News and views

1 | SMITH + NEPHEW

Smith + Nephew, the global medical technology business, announced new indications for use for its PICO 7 and PICO 14 Single Use Negative Pressure Wound Therapy (sNPWT) Systems. The US Food and Drug Administration (FDA) cleared the systems for use on closed surgical incisions, to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections (SSIs) for high-risk patients in class I and class II wounds
- Post-operative seroma
- Dehiscence

The development of post-operative surgical site complications (SSCs), such as surgical wound dehiscence, is a substantial burden for patients and healthcare systems, globally. Post-operative wound dehiscence cases from the Nationwide Inpatient Sample demonstrate 9.6% excess mortality, 9.4 days of excess hospitalisation and $40 323 in excess hospital charges relative to matched controls. In addition, it is estimated that 5% of all patients undergoing a surgical procedure will develop an SSI. In the United States alone, more than 500 000 patients are affected by SSIs each year, resulting in about 8000 deaths annually. SSIs are also the most common reason for readmission to the hospital, accounting for 19.5% of overall readmissions. However, 60% of all SSIs are considered preventable.

‘As a high-volume elective hip and knee replacement surgeon, I am sending more patients home the same day with outpatient surgery’, said Dr. Bashyal, Director of Outpatient Total Joints, NorthShore University Health System, Chicago, Illinois. ‘The PICO System, has been a game changer in managing closed incisions in my practice by helping to reduce the incidence of wound complications including drainage, seromas and superficial infections’.

As part of the process for FDA clearance of the PICO 7 and 14 sNPWT Systems, the clinical evidence was subject to rigorous review. Only the highest quality evidence was considered, such as randomised controlled trials. Overall, 25 studies enrolling 5560 patients were included, spanning a variety of surgical specialties such as caesarean section, orthopaedics and colorectal. By performing meta-analyses on these studies, the PICO 7 sNPWT System demonstrated statistical efficacy when compared to conventional dressings, including the reduction of the incidence of superficial and deep incisional SSIs for class I and class II wounds. The PICO System also reduced the odds of post-operative seroma and dehiscence.

Recently celebrating 10 years in clinical practice, PICO sNPWT has been used on an estimated 2.3 million surgical incisions, helping to prevent surgical site complications. The PICO System has helped reduce hospital stays and spared healthcare systems the associated costs of nursing time and resources.

Additionally, the PICO 7Y System, which treats two wounds simultaneously, was also cleared by the FDA to aid in the reduction of the incidence of superficial incisional SSIs for high-risk patients in class I wounds, post-operative seroma and dehiscence. The PICO System is demonstrated to be effective for up to 7 days for aiding in reducing the incidence of surgical site infection.

To learn more about PICO sNPWT see www.possiblewithpico.com.

2 | QUEEN’S UNIVERSITY BELFAST

Non-invasive, tiny indicator changes colour if the wound shows early signs of infection

Scientists at Queen’s University Belfast have invented a tiny indicator that changes colour if a patient’s wound shows early signs of infection.

The non-invasive indicator, which is around the same size as one of our fingertips, is the first of its kind. It does...
not make any contact with the wound but detects the beginnings of infection by sniffing the air above it.

It can be added to already existing bandages and allows infections to be detected without taking off the dressing – something which can inhibit the healing process and increase the likelihood of wound infection.

It is estimated that around 1% to 2% of people in developed countries will experience a chronic wound in their lifetime and in the United Kingdom £3.2 billion is spent each year treating the problem.

Professor Andrew Mills from the School of Chemistry and Chemical Engineering at Queen’s has been leading the project, alongside colleagues from the School of Pharmacy and School of Electronics, Electrical Engineering and Computer Science. The project was funded by the Engineering and Physical Research Council, which is part of UK Research and Innovation.

The research findings have been published in the Royal Society of Chemistry’s ChemComm journal.

Professor Mills says the research could have a major impact on healthcare globally: ‘The colour-changing indicator we have developed is just a tiny dot, but it could have hugely positive benefits for our patients and health care systems worldwide’.

Usually if a patient has a wound, especially a chronic wound, a nurse or doctor will check for infection every 2 to 3 days by removing the dressing. Changing a dressing can be unnecessary, painful and an infection risk. ‘All of this could be avoided with our indicator, saving time, money and pain’.

Explaining how the indicator works, Professor Mills says: ‘If infection is starting in a wound, there is often a sudden growth of aerobic microbiological species and as they grow, they generate carbon dioxide’.

‘Our indicator detects this rise in carbon dioxide causing the dot to change colour, flagging the infection in its early stages before it actually takes hold and overwhelms the patient’s immune system. This means it can be treated quickly, avoiding unnecessary pain for the patient and significantly reducing the possible need for hospitalisation’.

Professor Brendan Gilmore from the School of Pharmacy at Queen’s says: ‘This sensor can provide an early warning of infection before it has progressed to a chronic, persistent colonization of the wound by microorganisms which are by then much more difficult to treat effectively with antibiotics’.

‘The sensors respond quickly to the presence of infection and allow healthcare providers to make informed decisions about managing the wound, including whether or not to use antibiotics. Inappropriate antibiotic use is known to drive the emergence of antibiotic resistance. Crucially, these sensors can tell us whether or not the intervention has worked in killing the microorganisms which caused these infections’.

The project is entering the next phase where an app will be developed so that the patient will be alerted if there is an infection. The same information would also be sent to the patient’s nurse or doctor and be used to inform treatment plans.

‘We are incredibly pleased to now have our research findings published and to be able to offer a simple, inexpensive, non-invasive way to monitor the progress of healing wounds. We are currently in discussions with industry in how to take this forward and we hope to run clinical trials soon’.

Professor Andrew Mills
The School of Chemistry and Chemical Engineering, Queen’s University Belfast

3 | CONVATEC GROUP

ConvaTec Group, a global medical solutions company focussed on the management of chronic conditions, announced that it has entered into a definitive agreement to acquire Triad Life Sciences Inc., a US-focussed medical device company that develops biologically derived innovative products to address unmet clinical needs in surgical wounds, chronic wounds and burns. The transaction, which is subject to regulatory approvals and other customary conditions, is expected to close during Q1 2022.

For ConvaTec, this represents an entry into the large and rapidly growing wound biologics segment. This segment is currently estimated to be worth $1.8 billion per annum globally with a projected growth of high single digit percentage per annum. Regenerative medicine and biologically derived therapies are frequently used to treat hard-to-heal wounds which, in the United States alone, affect 3.7 million patients each year.

This proposed acquisition is consistent with ConvaTec’s FISBE strategy (Focus-Innovate-Simplify-Build-Execute). It strengthens ConvaTec’s Advanced Wound Care position in the United States (Focus) and secures access to a complementary and innovative technology platform (Innovation) that enhances advanced wound management and patient outcomes.

This technology, know-how and a pipeline of innovative products based on porcine placental tissue, offers attractive characteristics in the treatment of hard-to-heal wounds. Triad’s latest offerings, InnovaMatrixAC and InnovaBurn, are the first 510k cleared porcine placenta-derived extracellular matrix products in the United States. Sales of these products commenced in
2021. In addition, Triad has an attractive pipeline of new products for advanced wound care and also a technology platform with the potential to enter the regenerative medicine segment.

Founded in 2017, Triad Life Sciences is based in Memphis, Tennessee, and currently has over fifty employees. The company develops, manufactures and commercialises their product portfolio. These products are highly complementary to ConvaTec’s existing portfolio and will enable the Group to meet a wider range of needs of both patients and health care practitioners. This transaction will also be commercially complementary. Triad will bring expertise in this novel and rapidly growing segment, whilst benefitting from ConvaTec’s global commercial, quality & operations and R&D capabilities.

The initial consideration is $125 million with two potential additional payments of $25 million each relating to short-term milestones. There are also two earnout payments conditional on performance during year 1 and year 2 post completion, with the maximum earnout of $275 million based on stretching financial performance over the period.

This is an exciting opportunity for ConvaTec, with powerful strategic logic, a strong contribution to future growth and an attractive financial profile. The transaction is expected to be immediately accretive to sales growth, and the return on invested capital is expected to exceed the Group's cost of capital in year three. The consideration will be satisfied from existing cash balances and debt facilities.

4 | UNIVERSITY AT BUFFALO

Light therapy may accelerate the healing of skin damage from radiation therapy by up to 50%, according to a recent University at Buffalo-led study

The research found that photobiomodulation – a form of low-dose light therapy – lowered the severity of skin damage from radionecrosis (the breakdown of body tissue after radiation therapy), reduced inflammation, improved blood flow and helped wounds heal up to 19 days faster.

The findings, published on 28 December 2021, in Photonics, follow prior reports on the effectiveness of light therapy in improving the healing of burn wounds and in relieving pain from oral mucositis caused by radiation and chemotherapy.

The research was led by Rodrigo Mosca, PhD, visiting fellow from the Nuclear and Energy Research Institute (IPEN) and the Federal University of Rio de Janeiro, both in Brazil. Carlos Zeituni, PhD, professor at IPEN and the Federal University of Rio de Janeiro, is a senior author.

TO our knowledge, this is the first report on the successful use of photobiomodulation therapy for brachytherapy’, said senior author Praveen Arany, DDS, PhD, assistant professor of oral biology in the UB School of Dental Medicine. ‘The results from this study support the progression to controlled human clinical studies to utilise this innovative therapy in managing the side effects from radiation cancer treatments’.

Brachytherapy is a form of radiation therapy where a radiation source is implanted within the cancer tissue, exposing surrounding healthy tissue to lower doses of radiation than through teletherapy, a form which fires a beam of radiation through the skin to reach the tumour. Although brachytherapy has improved the precision and safety of cancer care, skin damage is still an unfortunate side effect.

‘For over 40 years, photobiomodulation has been known to accelerate the healing of acute and chronic wounds, triggering cellular processes that control inflammation, pain signaling, and tissue regeneration and repair’, said Mosca.

Research suggests that the effects of photobiomodulation do not extend to tumour cells, likely due to their perturbed metabolic and regulatory signalling, adds Arany.

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