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*January 2018 Enquiries: Chris Pockett, Head of Communications (+44 1453 524133)*

**Improving patient outcomes with smart implants**

**In the 16th century, broken bones were physically manipulated back to the correct orientation by a bone setter. Failing that, the local blacksmith would step in. Advances in medical treatments mean we no longer need to worry about a blacksmith fixing our broken bones.**

**Here, Matt Parkes, Senior Medical Development Engineer at Renishaw and currently working on a collaborative project with Western University in Ontario, Canada, discusses how smart implants are changing the way bone diseases and injuries are treated.**

Since the early 1900s, surgeons have been using metal implants in healthcare, typically to treat bone diseases including osteoarthritis and inflammatory rheumatoid arthritis, as well as in reconstruction therapy. Though a long-established technology, traditional implants often cause challenges for patients and surgeons. One area currently being developed is smart implants, which improve patient outcomes, bringing the technology into the modern age.

Implants can be smart in two ways, either by being additively manufactured to produce patient specific implants (PSIs) from computed tomography (CT) data, or by incorporating sensors. Still in the early phases of development, inbuilt sensors could collect patient-specific data, enabling surgeons and other healthcare professionals to tailor treatment to the needs of individual patients.

**The challenges with traditional implants**

One of the key challenges that traditional implants present is loosening. Particularly common following joint replacement procedures, loosening can be a result of poor osseointegration — the structural and functional connection of the implant with the patient’s bone. This can occur due to wearing over time and is exacerbated by factors including infection and poor compliance with advised physiotherapy regimes.

Another limitation of traditional metal implants is that they are only manufactured in a discrete number of shapes and sizes. Therefore, it’s unlikely patients will receive an implant that fits them accurately. This can cause poor physical function and contribute to loosening.

Poor physical function can also occur because of stress shielding — the process whereby metal implants remove stress from the patient’s bone. The bone responds by reducing in density and therefore becomes weaker.

The increasing incidence of obesity is one reason joint replacements are becoming more common in young people. This poses longevity issues as implants can reach their maximum lifespan and need replacing several times during the patient’s lifetime.

To combat these issues, researchers and engineers have been developing implants in new ways, using techniques such as additive manufacturing (AM). The technology aims to improve the form, fit and function of implants.

**Additive manufacturing**

AM has been used as a manufacturing method in the medical field for over ten years, but the technology is yet to reach its full potential in this industry.

Because AM builds an implant layer by layer, it’s possible to produce PSIs that are a more accurate fit for the patient. The manufacturing method also has fewer geometric constraints than subtractive manufacturing. PSIs designed and manufactured according to a patient’s CT scan encourages the implant to integrate with the patient’s bone, reducing the risk of loosening. As a result, patients are less likely to suffer pain or require revision surgeries.

As well as being able to manufacture an exact shape, AM enables surgeons to control additional properties of the material. They can design implants that mimic the patient’s bone stiffness, density and trabecular structure, which can reduce stress shielding and improve osseointegration and physical function further.

**Sensors**

Implants can also be made smarter by adding sensors. This allows clinicians to accurately measure patient data — the key to evidence-based medicine. One parameter a sensor could measure is temperature, as a raised temperature can indicate an infection before symptoms appear. This could benefit both patients and doctors by enabling treatment before the infection becomes complicated and expensive to treat.

Sensors can also be incorporated into bone reinforcement implants, which are used to help fractures heal. In this example, sensors can measure the strain exerted on the implant, which indicates the extent the fracture has healed. From this information, surgeons can determine the best time to progress the patient to the next stage of therapy and could identify healing problems earlier than currently possible.

As implant loosening can be affected by non-compliance with physiotherapy, technology has been developed to overcome this issue. Incorporating accelerometers to monitor the movement of patients would allow healthcare professionals to remotely obtain data. These could be used to determine whether a patient is complying with their prescribed physiotherapy and rest regime.

One institute developing technology in this field is a collaboration between Renishaw and Western University in Ontario, Canada, who have set up the Additive Design in Surgical Solutions (ADEISS) Centre to bring together clinicians and academics to generate novel 3D printed medical devices. ADEISS recently showcased the smart hip concept, which uses temperature sensors and accelerometers to collect patient data that can be communicated to a remote device.

By making use of advanced sensor technology, there is now potential for the development of implants that can detect an infection and subsequently secrete the appropriate dose of antibiotic to treat it before it becomes symptomatic. This could reduce the number of patients admitted to hospital.

**Changing the face of medicine**

The ultimate driving force for developing smart implants is the potential to considerably improve patient outcomes. AM offers several benefits, one major advantage being that the fit time schedule is reduced — a benefit to patients and surgeons. The benefits that smart implants have over traditional metal implants could mean that patients will suffer less pain and discomfort, will be less likely to become seriously ill due to infection and could be at lower risk of needing revision surgeries, critical for younger patients.

However, for widespread clinical adoption of smart implants, there are still challenges to overcome. Clinicians must run clinical studies to collect data on the safety and performance the implants offer to patients. This must all be done in line with regulations such as the EU Regulations on Medical Devices. A further key consideration is the processing of personal data in smart implants and how that data is used by the industry and clinicians.

The treatment of bone diseases and injuries has come a long way since the days of bone setters and blacksmiths. Patients can now receive metal implants specifically designed to their individual requirements. Pioneering research institutes are overcoming the hurdles and improving the technology, so the uptake of additively manufactured and data-driven implants is set to rise, improving outcomes for patients and hospitals.

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Notes to editors

UK-based Renishaw is a world leading engineering technologies company, supplying products used for applications as diverse as jet engine and wind turbine manufacture, through to dentistry and brain surgery. It has over 4,000 employees located in the 35 countries where it has wholly owned subsidiary operations.

For the year ended June 2017 Renishaw recorded sales of £536.8 million of which 95% was due to exports. The company’s largest markets are China, the USA, Japan and Germany.

Throughout its history Renishaw has made a significant commitment to research and development, with historically between 14 and 18% of annual sales invested in R&D and engineering. The majority of this R&D and manufacturing of the company’s products is carried out in the UK.

The Company’s success has been recognised with numerous international awards, including eighteen Queen’s Awards recognising achievements in technology, export and innovation.

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