

The digital surgery revolution

Digital technologies have the potential to transform surgery and medical device manufacturers are now evolving to advance this technology-driven revolution. So, how could ‘digital surgery’ lead to reduced variation, improved outcomes, and increased efficiency? **Louise Frampton** reports.

Pioneering medical technology firms are transforming the way surgical care is being delivered, driving a revolution in what has been coined ‘digital surgery’. One of the key innovators in this field is Johnson & Johnson MedTech. *The Clinical Services Journal* spoke to the J&J MedTech UK & Ireland leadership team to gain an insight into how technology is changing surgical approaches and improving outcomes for patients.

The increasing emphasis on connected digital technologies has been reflected in a recent company name change from ‘Johnson & Johnson Medical Devices’ to ‘Johnson & Johnson MedTech’. Transitioning from ‘Medical Devices’ encapsulates the company’s strategic decision to move increasingly deeper into the world of digital technology.

At the start of this year, J&J MedTech announced a partnership with Microsoft

to further enhance and broaden its ‘digital surgery ecosystem’ – the focus being on advancing surgical skills, enhancing workflows, and improving surgical decision-making, by leveraging Microsoft technologies to accelerate innovation. The company is bringing together the power of next-generation robotics, instrumentation, advanced imaging and visualisation, data and analytics, artificial intelligence, and machine learning.

“The world is becoming increasingly digital,” explains Hugo Breda, managing director of J&J MedTech for the UK & Ireland. “As a company, we are developing innovation that is changing the trajectory of healthcare. Innovation is in our DNA and there have been lots of ‘firsts’ in surgeries that have changed the way surgery is performed. Now, we are changing our name, as we believe the future is in combining

medical devices and implants, with digital technologies and data analytics.

“Digital technology will play an important role in surgery and the move from analogue to digital will be a game changer – we want to lead that transformation. It will ultimately transform healthcare and allow clinicians to treat more patients.”

Breda believes digital technology will be particularly important in tackling the backlog, in the wake of the pandemic, but it will also mean better outcomes and a better experience for patients.

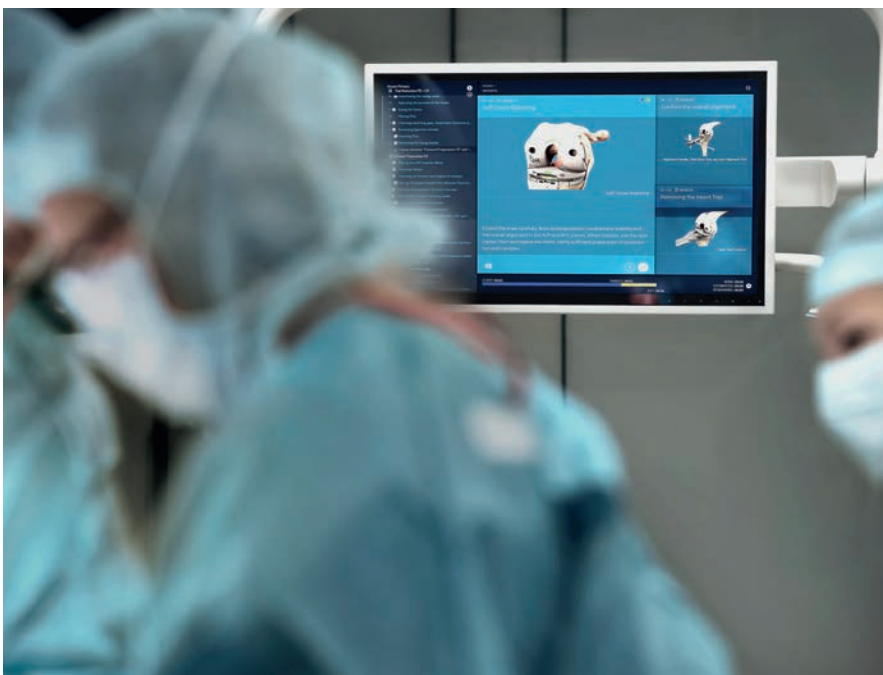
“We’re determined to help the NHS tackle its priorities – there are over six million patients on the waiting list; the healthcare system is struggling with capacity, staffing issues, and the effectiveness of treatments. Digital technology is revolutionising healthcare now, but it is important that it brings value – it can have the opposite effect of what healthcare needs if the system gets adoption wrong.

“Digital technologies must not increase the workload or create more stress, because they are something new and there is a learning process; they must not be implemented without proven outcomes or the ability to treat more patients per day. They need to be intuitive, easy to use, have a small footprint, be scalable, with a short learning curve, and provide immediate value,” Breda continues.

His vision, he explains, is to focus on four key aims: clinical outcomes, patient experience, reducing total costs of healthcare, and improving staff experience.

Gianluca Casali, medical director for J&J MedTech UK & Ireland, adds that it isn’t about “innovation for innovation’s sake”, but about responding to what is needed in the NHS.

“Even before COVID, there were increased demands from an ageing population, as well as challenges around ▶





winter pressures and a fixed NHS budget. The pandemic exacerbated the issues already present in the healthcare system, so we responded to these demands by leveraging technology – including offering tele-mentoring for theatres. The healthcare system has become more receptive to this digital technology, and we now realise that these technologies allow us to optimise the pathway for the long term,” he comments.

A digital ‘satnav’ for theatres

Bala Balaguru, a founding member of the Strategic Capabilities team at J&J MedTech in the UK & Ireland, reports that there has been “a massive uplift” in the interest in digital technology and platforms.

“Now is the time to integrate this technology into the surgery pathway going forward,” he asserts. “The NHS is tackling issues with the waiting list and availability of staff, so we have been working with a large university hospital in the Midlands, to overcome these challenges, as the Trust has been restarting colorectal surgery services following the pandemic.

“The Trust wanted to optimise theatre capacity, so we helped to implement the Surgical Process Institute (SPI) – a digital system that can be integrated within any theatre. This is essentially a digital ‘satnav’

for theatres, with ‘black box’ capability. A surgeon, with an iPad and mounted screens in theatre, can list the key steps of the procedure that are then digitised, uploaded into SPI, and visualised on a monitor in theatre. Even if the hospital staff are new to the theatre or new to the surgeon, that day, the team can follow each step, as the surgery progresses, with the flow controlled by the surgeon via a foot pedal. This enables the scrub team to prep in advance of each step and ensures a seamless workflow,” he explains.

The use of SPI in theatres means that everyone involved in the process can follow the operation’s advancement in real-time and continuously prepare for any upcoming issues. All procedural steps are illustrated chronologically and documented, including any necessary deviations that may be required, during the course of the operation.

The technology provides a way of standardising surgery by translating the whole surgical experience into a detailed, step-by-step checklist that follows “best-in-class standards”. This means that important safety checks are completed every time, in the same order, and all supporting processes are harmonised.

New colleagues – especially agency staff – can be integrated faster through

digital support and the standardised process, while performance indicators, such as surgical times and deviations from standard processes, can be analysed.

Balaguru points out that the “steered workflow” also reduces human error. As the steps of the procedure are followed in a standardised way, there is less variation, which leads to better outcomes. Fewer errors during an operation also translate to lower costs for follow-up treatment. SPI enables operations to be carried out faster, and ensures better management of the surgical theatre’s valuable resources, while the fact that operations can be performed with less variation leads to lower surgical costs for individual procedures.

“The technology is simple and can be implemented in theatres in a matter of minutes. Given the backlog, we believe all theatres should be taking these productivity measures and looking at ways to decrease variation from the norm, so that the waiting list can be reduced,” Balaguru asserts.

“You can also see that theatres are running behind. The chief exec can see the full flow of theatres across multiple sites and there is also potential to see this at an ICS level. These rich sources of data give you the full management control you need to run an effective theatre service,” he continues.

The technology has been shown to reduce unwarranted variability by up to 45%¹ and improved efficiency, through the reduction of surgical time.²

The ‘black box’ for theatres

The system can also be used to drive improvement through a ‘black box’ element. It is not just the surgeon that can see their own performance; the whole surgical unit can look back at their performance. If variation is identified, for example, it is possible to establish whether this is an isolated or regular occurrence. It also allows

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Hugo Breda, managing director of J&J MedTech for the UK & Ireland.

theatre teams to consider: is this variation a serious problem that needs to be fixed or is it actually an improvement? If the latter is the case, is there a need to change practice? The black box allows theatres to answer these difficult questions.

“You can generate a wealth of data that you can use to improve your existing workflow and to make it better and more precise,” adds Breda. “This is how we see digital technology changing the way the NHS works, in the future. During the pandemic, we worked with UK trauma units, using SPI, as these were being set up urgently in new centres. SPI was used to support this delivery. We are now making sure this data is also shared appropriately across the NHS and are working at high levels within Government to share this capability across the system.”

Improving surgical skills

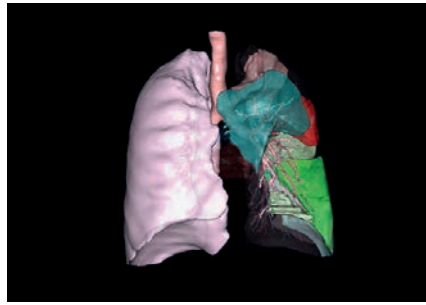
Data on surgeon and theatre performance is just one aspect that could drive improvement in the future. Digital technologies have the potential to reinvent surgical skills improvement and professional education. For example, C-SATS (Crowd-Sourced Assessment of Technical Skills) connects an operating room to the cloud to collect, analyse and compare surgical videos of a surgeon, and provides a personalised support and training programme.

Surgeons of all levels can track their performance, 24/7, and continuously refine their skills and technique based on AI-driven clinical insights and analytics, as well as unbiased assessment and expert feedback.

“As an ex-surgeon, I am really excited about this!” exclaims Casali. “Trainees can receive a standardised assessment of the quality of their movements, the precision of their technique, and the way they handle the tissues. They get scored and are provided with insights on how they can improve. They can watch a video of the procedure they performed in parallel with a procedure that has been performed perfectly, to compare their technique.

“As the video images can be synchronised, they can clearly see aspects of their technique that deviate from best practice – such as the tissue being pulled and distorted, compared to a video where the tissue is relaxed, with no risk of injury, for example,” he explains. “Part of the assessment is performed by a machine learning algorithm and the rest is impartial, as the consultants undertaking the assessment do not know who you are.

“It can be two or three consultants providing the feedback – who may be on the other side of the world. It takes away any bias during assessment – this can be



particularly valuable for a female surgeon working in a male-dominated environment, for example.”

He points out that the technology is also helpful for the more experienced surgeon who receives very little feedback: “Some consultants continuously get better throughout their career as they actively seek feedback, while some plateau and others start to deteriorate. This system allows you

to identify these trends and issues.

“This is revolutionising the way training and quality are assessed for the entire career of surgeons and has the potential to greatly improve the service we are providing to patients.”

Towards a ‘digital ecosystem’

J&J MedTech is also working on a digital ecosystem, which supports the entire patient pathway. There is a transition away from the supply of individual digital assets, towards an integrated approach.

“By building an ecosystem, you can continually integrate new technologies. We identify the customer’s needs and fit the building blocks into their ecosystem. The idea of a digital ecosystem is that all the technologies should be talking to each other and communicating with the NHS systems. Interoperability is key,” says Balaguru. ▶

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J&J MedTech UK & Ireland is already making available an orthopaedic end-to-end digital surgery ecosystem – called the Velys Digital Surgery platform. This ‘ecosystem’ uses digital technology, robotics, and data insights to elevate the orthopaedic experience for patients, surgeons, and their teams across the entire continuum of care – from the pre-operative stages of the pathway, right the way through to the post-operative.

In addition to robot-assisted surgery technology, to enhance the precision of orthopaedic surgery, the digital surgery platform includes the development of ‘Velys Insights’ – an integrated clinical support solution that connects care teams to real-time, patient-specific data to help inform decisions pre-op and post-op.

The technology includes two key capabilities: ‘Care Coordination’ to help improve case management, surgery readiness and workflow efficiencies, and ‘Patient Path Management’ designed to help care teams educate, support, communicate with, and remotely monitor patients using the Velys Patient Path mobile app during their knee, hip, or shoulder replacement journey. It provides the opportunity to assess a patient pre-operatively and track the patient post-operatively in a user-friendly way. The platform also includes image guidance capability, offering precise analysis of implant selection and positioning through user-friendly non-invasive navigation, pre-operative digital templating and case planning.

3D visualisation

“In addition, to these digital technologies is the development of cutting-edge visualisation systems, offering better insights, better treatments, better workflows and, ultimately,

better outcomes. An example of these visualisation systems is the ‘Visible Patient’ which is a patient-specific 3D visualisation technology,” Breda continues.

The interactive Visible Patient Planning software and virtual 3D model, created from a pre-operative CT or MRI, illustrate spatial relationships between diseased tissue and surrounding anatomy for each patient. Ultimately, this will help to provide a clearer “roadmap” for surgery.

“It helps surgeons to be more precise and to reduce the amount of tissue they need to remove,” reports Casali. “Instead of a 2D map, you can virtually ‘walk into’ the surgical field. You can find the tumour and find the vessels that supply the area. It is revolutionary as a training tool, but it is also revolutionary in reducing the impact for curative surgery for cancer, for senior consultants.”

He explains that the visualisation solution allows a surgeon to convert from performing a lobectomy, which involves removing a third of the lung, to a segmentectomy, which removes up to 80% less lung tissue. Surgeons can also transform a total nephrectomy into a partial nephrectomy, for example.

The vision of J&J MedTech is to ensure the solution is accessible to anyone, so they have kept the technology simple – it is an easy to install App that can be accessed with existing IT technologies found in all healthcare facilities.

The 3D reconstruction is achieved through AI. However, around 20% of the work is refined by radiologists. The model is then downloaded and can be visualised on an iPhone, iPad or laptop. However, it is also possible to wear HoloLens holographic smart glasses, to interact with the visualisation.

“In its most simplistic form – on a laptop – surgeons can visualise the chest cavity, for example, move organs from view and drill down into the exact area that they want to look at. It offers an opportunity for unparalleled pre-planning and aims to increase the number of more targeted operations, shorter lengths of stay and better outcomes. It is also good for patient education and as an aid for communication between patient and clinician, so they know what to expect,” says Casali.

“Instead of having to draw on a piece of paper, you can show the patient the tumour and explain what you are going to do. The more you have this type of engagement and understanding, the more empowered the patient becomes – they are no longer a passive recipient of treatment passing through ‘a factory’; the patient is able to make informed decisions about tissue sparing approaches.”

“Ultimately, if you can opt for partial rather than total organ removal, the recovery is quicker, you can reduce the risk of infection, and the cost of the procedure will be reduced. It is very cost-effective, but – importantly – it has a short learning curve and isn’t creating more workload for the staff. This is how we believe digital technology can bring real value, both now and in the future. It is already transforming the way surgeons perform,” adds Breda.

Challenges to digital adoption

Following the accelerated adoption of technology, during the pandemic, there has been increased interest and excitement around the application of digital technologies in healthcare. But what are the challenges ahead, in terms of innovation adoption?

“We now understand that when the NHS

wants to do something, it can scale it quickly. We want to ensure we're continuing with the momentum in making digital advances but there are also understandable concerns around privacy and digitisation of healthcare. There are other industries, such as banking, that have solved issues around privacy and are working with highly sensitive data – there are solutions that exist. We are actively working with policymakers, governmental bodies, hospitals and care providers to build guidelines that allow a trusted exchange of healthcare data," says Casali.

He adds that there are also challenges around interfacing with old digital infrastructure in the NHS: "There is a tendency to have a plethora of technologies that don't talk to each other, with different interfaces, which results in increasing complexity within theatres. All too often, this also leads to a situation where one person may know how to use the system – but, if they are not in, the technology doesn't get used. We are therefore developing digital technologies that allow the integration of solutions, to overcome these issues."

"The IT infrastructure in the NHS is developing, but it is still not where it needs to be," agrees Balaguru. "We want to ensure the technologies we develop can go into the NHS now and can also seamlessly improve and be upgraded, as the NHS develops and improves on its digital journey. There is no point in implementing a system that won't last more than 5-10 years. The NHS is now investing in its digital strategy, and we are building technologies that will survive into the future. It is also important that, as new technologies come in, that the NHS keeps an open door to them."

Another challenge, according to Breda, is persuading healthcare providers to look beyond the initial cost of investment, to understand the value and longer-term cost benefits across the whole of the care pathway.

"This requires a different mindset – procurement needs to be along the patient pathway and across different siloes. It is about adopting 'technology' rather than just 'a device'. Now that the UK has its own regulatory system [post-Brexit], the government now has a huge opportunity to build a system that enables technology to be adopted faster, without bureaucracy, which is approved for use in the UK.

"If something is approved by the FDA, why does it have to take years to reach the UK for instance? There is an opportunity for an independent regulatory system to be created that speeds up innovation and enables faster access.

"We also need to move to digital labels on medical technologies, as part of this transformation of regulatory requirements, so that data can be added to, or changed,

without having to physically transport the item.

"One of the biggest challenges that the healthcare system is facing, in the next few years, is the supply of products. We cannot let patients down because the product is not there. The product shouldn't be sitting somewhere in a facility because it needs the right label to be put on it, when it could be changed in just a few seconds, centrally. While this may seem basic, this is also part of digital innovation."

The future

In the future, the J&J MedTech leadership team say there will be more predictive analytics – building on machine learning and artificial intelligence capabilities, combined with enhanced visualisation systems.

"In terms of R&D, we are looking for further opportunities to develop our capabilities across new technologies as the digital acceleration continues to advance," Balaguru comments.

Casali predicts there will be increased use of technologies that reduce the cognitive workload for surgeons. However, just as automotive technologies are increasingly using GPS for navigation and can now correct drivers when they deviate across 'the white lines', digital surgery technology will also seek to help surgeons navigate surgery and correct them when they deviate from best practice during a procedure. The technology has the potential to provide "guidance away from mistakes" or unwanted manoeuvres.

Ultimately, the data captured from the plethora of digital assets in operating theatres will offer the potential to generate further improvements and insights in surgery. However, the leadership team emphasise that the rich data captured "must be used in a valuable way" that will drive better outcomes and efficiency. Essential to this will be ensuring that every technology element along the patient pathway is able to talk to each other – forming a healthcare 'ecosystem'.

"Our priorities, in the immediate future, are to align with the priorities of healthcare systems – to help the NHS to tackle the unprecedented waiting list, improve clinical outcomes and patient experience, as well as improve staff engagement. These are the priorities that we will keep on investing in... The bigger picture will be all about making medical interventions smarter, more personalised, and less invasive," Breda concludes.

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References

- 1 SPI's customer data analysis overview from 1/2/2017 to 1/7/2018, N = 53 surgeries
- 2 SPI's customer data analysis overview from 6/12/2019 to 3/18/2020, N = 177 surgeries

Hugo Breda

Hugo Breda is now the managing director of Johnson & Johnson MedTech UK & Ireland (J&J MedTech), after joining the organisation 25 years ago. He has driven the company towards addressing the quadruple aim of improving patient outcomes and experience, while reducing the total cost of care and improving staff experience. Hugo joined J&J in Belgium, as a sales rep for Janssen (the pharmaceuticals company of Johnson & Johnson). He then went on to lead Oncology, CNS, Immunology and General Medicine businesses in Austria, Switzerland and France, before serving as J&J MedTech general manager in Belgium & the Netherlands, then as VP of Strategic Capabilities for MedTech EMEA.

Gianluca Casali

Gianluca Casali is the medical director for Johnson & Johnson MedTech UK & Ireland and has been instrumental in leading initiatives that shape the healthcare system. Before joining J&J MedTech in 2019, he practiced as a cardio-thoracic surgeon for over 20 years. He pioneered the introduction of VATS lobectomy, a minimally invasive treatment of lung cancer when he moved to Bristol as the standard of treatment for early stage lung cancer and has also served as lead clinician for thoracic surgery, (University Hospital Bristol), lead for lung cancer, (University Hospital Bristol) and deputy divisional lead for the Division of Head Neck and Surgery.

Bala Balaguru

Bala Balaguru was a founding member of the Strategic Capabilities team at Johnson & Johnson MedTech in the UK, and has recently assumed the lead as commercial & strategic capabilities senior director for the UK & Ireland. He has been one of the driving forces behind UKI's MedTech journey, and has helped develop commercial models to drive the business forward. Prior to this, Bala has worked across the UK health sector in the delivery of clinical services in acute hospitals, as a regulator in DH and as a management consultant to the health sector in two Big 4 firms.