now improved by novel fabrication and prototyping methods such as 3D printing, laser processing and smart, bio-inspired and nanoengineered materials and boosted by computational fluid dynamics-based performance optimizations,' said Dr Roman Grzegorz Szafran from the Department of Biochemistry, Molecular Biology and Biotechnology, Faculty of Chemistry at the Wroclaw University of Science and Technology, Poland.

The field of intelligent microfluidics is emerging, using artificial intelligence (AI), especially machine learning (ML) and deep learning (DL), for the monitoring and control of microfluidic systems. This provides new challenges and opportunities to accelerate chemical uses and synthesis at reduced costs. AI will make it possible to process and interpret the vast quantities of data generated by biochips. This will improve the accuracy of the results and the ability to extract useful information. For example, ML algorithms can be used to analyse the molecular profiles generated by biochips to detect specific biomarkers of disease, or to predict a patient's response to a given treatment.

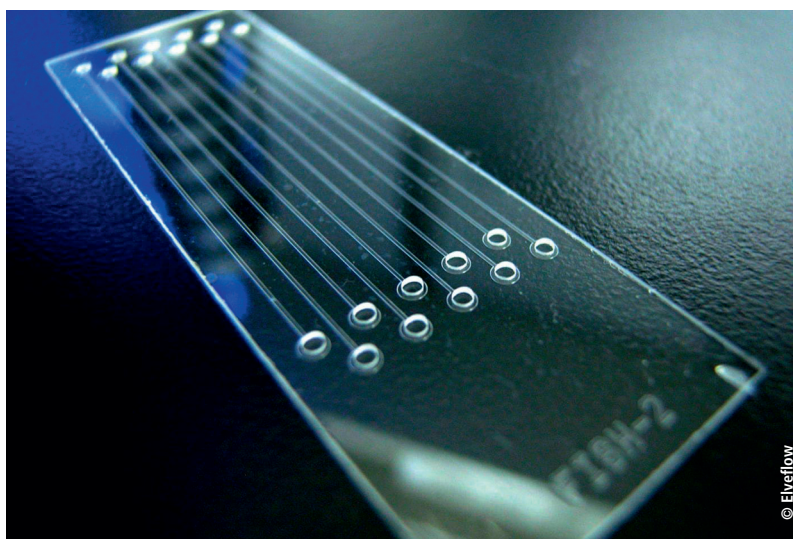
Next generation lab-on-a-chip platform

'Thanks to these latest technical advances, lab-on-a-chip technologies provide numerous advantages including reduced preparation time, small sample and reagent volume requirements, precise control over the cell microenvironment and ease of integration,' said Nan Lu from Hewlett Packard and Nanyang Technical University, Digital Manufacturing Corporate Lab in Singapore. Its team has just developed a point-of-care blood diagnostics tool utilizing a "label-free" microfluidic technology with ML approaches that rely on intrinsic cell properties for blood fractionation and disease detection without antibody binding.

In 2023, the new operational platforms for lab-on-a-chip devices use high-resolution, high-speed, multifunctional electronic and photonic chips to expand the capabilities of conventional sample analysis. 'We have studied the contribution of these next generations of hybrid microfluidic and integrated circuit chips in three particular active areas: high-throughput integrated flow cytometers, large-scale microelectrode arrays for stimulation and multimodal sensing of cells over a wide field of view and high-speed biosensors for studying molecules with high temporal resolution,' said David Issadore, Professor of Bioengineering at the University of Pennsylvania, USA. The platforms have enabled the development of new lab-on-a-chip devices that are more reliable, cost-effective and user-friendly.

Chemical and biological applications

Versatile platforms based on lab-on-a-chip technology are used for a wide range of chemical and biological applications that is expanding at a breathtaking pace. Applications include DNA sequencing, protein analysis and cell sorting. Recent studies have shown that lab-on-a-chip can be used to detect biomarkers in a variety of diseases, including cancer, cardiovascular disease, kidney disease and infectious diseases caused by viruses, bacteria and parasites.



According to the World Health Organization (WHO), the use of biochips can improve epidemiological surveillance and reduce the burden of preventable infectious diseases worldwide by up to 40%. During the Zika virus epidemic in 2015 and 2016, the use of biochips made it possible to monitor the virus' spread more rapidly and more accurately.

One study has shown that integrating biochips into field laboratories can help detect the Zika virus with a high level of sensitivity and specificity, enabling more efficient management and more informed decision-making in public health. Ideal for point-of-care testing, lab-on-a-chip has the potential to bring diagnostic capabilities closer to the patient, reducing turnaround time for test results and enabling timely interventions. According to Market Data Forecast, the global lab-on-a-chip market is expected to increase from US$ 6.43 billion in 2023 to US$ 9.85 billion by 2028, growing at a CAGR of 8.9%. However, all leading companies face major challenges when it comes to the adoption of lab-on-a-chip systems for in vitro diagnostics: the reliability of routine droplet processing in microfluidic biochips. This process involves the generation, manipulation and detection of droplets in microfluidic channels.

The reliability issues are due to the complexity of the process, involving factors such as sensor stability, reproducibility and long-term performance. Researchers are employing strategies such as improved material selection, optimized fabrication processes and rigorous quality control measures to enhance the reliability of the devices. Recent advances in skin-worn systems for biofluid sampling and biomarkers have shown promise by overcoming this reliability challenge. ■

Report: Bernard Banga

Confirming initial positive findings

First-tier rapid serology testing for Lyme disease

Lyme disease, the most common tick-transmitted bacterial infection in the world, is challenging to diagnose. Initial early stage symptoms may include skin rash, fever, headache, fatigue, swollen lymph nodes, and/or body and joint aches. However, these symptoms are also associated with many other diseases and medical conditions.

In many cases, Lyme disease can be diagnosed based on clinical findings and a history of a tick bite or probable exposure. Laboratory testing is problematic, both with respect to confirming and ruling out the disease. Lyme disease serologic testing measures the levels of antibodies generated by the body in response to the infection. However, these antibodies may take several weeks to develop to a level where they can be reliably detected. Consequently, both false negative tests and false positive tests are a problem with first-tier Lyme serological assays. For this reason, a second-tier laboratory test is needed to confirm initial positive findings.

An on-site, point-of-care, rapid testing system that produces first-tier testing results within 3-15 minutes alleviates delays associated with initial analysis by an external laboratory. This rapid test, utilizing an advanced immunofluorescence-based lateral-flow technology (Quidel Sofia 2 Lyme+Fluorescent Immunoassay with CE Mark), has been available for clinical use in Europe since 2018, and also in the United States (Quidel Sofia 2 Lyme Fluorescent Immunoassay) (FIA).

Treating early stage localized Lyme disease with antibiotics

Positive test results help reinforce a physician's decision to prescribe antibiotics while awaiting the results of a second-tier test, especially if the physician believes that a patient may have been exposed to ticks. Antibiotics are very effective in treating early stage localised Lyme disease, and to prevent it from developing into second and third stages that are more difficult to cure and can cause serious medical problems.

The rapid test is also useful for patients who presented with Lyme disease symptoms but had negative test results, and who have returned weeks later for a follow-up test to definitively confirm the initial results.

'In my opinion, the rapid FIA test's primary benefit is actually to rule out Lyme disease, not diagnose it, because it has a high negative predictive value (NPV),' says Professor of Laboratory Medicine and Pathology Elitza S. Theel, PhD, who also co-directs Mayo Clinic's Vector-Borne Diseases Laboratory Service Line in Rochester, Minnesota, US.

Researchers at Massachusetts General Hospital in Boston are the first to formally evaluate the performance of this single-use cartridge-based assay using lateral flow technology with an instrument reader, comparing it with a next-generation polyvalent enzyme immunosorbent assay (EIA) testing system (Zeus ELISA Borrelia VlsE1/pepC10 IgG/IgM (Zeus VlsE, Zeus Scientific), currently in use at the hospital. They report in the American Journal of Clinical Pathology that both of these first-tier serology assays show excellent agreement when combined with second tier immunoblot tests as a part of a standard two-tier testing protocol.

Lyme Test Cassette. © Quidel

Rapid first-tier testing at a hospital, clinic, or doctor's office may be very good news for the estimated 600,000 individuals who annually contract Lyme disease. Central and Eastern Europe as well as Eastern Asia have the highest incidence, led by Scandinavian and Baltic countries, Austria, the Czech Republic, Germany, and Slovenia, according to statistics from the US National Institutes of Health (NIH).

'The test is well suited for laboratories and settings that wish to perform rapid Lyme testing on demand in a random-access mode as opposed to many Lyme assays that require batching,' writes the study's principal investigator, Elizabeth Lee Lewandrowski, PhD.

No refrigeration needed

The Sofia 2 analysers also offers additional benefits to healthcare providers. Testing materials do not require refrigeration. The test analyser is compact and portable, interfaces directly with most laboratory information systems (LIS) and may be configured for either single tests or batch testing to accommodate fluctuating volumes. Unlike most EIA testing systems, it provides differentiated IgM and IgG results, the FIA will generate differentiated IgM and IgG antibody results in a single test. (IgM antibodies are associated with early-stage Lyme disease; IgG antibodies appear later after infection).

For the comparative evaluation, the researchers tested serum specimens from 179 patients experiencing potential Lyme disease symptoms who presented at Massachusetts General Hospital. The researchers reported that positive predictive agreement (PPA) was 78.8% and negative predictive agreement (NPA) was 94.5%, which they said demonstrated clinically acceptable performance. Results of first-tier Lyme diseases tests differ, based on manufacturer, a key reason why a two-tier testing system for positive findings is a necessity. Additionally, the first-tier tests had a 96.2% PPA and a 100% NPA with the second tier immunoblot test performed at Mayo Medical Laboratories in Rochester, MN.

Global research initiatives are underway to develop direct diagnostic tests able to detect all major Borrelia species known to cause Lyme disease. The challenges to overcome are significant.

'Accurate and timely diagnosis of Lyme disease, particularly during infection, remains one of the greatest unmet needs in the realm of infectious disease diagnosis,' comments Theel. 'As pathologists and microbiologists, we have been moving our diagnostic capabilities for Lyme disease incrementally forward, with the development of increased sensitivity or novel direct detection methods. But we are still far from closing this diagnostic gap.' ■

Report: Cynthia E. Keen

Elizabeth Lee Lewandrowski

Elizabeth Lee Lewandrowski, PhD, is an Assistant Professor of Pathology at Harvard Medical School and Research Faculty and a Clinical Laboratory Scientist in the Department of Pathology at Massachusetts General Hospital in Boston. Her primary research interests are in laboratory markers of cardiovascular disease, Lyme disease, and outcomes research in point-of-care testing. Dr Lewandrowski is a member of the Advisory Board of Harvard Medical School Harvard Health Publishing Lyme Wellness Initiative and the Research Director of Invisible International, an organization which offers free online courses about diagnosing and treating vector-borne diseases.

Elitza S. Theel

Elitza S. Theel, PhD, is Director of the Infectious Diseases Serology Laboratory, Co-Director of the Vector-Borne Diseases Laboratory Service Line, and Professor of Laboratory Medicine and Pathology at Mayo Clinic in Rochester, Minnesota, US. She is a clinical microbiologist specializing in infectious disease serologic testing. Her specific interests and clinical focus include developing and evaluating novel serologic assays for the detection of vector-borne diseases, viruses, and dimorphic fungi.

Immunoassay

User experience: simple and smart

AutoLumo A1860/A1800 is the new generation of Autobio AutoLumo Series with compact structure and innovative design, providing simpler, smarter and better user experience for small and medium size labs.

According to the manufacturer, the device is characterized in particular by its simple operation and by enormous time savings and is intended to lead laboratories into a new generation of immunoassays.

Highlighted is the low carryover: the vacuum around the wash station ensures low carryover, which is particularly advantageous for infectious diseases.

An integrated RIDE module that combines reading, injection, discarding and elution achieves a low error rate.

It is also characterized by the iconic management of consumables and the automatic switching of dual substrate.

The bi-directional floating magnetic separation reduces non-specific absorption. 25 reagent positions meet various clinical demand. With a throughput of 180 tests/hour, the instrument is a gamechanger in the stressful daily laboratory routine.

Autobio is a leading provider of comprehensive solutions for medical laboratories. The company specializes in R&D, production, marketing and service of clinical diagnostic products.

Focusing on immunoassay, molecular, microbiology and POCT fields, Autobio helps healthcare professionals tailor treatment with fast, reliable and accurate diagnosis solution for various diseases and dysfunctions. Currently, Autobio has 529 product registration certificates, 322 CE marked and 528 patents. ■

The AutoLumo A1860/A1800
© Autobio Diagnostics

» Hall 1 / F17

French Healthcare

Choose France™

Bonjour!
Guess who is investing €7.5 billion in healthcare innovation?

Meet us at MEDICA 2023

Halls 3, 4, 5, 7a, 15

FrenchHealthcare.fr

@FrHealthCare_EN French Healthcare #FrenchHealthcare

Sustainability in medical imaging

Reducing environmental pollution after contrast-enhanced scans

Radiologists called for action to reduce the release of contrast media in the hospital's wastewater after contrast-enhanced examinations in a dedicated session at ECR 2023.

An estimated 300 million CT examinations are being performed each year in the world. This number is expected to grow, and with it, the amount of iodinated contrast media (ICM) used in radiology, according to Professor Olivier Clément, Head of Imaging at Georges Pompidou European Hospital in Paris, France, and Chair of the contrast media committee of the European Society of Urogenital Radiology (ESUR). 'If you assume that 40% of CT scans are being carried out with an average of 100ml of contrast media, you end up with 12 million litres of ICM that are being injected in patients and then evacuated in the sewage,' he told the audience in Vienna. This contamination of the aquatic environment is being increasingly studied. In Germany, for example, about 200 kg of contrast media are released in the Rhine river every day. 'That means 70.9 tonnes per year. It's a lot and it means that we can really recover ICM from the aquatic environment,' he said.

There are also review studies about contrast media's effects on the environment. In a paper published in the Science of the Total Environment in 2021, a team of Indian researchers found that, whatever the contrast media used, a large amount was found not just in hospitals' sewage waste water but also in surface, ground and drinking water in North America, Asia and Europe. 'It's a global problem, a world issue of contamination of surface and drinking water due to contrast media release,' he said. The contribution of ICM to water pollution can be as high as 80% in the mass loading of pharmaceuticals in a hospital's effluent, because of the amount of ICM that is being injected, he went on. 'When we inject antibiotics, we inject up to three grammes per patient. But when we inject ICM, we inject up to 45 g per patient so the mass of CM is much higher.' The expert stressed that in themselves, ICMs are not dangerous – the danger comes from the disinfection process in the treatment plants, which use chemicals such as chlorine and chloramine. These products create toxic iodinated disinfection by-products (IDBPs) that can be found in the aquatic environment and drinking water. 'This is really the environmental problem of using contrast media,' he said.

Radiologists should be aware of the issue and work to decrease pollution linked with ICM use. 'First we should inject less contrast media and respect the indication, i.e., always inject dose which is related to weight, especially for oncologic imaging,' he suggested. 'We should reduce waste and use the adequate vial for the patient, i.e., open a vial of 100 ml when we use 90 and not a vial of 150. We should also recycle the residue in the vial.'

Taking steps is also important because of the high demand for ICM all over the world. 'Vendors can produce a certain amount of ICM per year that isn't even sufficient for all the examinations,' Clément said. 'So, we must think of how we use these products and find new ways to inject less contrast, with low kV and AI for example.' Although software solutions are being trained to reduce ICM dose, a small amount of contrast media remains necessary to actually create contrast in the image, he believes. 'We will still need contrast media in radiology for a long time.' Strategies to reduce pollution include releasing ICM in hospital circuits linked with specific plants, installing dry toilets for patients who have undergone a contrast-enhanced examination, and collecting urine in bags to be incinerated, since incineration is less polluting than using ICBPs to purify the water. 'The radiology community should be aware of the huge amount of iodine contrast media released in the environment,' he concluded. 'We should inject wisely, know about toxic IDBPs in plants and take specific measures to decrease the effluence.'

Twelve million litres of iodinated contrast media (ICM) are being injected in patients and then evacuated in the sewage worldwide every year. © pangoasis - stock.adobe.com

Surprisingly high 'green sensitivity' in patients

Iodine contrast media are not the only source of concern when it comes to residuals in hospitals' wastewater. About 50 million of gadolinium-based contrast agents (GBCA) doses are being injected per year and then evacuated in the sewage, according to Professor Francesco Sardanelli, Director of the Department of Radiology at the Research Hospital (IRCCS) Policlinico San Donato in Milan, Italy, where the Greenwater study was recently launched. As previously reported, the project aims to evaluate the extent of retrievable ICM and GBCA from the urine collected after CT and MRI scans, and to assess patient acceptance to participate in the study – the 'green sensitivity'.

The study was carried out with urine collection within 60 minutes of administering the contrast agent, so about 30 minutes after the examination. Results have been both surprising and encouraging, Sardanelli explained. 'The first unexpected finding to me was the high acceptance from patients,' he said. '94% of them agreed to take part in the study and stay half an hour more in the department. That means that we can go in this direction quite effortlessly.' The fact that patients wanted to cooperate in the project is very good news for manufacturers and hospitals, he added. 'It shows patients are highly sensitive to sustainability. Even in a hectic city like Milan, people took the time. We have to use this availability.' The future is to recycle both iodine and gadolinium agents, by creating virtuous cycles in which the product comes back to the producer after it has been injected in the patient. 'That would make sense,' he concluded. 'Recycling is the solution.' ■

Report: Mélisande Rouger

Olivier Clément

Olivier Clément is Professor of Radiology at Descartes Paris University and Head of Imaging at Georges Pompidou European Hospital in Paris, France. He is also Chair of the contrast media safety committee of the European Society of Urogenital Radiology (ESUR).

Francesco Sardanelli

Francesco Sardanelli is Professor of Radiology at Milan University and Director of the Department of Radiology at the Research Hospital (IRCCS) Policlinico San Donato in Milan, Italy.

Eco-sustainable

Medical waste treatment

Advertisement

Newster's Frictional Heat Treatment enables hospitals to process hazardous solid waste onsite in a sustainable and cost-effective way. It is a sustainable alternative for the treatment of medical waste.

The equipment is tailored to the needs of the healthcare facility and can be installed onsite in a small sized room. The running costs inclusive of energy consumption, maintenance, operating staff and consumables allows a significant reduction of the cost of disposal. The patented technology employs the heat generated by the shredding action to sterilize the waste at the same time without the emision of persistent organic pollutants (POP) emission into the atmosphere according to the Stockholm Convention.

It is a patented technology specific for the treatment of solid infectious healthcare waste, including sharps, dialysis filters, PPEs, non-woven materials and fabrics. There is a 25% weight reduction and a 75% volume reduction. The sturdy design allows the sterilizer to work for several shifts, each lasting 35-40 minutes. The power inverter allows to reduce energy consumption.

The sterilizing unit is designed for on-site installation up to 600 beds hospitals and external centralized plants. ■

Hall 11 / G67

Portable imaging

Going mobile: point-of-care ultrasound

Significant advances in point-of-care ultrasound (POCUS) have made it a versatile tool for assessment, diagnosis, and follow-up across various fields. New developments continue to expand its applications, improving patient care and outcomes.

Ultrasound has many benefits – including, but not limited to its portability, non-invasiveness, low cost, absence of radiation, real-time imaging capability and bedside assessment. For these reasons, POCUS has rapidly emerged as an excellent multimodal tool and has been gradually incorporated as an adjunct to physical examination in order to facilitate evaluation, diagnosis and management.

'POCUS can assist in the evaluation of undifferentiated sepsis. It can also contribute to the differential diagnosis of other types of shock, thus facilitating the decision-making process,' said Effie Polyzogopulou, Assistant Professor of Emergency Medicine at the National and Kapodistrian University of Athens, Greece, and Chair of the European Society for Emergency Medicine (EUSEM) Ultrasound Section.

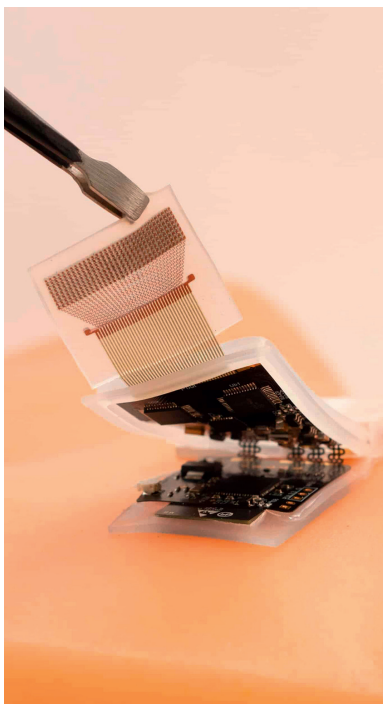
In the latest Global Burden of Diseases report, sepsis-associated morbidity was estimated at 48.9 million global cases while the mortality rate was reported at 11 million deaths, or one in five deaths worldwide. Detection and exploitation of enhanced bedside techniques to facilitate early diagnosis and effective management of sepsis become imperative. In this context, POCUS has high specificity, more than 91% for the four subtypes of non-traumatic hypotensive shock and approximatively 80% for mixed types. 'Hence the importance of the roll-out and deployment of POCUS in the emergency department with focused cardiac ultrasound, lung ultrasound, abdominal, pelvic and urinary tract ultrasound, as well as vascular and transcervical ultrasound,' said Polyzogopulou.

Integration of point-of-care diagnostics into a wider variety of fields

Several main technological advancements have contributed to the development of POCUS enhancing bedside patient care:

- First, rapid technological advances in electronics and piezoelectric materials provided further improvements from bistable to greyscale images and from still images to real-time moving images.
- Second, increases in processing power have allowed for faster and more powerful systems incorporating digital beamforming, increased enhancement of the signal, and new ways of interpreting and displaying data, such as 3D power doppler imaging.
- Third, handheld ultrasound systems allow for portable imaging. This makes ultrasound more ubiquitous, particularly at the point of care. POCUS devices are easier to use, take up very little space, and can be carried in a pocket. Many handheld ultrasound devices also provide comparable image quality to most mid-range traditional ultrasound systems.
- Fourth, innovations in miniaturization and wireless connectivity continue to improve the portability and ease of use of ultrasound devices.

The recent development of a multisystem point-of-care ultrasound skills assessment checklist has been a significant advancement. This consensus-based, multispecialty POCUS checklist evaluates skills in image acquisition and anatomy identification for various systems and disciplines. 'This 153-item checklist serves as a standardized tool to assess and evaluate the proficiency of clinicians in performing POCUS examinations across different specialties,' said



A wearable ultrasonic-system-on-patch for deep tissue monitoring.
© Muyang Lin, University of California, San Diego

Nilam J. Soni, Professor of Medicine and Academic Hospitalist at the University of Texas School of Medicine in San Antonio and the South Texas Veterans Health Care System. Although portable ultrasound equipment has achieved technical integration and miniaturization, 'there are still challenges for development of US devices and applications to move forward into a subspecialty of clinical disciplines,' said Chengzhong Peng, MD, Chief Physician at the Shanghai Tenth People's Hospital of Tongji University and the Shanghai Engineering Research Center of Ultrasound Diagnosis and Treatment.

A specially designed ultrasound machine with new concepts is needed in developing specialty-oriented instruments. POCUS is rapidly evolving, with the integration of cutting-edge technologies such as artificial intelligence (AI), cloud computing, 5G networks, robots, and tele-remote technology, Dr Peng points out. This integration is transforming the specialized POCUS system into an intelligent terminal platform. Tele-remote ultrasound allows for remote real-time diagnosis and interventional procedures through high-precision synchronization via video, audio, text, and other multichannel communications. Using a remote robotic ultrasound system, experts can use their own skill for remote ultrasonic scans and providing medical diagnosis based on real-time ultrasound imaging generated by robotic scanning.

These advances are further driven by the advent of 5G technologies, which play a crucial role in enabling long-distance, real-time, high-bandwidth, high-resolution, and low-latency requirements. This has proven invaluable during the Covid-19 pandemic, allowing remote assessment of patients' lung lesions and guidance during interventional procedures, thus conserving expert resources and minimizing cross-infection risks. However, remote ultrasound is not conducted for large-scale clinical applications, and it can only be used as a basic screening tool for special situations at present due to the lack of unified standards for image acquisition, quality control, data transmission, and security.

AI integration in ultrasound imaging: advances and challenges

With the recent integration of AI into diagnostic ultrasound imaging, POCUS aims to harness the power of this technology for rapid image processing, standardization, and continuous workflow.

Ultrasound with AI technology has been applied in clinical practice, improving the accuracy of clinical ultrasound diagnosis. For example, a study published in Ultrasonics showed that the coincidence rate by AI-based ultrasound systems in the interpretation of benign and malignant thyroid nodules increased from 64% to 84%. However, there are still many challenges in AI ultrasound applications. The huge quantity of data generated puts higher requirements on algorithms and computing power. Computing power limitations need to be solved to ensure that the AI model can be effectively used on tablets and mobile phone platforms.

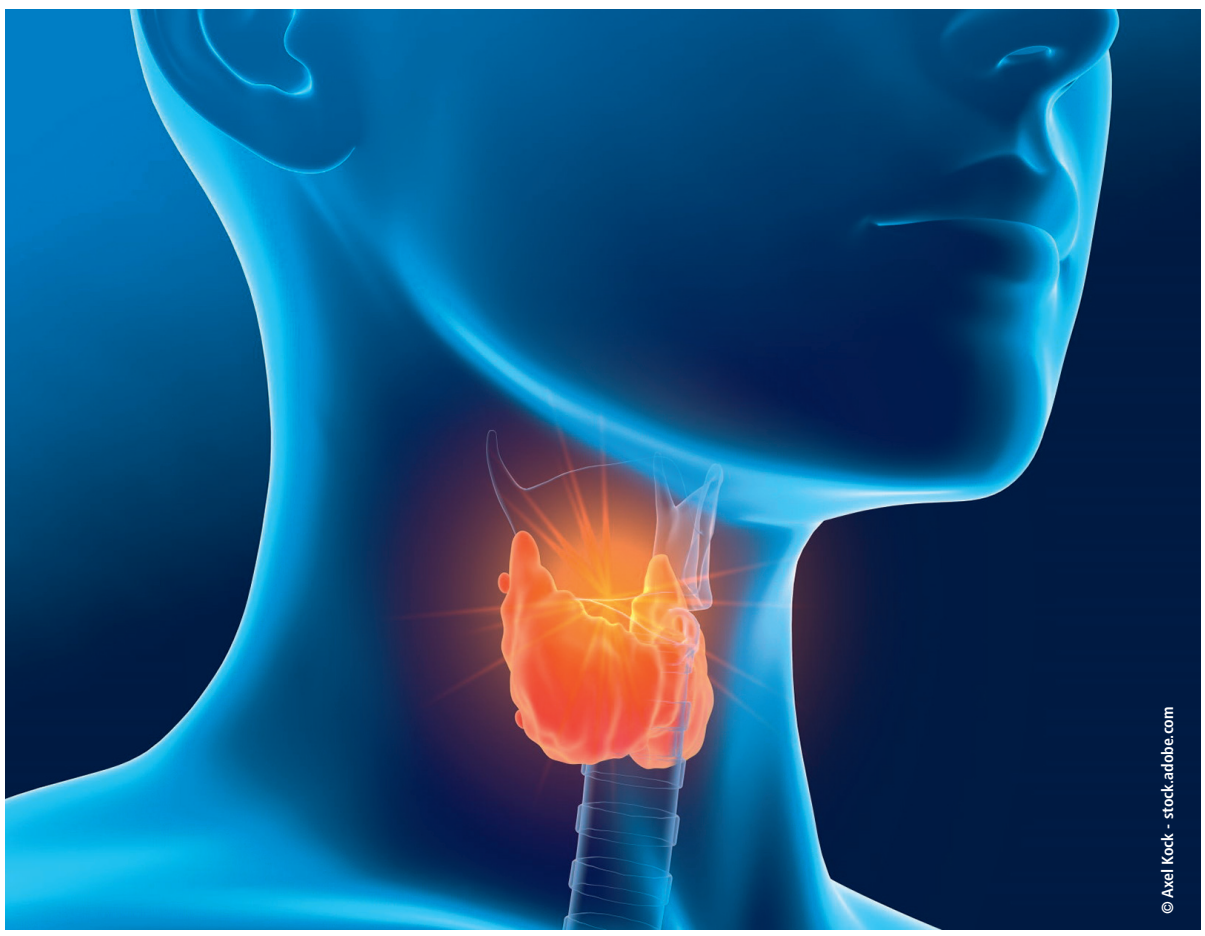
Last, but not least, cloud computing is a new type of computing platform that has the advantages of low cost, high reusability, high performance, and easy expansion. It accelerates the integration of a large number of algorithmic formulas and storage resources, and then distributes them to specific users accordingly. Recently, with the application of mobile terminal devices, cloud computing technology has brought about new changes for ultrasound diagnosis. The ultrasound system on the patient side is responsible for collecting image data, while the mobile device on the doctor side displays the image data. This data can be transmitted in real time between the two locations, and remote consultations can be provided via 5G technology and cloud platforms. These technological developments have paved the way for next-generation POCUS devices that are highly portable, user-friendly, and accessible. Notably, handheld ultrasound systems are experiencing rapid growth in the market. According to Strategic Market Research, the global Point-of-Care Ultrasound market valued at $3.24 billion in 2022 is projected to grow at a robust compound annual growth rate of 5.7% by 2030, reaching $5.9 billion. As this technology continues to evolve, it holds the potential to transform healthcare delivery and enhance patient care across the globe. ■

Report: Bernard Banga

Non-invasive

High-intensity focused ultrasound ablation treatment for benign thyroid nodules

High-intensity focused ultrasound (HIFU) ablation is a non-invasively treatment for benign thyroid nodules that are causing distress to patients. Brian Lang, a preeminent investigator, proponent, and pioneer of this technique, talks about this still novel thermal ablation treatment.



Up to 60% of the world's population has thyroid nodules, most of which are benign and cause no problems. However, between 10% to 15% can progress and grow to a size that causes discomfort, cosmetic disfigurement, and/or obstructive symptoms. In these cases, surgical resection or thermal ablation is required to shrink the volume and size of the nodule.

Types of thermal ablation include HIFU ablation, radiofrequency ablation, laser ablation, microwave ablation, and ethanol ablation, all of which are non-invasive. Ablation is a safe, tolerable, less expensive, outpatient procedure that does not require general anaesthesia. Organ function is preserved and kept intact, compared to surgery, which removes portions of the thyroid.

Size matters (and so does growth)

'HIFU ablation is appropriate for patients with small-to-medium sized, benign solid nodules greater than 40 mm in size or which are experiencing interval nodule growth greater than 20% in one year.

The distance from the skin to the center of the nodule should not be less than 7 mm or greater than 30 mm, because HIFU can cause skin burns if too close and the ultrasound energy will dissipate and not be as effective if too far,' explained Lang, who has performed more than 600 of these procedures. Lang, Clinical Professor in the Department of Surgery at the University of Hong Kong, and chief of the Division of Endocrine Surgery at Queen Mary Hospital, said that the HIFU treatment utilizes multiple high-energy ultrasound waves focused at one particular area to cause intense vibrations of tissue, generating heat that causes necrosis at the target location. Thermal injury occurs when tissue temperature reaches 56°C for a duration of one second or more, causing protein denaturation and coagulation necrosis.

Acoustic cavitation – the formation of microbubbles which expand and collapse – causes mechanical damage to nearby cells, resulting in coagulative necrosis and apoptosis. Cell arrest also occurs, activating immune cells that detect and destroy tumour cells. The total on-beam HIFU treatment time for a 3 cm nodule takes between 30-45 minutes, with a patient spending 4–6 hours at an outpatient clinic. Two sequential treatments six months apart are recommended for larger nodules.

Shrinkage may vary

Thyroid nodule shrinkage following HIFU ablation is not uniform, and the reasons for this are still being investigated. 'HIFU can generally achieve a volume shrinkage between 45% to 70%, with the smallest nodules having the greatest shrinkage,' said Lang. '80% of my patients had a greater-than-50% shrinkage at six months. Also, the number and severity of pressure symptoms tend to be significantly reduced at 12 months.' The extent and duration of shrinkage beyond two years is not yet known and is also currently being investigated.

Preventing heat injury

Great care must be taken to prevent heat injury to the carotid artery, trachea, and recurrent laryngeal nerve. Skin burns are the most commonly reported side effect; transient vocal cord palsy occurs in less than 5% of patients.

Lang and his colleagues at the University of Hong Kong have conducted numerous research investigations of the usage and efficacy of HIFU as a treatment for benign thyroid nodules. Noteworthy clinical trial findings include:

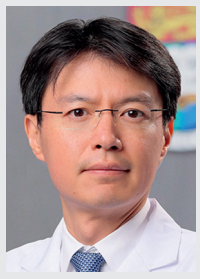
- The addition of percutaneous ethanol injection (PEI) in combination with HIFU ablation in benign thyroid nodules is associated with a significantly better six-month efficacy then HIFU alone and has a comparable safety profile.

- HIFU ablation is a feasible treatment in patients take an anti-coagulation or anti-platelet agent during treatment. It might be preferable to surgery in patients who continuously require an anti-coagulation or anti-platelet agent.

- For the 85% of patients who experience pain during HIFU ablation, the additional administration of a perithyroidal lignocaine infusion (PLI) in conjunction with intravenous doses of a sedative and an opioid provides greater pain relief. A randomized 205-person study identified lower body mass index (BMI) and older age as independent indicators of experiencing less pain.

- Two sequential HIFU ablation treatments six months apart generate more nodule shrinkage than a single treatment of large thyroid nodules (with a volume of at least 20 mL and up to 50 mm in diameter). Patients undergoing two treatments are not at greater risks of treatment-related side effects. ■

Report: Cynthia E. Keen



Brian Hung-Hin Lang

Brian Hung-Hin Lang, MD, is the Li Shu Fan Medical Foundation Professor in Surgery at School of Clinical Medicine at the University of Hong Kong, and also serves as its Director of the Surgical Skills Training Center. He is the chief of the Division of Endocrine Surgery at Queen Mary Hospital in Hong Kong, specializing in thyroid, parathyroid, adrenal diseases, and ablation of thyroid nodules. Lang has pioneered the use of high intensity focused ultrasound (HIFU) in the treatment of benign thyroid disease.

mgo fachverlage

Publisher
mgo fachverlage GmbH & Co. KG
E.-C.-Baumann-Str. 5
95326 Kulmbach/Germany
Phone +49 (0) 9221 949-311
Fax +49 (0) 9221 949-377

Managing Directors:
Walter Schweinsberg, Eva-Maria Bauch, Bernd Müller

Editor and Production Manager:
Sonja Buske (SB)
Phone: +49 201 17755092
E-Mail: s.buske@mgo-fachverlage.de

Editor: Wolfgang Behrends (WB)

Founded by Heinz-Jürgen Witzke
ISSN 0942-9085

Correspondents
Austria:
Michael Krassnitzer (MK)
Belgium:
Bernard Banga (BB)
Germany:
Cornelia Wels-Maug (CWM)
Dr Christina Czeschik (CC)
Great Britain:
Mark Nicholls (MN)
Spain: Mélisande Rouger (MR)
USA: Cynthia E. Keen (CEK)

Printed by: mgo360 GmbH & Co. KG, Bamberg, Germany

Representatives
Germany, Austria, Switzerland:
Julia Lutz
Phone: +49 9221 949-407
E-Mail: j.lutz@mgo-fachverlage.de

France, Italy, Spain: Eric Jund
Phone: +33 493 58 77 43
E-Mail: jund@european-hospital.com

GB, Scandinavia, BeNeLux:
Simon Kramer
Phone: +31 180 6200 20
E-Mail: kramer@european-hospital.com
Taiwan: Charles Yang
Phone: +886 4 232 236 33
E-Mail: medianet@ms13.hinet.net
USA & Canada:
Hanna Politis, Media International
Phone: +1 301 869 66 10
E-Mail: hanna@media-intl.com

All company, brand and product names in this publication are the property of their respective holders. Users must obtain permission from those holders before copying or using the owner's trademarks, product and company names or logos.

RFA, MWA, CRYO and IRE under scrutiny

Thoracic interventions: new tools in the arsenal

Experts presented state-of-the-art and emerging techniques to treat chest tumours and discussed common issues in the management of pneumothorax at RSNA. Current ablation methods in the thorax include radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation (CRYO), irreversible electroporation (IRE) and pulsed electric field.

Transbronchial thermal ablation is an investigational method that could be interesting for the treatment of lung tumours, said Professor Michael Lanuti, MD, Director of Thoracic Oncology for the Division of Thoracic Surgery and the Thoracic Surgery liaison to the Massachusetts General Hospital Cancer Center in Boston. 'Image-guided thermal ablation is already adopted as a tool in the armamentarium for oligometastatic disease, lung cancers or in case of failure of stereotactic radiotherapy,' he told the audience.

Thanks to new technology providing higher resolution, surgical teams can now navigate to the lesion site using electromagnetic navigation bronchoscopy or newer navigation platforms such as ION and Monarch. For real time confirmation of position, they can use cone beam CT or CT fluoroscopy, or ultrasound bronchoscopy when it is available. 'The main benefit for bronchoscopic ablation is that it can reach nodules in the middle lung zone that cannot be reached with the percutaneous technique,' Lanuti said. 'If the bronchoscopic ablation is implemented with robotic navigation, the no-hand approach makes it possible to perform cone beam imaging without provider exposure to radiation.' The technique choice will depend on the lesion location – the concept of lung zone dependence, he explained.

Heat management in different tissues

'In the periphery, many of the approaches are applicable, but in the central zone, most are dangerous. This might be where image guided RFA or non-thermal pulsed electric field can play a role,' he suggested, adding that there are other factors to consider before deciding on therapy. 'CRYO is associated with less pain for a lesion that is located along the pleura or for peripheral location close to the chest wall.'

Heat management is a factor for the percutaneous approach as well as transbronchial thermal ablation. 'There's the suspicion that microwave could mitigate this phenomenon,' Lanuti said. 'But CRYO is usually preferred for lesions abutting airways.' Transbronchial thermal ablation should be performed in tumour locations that allow for it. 'The propagation of heat or cold is unreliable in a tissue where you had previous radiation,' he said. Interstitial lung disease is under evaluation and thermal ablation coming down the airway might reduce the risk of pneumothorax. Transbronchial thermal ablation could be used as part of a one-stop-shop approach, where teams can diagnose and directly treat the lesions. 'We're still in the clinical trials. To be successful at this, you need to have a champion in your institution, and that can be either a pulmonologist or a thoracic surgeon.

A lot of pulmonologists are moving in that space, as well as theragnostics interventionists, who can biopsy the lesion and treat it,' said Lanuti, who recommended using transbronchial thermal ablation for tumours smaller than 2 cm. 'The benefit is that it's repeatable, and with bronchoscope techniques, perhaps there's less pneumothorax. We need prospective studies to standardize the technique,' he concluded.

Chest tube management

In the following talk, Maria Lucia Madariaga, MD, Assistant Professor of Surgery at the University of Chicago, focused on the finishing touches of chest tube placement after pneumothorax (PX), an action that is required in 2 to 15% of all PX cases. 'When a patient has a lot of soft tissue or they're obese and you put a pig tail in, the pig tail could migrate out of the pleural phase even though it may look like it's still attached to the skin,' she said. The two most important things to remember in this scenario are how to tape the tube to the patient and how to secure the chest tube connections, she explained. 'A loose chest tube stitch could also have fatal consequences. It's very important in your daily examinations of the patient to make sure that attachments are attached to the patient. Bad stitching of the chest tube can lead to chest tube falling out. Once you saw the tube in, whether you do a single stitch at skin level or Roman sandal technique, make sure the tube is not able to move in and out.'

A Heimlich valve sometimes comes as part of the chest tube in surgeon kit as a way to evacuate air. However, some surgeons may be confused as to what to do with it, Madariaga said. 'One common misconception is that the valve is placed in series with the whole chest tube contraction. You don't need to use this valve unless you're taking the patient home.' A bad tape job is when the connection is obscured. 'The tubing connecting to the pleurevac and the tubing connecting to the patient could be completely disconnected within this tape monster and you would never know,' she said.

A good way to secure connection is to make it visible, 180 degrees from the tubing and to use one single line of tape. 'Using tie bands at the connection sites can also show you that the connection is secure and visible,' she suggested.

There are many new promising treatment options for tumours in the chest area, especially the lungs. © totojang1977 - stock.adobe.com

Connection check for long-time intubated patients

After the tube has been placed, it is kept either on suction, to make sure that the lung is fully adhered to the chest wall, or on waterseal, as an intermediate step when suction is not necessarily needed. On their daily rounds, medical teams should assess for crepitus at the site of the chest tube, she recommended. 'If the patient is on positive pressure ventilation or unstable, you might consider not taking the tube out.'

Looking at the chest tube itself, teams should check the tape to make sure it's secured to the skin. 'If a patient has been intubated for a long time, those stitches might erode through the skin and it might be able to come out quickly,' the expert cautioned. 'Make sure that all the connections are intact, because if you're trying to assess for an air leak, for example, you won't have an accurate reading if there's a kink in your tube.'

Looking at the pleurevac or any other device connected to the chest tube, teams should watch out how much volume is coming out in a 24-hour period. 'You won't take out the tube if there's too much volume. Another sign of the chest tube functioning is if the water column on your pleurevac is tidaling when you open it.' ■

Report: Mélisande Rouger

Platform for new companies

Start-ups are shaking things up

For years, Medica has also been the global leading event for start-ups seeking to enter the health sector. Among the more than 5,000 exhibiting companies, there will accordingly again be several hundred young developer teams seeking business contacts for cooperation concerning funding, production, product approval, marketing or sales of their product ideas.

Numerous programme highlights place a targeted focus on the start-up scene and offer start-ups an ideal platform to present their innovative solutions and to do business with the international world of professional healthcare. Among those worth mentioning are the 12th Medica Start-Up Competition, the 15th Healthcare Innovation World Cup and the Medica Start-Up Park.

At the Medica Start-Up Competition, the focus is on the entire spectrum of innovations for the healthcare sector: from artificial intelligence (AI) to health apps, solutions for laboratory diagnostics and medical robotics. For the first time this year, "Sustainability" features as a novel category.

Previous year's winning team continues to profit from global visibility

The Spanish start-up Idoven was the winning team in the competition of 2022 and has subsequently profited immensely from participating in the event. The young company has, in their own words, developed an AI-based platform for "cardiology-as-a-service". This proprietary AI uses electrocardiographs (ECG) of any length and by any diagnostic tool to improve the accuracy and consistency of the interpretation.

Rika Christanto, COO at Idoven, is pleased with the effect of participating at Medica and the competition finals on the stage of the Medica Connected Healthccare: 'I was very surprised at how global this trade fair is!' The Medica Start-up Competiton gave her start-up an immense global visibility, notwithstanding which Idoven also wants to enter the German market.

According to Christanto, it was also helpful to share experiences with other start-ups during Medica, for example concerning how to overcome legal obstacles to entering the market. Currently, Idoven is strengthening the partnerships that came out of Medica 2022, for example with the company GE Healthcare regarding a project to reduce the necessary efforts for interpretation of ECGs in a clinical setting. 'We also signed an agreement with AstraZeneca regarding a cardiac insufficiency project", says Christanto. This is primarily concerned with avoiding hospitalisation of affected persons. Together with the pharmaceutical company, the start-up is therefore working on solutions to improve individual therapies. To do this, Idoven's analytical platform uses early data from patient records to estimate the effectiveness of planned treatments and the necessity for changes. In order to continue this growth course, Idoven is looking for further partnerships, working intensely on the performance of its proprietary AI tools and on the evaluation of the usefulness of their solutions in clinical practice.

Healthcare Innovation World Cup: the next generation of intelligent medtech devices

For start-ups, scale-ups and smaller mid-level companies, participation in the 15th Healthcare Innovation World Cup could also be interesting. The focus here is on intelligent "Internet of Medical Things" (IoMT) solutions, e.g., digital biomarkers, smart band-aids or wearables with network connectivity. The 12 finalists, chosen by a renowned professional jury, are invited to present their businesses during Medica 2023 on the programme stage of the Medica Connected Healthcare Forum (Hall 12).

The previous year's winner was ViewMind Inc., a company specialising in the management of neurodegenerative diseases like multiple sclerosis or Alzheimer's. Mark Edwards, CEO and co-founder of ViewMind Inc., says that while the effects of winning cannot be quantified, 'I can say that winning was very helpful to make the company and its products known.' This start-up, too, has completed another round of financing, which was facilitated by their success at Medica. The already CE-certified ViewMind product, which is already on the market, was validated in approx. 30 clinical trials on four continents with thousands of patients. Approval by the FDA is currently ongoing. ViewMind initially addresses the pharmaceutical industry, says Edwards, but also the healthcare sector in general. 'We are working on clinical trials with several pharmaceutical companies in order to give them a tool with which to find suitable participants, set up cohorts precisely and measure the effects of therapy with corresponding sensitivity.' The start-up sees itself as a pioneer for the development of precision drugs.

Meet-up point at Medica Start-Up Park

The Medica Start-Up Park also emphasises networking and has established itself as the central meet-up point for the start-up scene. The start-up initiative „Up To Future" from Ukraine will be there for a second time. In 2022, registration could only take place shortly before the trade fair. Among the Ukrainian start-ups promoted by the initiative was HandyUsound with its product idea for a portable ultrasound system. The product met with such a great response from the trade fair audience that the founding team wants to use the opportunity again this year to make further business contacts.

Megnosis from Korea is also participating in the Medica Start-Up Park this year. The company has developed EEG helmets which are intended to detect dementia at an early stage and ameliorate the effects through the stimulation of brain cells and neurons.

Germany is also represented at the joint stand. One example is AssistMe. For Medica 2023, they will present a smart sensor system for use in underwear for incontinence. The system serves as a kind of indicator for liquids. Through a clip connected to the incontinence aid, data retrieved is transmitted to a software cloud system. This way, nursing staff in an institutional setting can better care for residents according to their needs, because with one glance at a central location, staff can determine when it seems necessary to change which person's incontinence aid. ■

» Start-Up Park: Hall 12