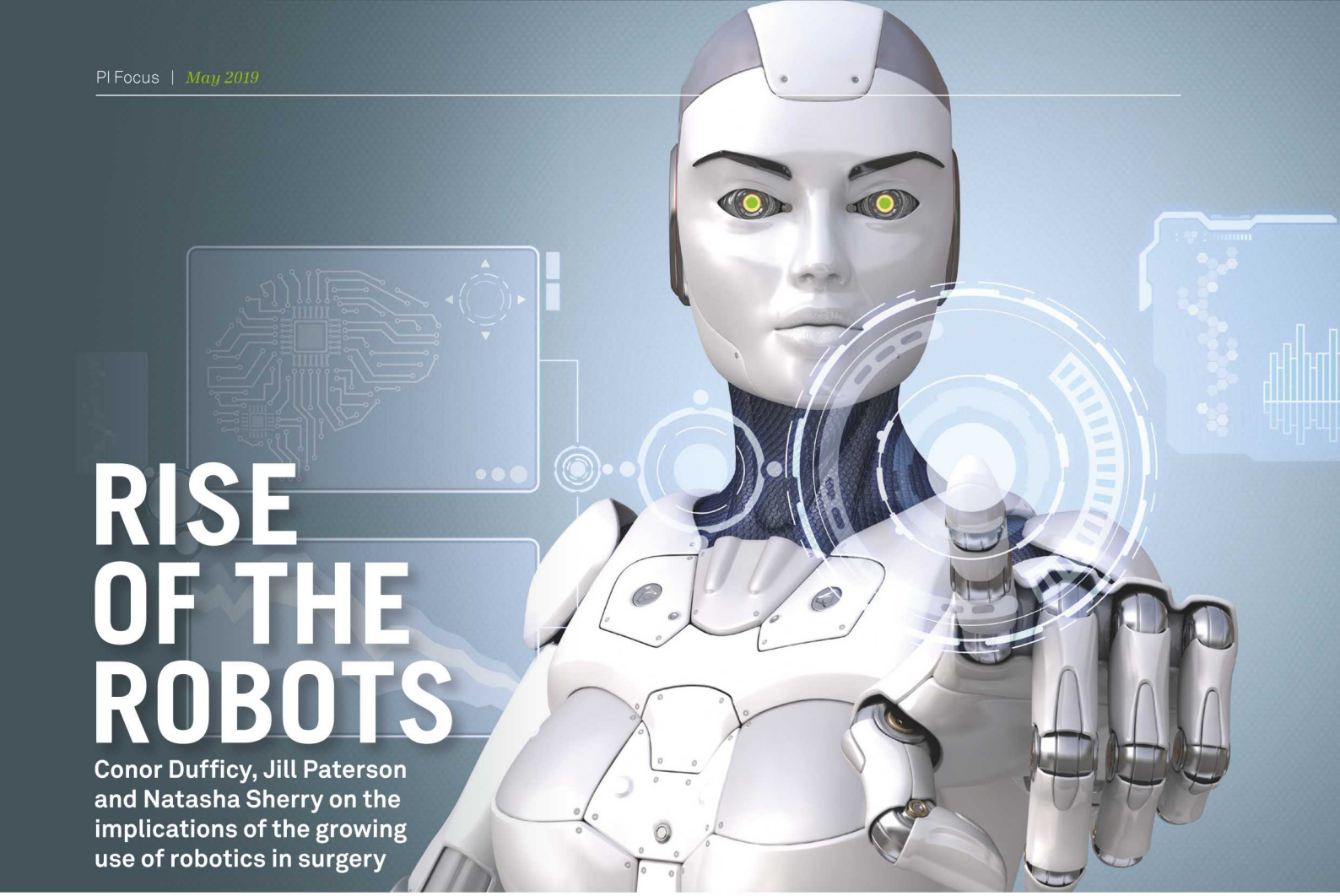

RISE OF THE ROBOTS

Conor Dufficy, Jill Paterson and Natasha Sherry on the implications of the growing use of robotics in surgery

The last message from Mars from Nasa's roving robot 'Opportunity' in February this year – 'My battery is low and it's getting dark' - was almost childlike and forlorn.

News of Opportunity's 'death' sparked worldwide expressions of consolation. Robots have become such a part of our existence that we personalise them and even grieve their loss.

Robots have been assisting in surgery since 1983 when the *Arthrobot* was used to position a patient's limb on voice command by the human surgeon.

From the mid-2000s, there has been rapid expansion and robots have been used ever-more extensively, with more than 1,500 robotic prostatectomies being carried out in the UK per year, and improvements to patient safety and recovery time being major reported benefits (see *Estey EP (2009) Robotic prostatectomy: The new standard of care or a marketing success? Canadian Urological Association Journal. 3 (6): 488-90*).

In the US, the numbers are vastly higher, even allowing for the population difference, with an estimated 693,000 robotic interventions in 2017 (see *https://idataresearch.com/robotic-surgery-statistics-show-movement-towards-more-minimally-invasive-procedures*).

Robotic surgery reduces fatigue and stress experienced by surgeons, if performed correctly.

It allows surgeons to carry out extremely fine and precise endoscopic procedures, removing any physiological tremor and improving access to, and the three-dimensional appreciation of, the anatomical terrain.

The House of Lords Select Committee on Artificial Intelligence has actively encouraged the development, and eventual deployment, of AI systems in healthcare and in the NHS, in particular (see *House of Lords Artificial Intelligence Select Committee's Report on AI in the UK: Ready, Willing and Able? 16 April 2018*).

This increase in computer-enhanced robotic surgery brings new problems to the medical, legal and ethical aspects of patient care.

With innovation comes risk, and while new products are introduced to the market at lightning-quick speeds, the question of whether the regulations governing these products can adapt to this rapidly changing world remains unanswered.

Responsibility for failure or underperformance may also be unclear.

Is the 'failure' caused by the 'product' – or its use? Whether the fault lies with the surgeon or the trainer / manufacturer / hospital for setting inadequate guidelines may need resolution.

Sometimes the surgeon will not even be in the same location as the patient, perhaps not even the same jurisdiction. Litigation involving the use of robotic surgery may become very complex.

Nasa's roving rover appears to have shown that a robot can 'live', 'die', be missed and mourned. But, at least for now, it cannot be sued!

The EU has already begun consideration of a legal framework for robotic surgery (see *European Civil Law Rules In Robotics - A Study PE 571.379 and European Parliament resolution of 16 February 2017 P8TA(2017)0051 Civil Law Rules on Robotics and Report on a comprehensive European industrial policy on artificial intelligence and robotics (2018/2088(INI))*.

The EU Parliament has proposed regulations to ensure that the procedures for testing new

medical robotic devices are safe, with associated guidelines and codes of conduct.

The Parliament considered various civil liability regimes including strict liability, a risk management approach and obligatory insurance. They asked the EU Commission to consider how to apportion liability between trainers and surgeons, and even contemplated legal personhood for the robot itself.

The Commission has since considered a review of Directive 85/374/EEC on Liability for Defective Products. However, no legislation has been passed to date.

Case study

In 2015, 69-year-old Stephen Pettitt died due to complications arising from heart surgery at the Freeman Hospital in Newcastle, which was undertaken with assistance from the surgical robot *Da Vinci*, the first of its kind in the UK.

At the inquest touching his death in November last year, coroner Karen Dilks found that 'Mr Pettitt died due to complications in an operation to treat mitral valve disease and in part because the operation was undertaken with robotic assistance.'

Several issues in Mr Pettitt's care serve as serious warnings to the surgical community.

First, it was discovered that the operation lead, Sukumran Nair, had received no prior one-to-one training with *Da Vinci*, but had only practised alone on a simulator.

The learning-curve that naturally follows the introduction of any new technology is well-known in the medical community, and evidence was given at the inquest (by assistant surgeon Mr Thasee Pillay) that as many as 40 robotic operations would need to be carried out in order 'to overcome the learning curve'.

This then poses the questions: should more training have been required by the hospital and undertaken by Mr Nair prior to him being permitted to operate using the device? And what should the benchmark for him to have been permitted to perform the surgery have been?

Second, the role and responsibility of third parties brought in to oversee or assist during operations should be clearly defined prior to surgery.

In Mr Pettitt's case, 'proctors' or experts in robotic surgery were supplied by Edwards Lifesciences, an American medical equipment company, but walked out of the operation midway.

The inquest later heard evidence that in any event, as they were not registered with the GMC, they would not have been qualified to intervene.

This creates clear risks for patients where reliance is placed on the expertise of third parties who appear to owe the patient no established duty of care.

The coroner called for national guidelines in relation to proctors.

Third, the proper procedure for consenting patients undergoing such novel surgeries must be evaluated carefully by hospitals and medical practitioners, to ensure that patients are aware of the risks and benefits - particularly in comparison with traditional procedures.

In Mr Pettitt's case, the inquest heard that he had not been told that surgery involving the *Da Vinci* was riskier than conventional surgery, which would have carried a 1% - 2% risk of death.

What are the legal considerations for cases like these?

From a legal perspective, the use of robotics in surgery creates new areas of uncertainty, and places greater demands on our existing legal framework to regulate products that were not anticipated during initial drafting; and to separate the user from the product when default occurs.

For the legal practitioner, taking on these types of cases could mean treading into unchartered territory, and extra consideration will need to be given to each stage of the litigation.

The first step in investigating a claim where injury has potentially been caused through the use of a surgical robot will be to identify what caused the robot to function incorrectly.

A vast number of issues must be considered, including erroneous surgeon engagement with the robot, poor training of the surgeon, defective design of the robot's hardware, manufacturing faults, and software errors.

The number of elements to examine becomes even more numerous in cases of robotically-assisted minimally-invasive surgery, where the surgeon uses a telemanipulator or computer control to direct the surgical instruments.

The most common robotic malfunctions are instrument alteration, mechanical arm alterations, console defects, optical system problems, or software issues (see *Malfunctions of robotic system in surgery: role and responsibility of surgeon in legal point of view DOI 10.1515/med-2016-0055*).

Once the cause of the malfunction has been determined, the correct defendant can then be identified.

Claims in product liability are governed primarily by the Consumer Protection Act 1987 (CPA), with 'producers' being liable.

Producer is defined by s.1(2) to include the manufacturer, those who hold themselves out as a producer, importers into member states, and suppliers of the product (by virtue of s.2(3)).

Therefore, it should be relatively straightforward in cases of defective hardware design to bring actions against the hardware manufacturer.

It is unclear, however, whether software used to operate the robot would constitute a 'product' for the purposes of the CPA (see *Butterworths Common Law Series: The Law of Product Liability (2nd ed.) at 4.58 – 4.65*).

It is also unclear if a software developer and the underlying patient would have sufficient proximity for a claim in negligence - or even if an injury from surgery would be 'foreseeable' to a company writing a line of code.

The extent to which surgeons will be responsible for damage caused by a defective robot has yet to be determined.

In Mr Pettitt's case, complications led to him developing a bleed that blinded the robot's camera, after which the surgeons decided to move to open heart surgery.

Unfortunately, despite moving to a more conventional method, Mr Pettitt's heart tissue had deteriorated to such an extent that he died from multiple organ failure in the following days.

The stage at which a surgeon decides to abandon robot-assisted surgery and revert to more traditional methods, therefore, is likely to become a key question when considering causation in cases of injury or death.

What can be done to minimise risk?

It is clear that the use of robots in surgery will only increase with each technological advancement, but it is important that steps are taken to minimise the risks associated with these innovations.

After initial introduction to the market, ongoing monitoring of adverse events associated with these devices will be of key importance, and a cohesive approach should be taken by medical practitioners, manufacturers, and software developers if these are separate entities in recording these events.

In the US, a database called The Manufacturer and User Facility Device Experience (MAUDE) was developed as a way for healthcare professionals, patients and consumers to voluntarily report device-related safety issues to the FDA.

Collecting data in this manner has the benefit of allowing objective analysis to be performed, without relying on manufacturers to carry out their own post-market monitoring.

However, this system of reporting is not without its limitations.

The voluntary nature of data collection creates the risk of under-reporting and introduces bias into any analysis that might subsequently take place.

If a similar system were to be implemented in the UK, it is crucial that a clear and consistent method of reporting events is adopted, and for reporting to be made compulsory by health care professionals using the products, to ensure that the statistics derived from the database are reliable.

Sufficient information must also be included by those reporting adverse events to ensure that the data is meaningful, and that action can be taken when concerns about a particular product develop.

Mr Pettitt's tragic death demonstrates the importance of having a consistent approach to the training of surgeons in the use of these devices, including a 'benchmark' that surgeons must meet before being permitted to operate on patients.

Generally, individual hospitals set their own standards for the training of surgeons in novel procedures, but this leaves them open to risks that could be minimised if there were a standardised training requirement for robotic devices, which could perhaps be set out by the manufacturer.

Informed consent in robotic surgery raises new issues.

Because of the intrinsic complexity of the surgery, it may be very difficult to explain it in a readily comprehensible form to the patient, particularly in light of the patient-specific requirements of *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

To ensure that patients give informed consent to procedures involving the use of robots, it will be important that, at the very least, patients are made aware of their surgeon's level of training and experience in using the product, particularly in light of the steep learning curves associated with new medical technology.

Patients should be informed about the possibilities of robot or software malfunction, and they should be offered alternative methods by which their surgery can be carried out, such as traditional methods, if appropriate.

Patients should be told if the proposed robotic surgery reduces the risk of adverse outcomes, or not, when compared with a more conventional approach.

The learning curves referred to above will normally mean the number of procedures that a surgeon has to perform to reach an acceptable level of experience, length of operation and margin for error.

A study of learning curves in robotic-assisted prostatectomy, and how quickly surgeons could adopt the requirements, showed very broad variation (see *The cost of learning robotic-assisted prostatectomy Steinberg, Merguerian, William, BihrleIII, Seignea j.urology.2007.11.118*).

Proficiency will generally require the surgeon to have facility with use of the system, knowledge of the medical instruments employed and their robotic control, and the capability of resolving technical problems with the system.

It is not unusual for manufacturers in the US to deny any liability for training and proctoring for these devices.

When introducing new products onto the market, manufacturers should ensure that the 'known unknowns' regarding the products have been properly communicated to medical practitioners to ensure that the potential risks are as transparent as possible.

Conclusion

In 1942, in his short story 'Runaround', Isaac Asimov presaged the problems of human and robot interaction and set out the Three Laws of Robotics.

The first of these was that a robot may not injure a human being or, through inaction, allow a human being to come to harm.

However, unintended harm would seem to be an inevitable part of human interaction, and one needs to consider the implications when harm ensues if that interaction is with the assistance, or through the medium, of a robot.

The introduction and continued development of robotics for new surgical uses is undoubtedly a cause to celebrate, but manufacturers and developers need to ensure that they take the time to risk-assess their products properly before release onto the market.

A cohesive approach between product-developers and hospitals, in particular setting benchmarks for learning objectives, should also be encouraged to ensure that patients are provided with the best care possible.

The legislature, too, needs to consider ways to improve the delineation of liability between the various parties involved.

Asimov's three laws would never have been enough.

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