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SPINAL CORD INJURY BC

WINTER 2020



Better Bug Beaters

New research creates hope for antibiotic-free methods of treating two of the most troublesome infections for people with SCI

Pressure Relief

Could an innocuous white powder revolutionize pressure ulcer treatment?

What if we told you that a daily sprinkling of a fine white powder on your open pressure ulcer might cut the healing time in half, or even more? If you think we've lost the plot or have joined Gwyneth Paltrow in the snake oil business, we wouldn't blame you. In fact, we'd be happy if this was your reaction, since we believe in science here at SCI BC—and the basis for all good science is healthy skepticism.

But we're keeping an open mind about Amicapsil, a compound developed in the UK that's based on something called MPPT, short for micropore particle technology. You may want to do the same. Amicapsil has a growing number of highly-satisfied end users with SCI, mainly in the UK. Yes, it's true that anecdotes do not constitute conclusive proof. But there's also a growing amount of scientific evidence to support Amicapsil—enough to suggest that there may be something to it, and that, given the enormous implications of pressure ulcers, it needs to be investigated fully.

Staggering Costs, No Treatments

People with SCI aren't the only ones prone to pressure ulcers, but we think it's probable that no one is impacted more by them. Lack of muscle mass below injury means people with SCI lack "padding" to prevent pressure ulcers. Lack of sensation means those with SCI often don't know they've injured themselves or that a pressure ulcer is getting more serious. And it's recognized that people with SCI have compromised immune systems that makes it easier for pressure ulcers to become serious.

The costs of pressure ulcers are enormous—to individuals, and to society. On an individual level, a serious pressure ulcer can stop us in our tracks, with the only remedy being weeks, months or even years of bedrest. The combined costs to our healthcare system are even more jaw-dropping. There's no current estimate of the economic burden of treating pressure ulcers in Canada, but extrapolating the results of a recent study in the UK suggests the annual cost to our healthcare system is a

whopping \$490 million per year. And that's not even considering the byproducts of this treatment: tons of non-recyclable plastic waste, and tons of antibiotics released into the environment.

Despite this, it might surprise you to learn that there's no gold standard for treating pressure ulcers—particularly deeper wounds that refuse to close and heal. Nor has there ever been any game-changing research or treatment breakthroughs. Strategies once hailed as promising have since been determined to be ineffective at best, and harmful at worst. These include a wide range of antimicrobials, including antibiotics, natural ingredients like honey that have antimicrobial properties, and antiseptics.

What we've known for some time is that, once infected, pressure ulcers become difficult to close and heal. Not surprisingly, health professionals have looked to antibiotics and antiseptics to stem infections, and still do. But several recent summaries of existing research have raised serious doubts about these approaches. One, published in 2016 by the highly skeptical Cochrane Library, concluded that, "There was no consistent evidence of a benefit to using any particular antimicrobial treatment for pressure ulcers." In the USA, the FDA concluded in 2016 that there is no evidence that antibiotics or antiseptics have any effect on wound infection or support healing. In the UK, the National Institute for Health and Care Excellence (NICE), in its guidance on pressure ulcers, specifically states that antibiotics and antiseptics should not be used for treatment.

Bacteria: Friend or Foe?

Recently, there's been some research findings that are changing our understanding of how pressure ulcers and other wounds heal—and the use of Amicapsil builds on these findings.

At the heart of this is a growing realization of the importance of our skin's microbiome—an ecosystem of bacteria, fungi, viruses, and mites. When balanced, it's an integral part of our body's defence against infections. That's right—when it comes to our skin, a healthy microbiome of bacteria and fungi, working in concert with our bodies' immune system, is actually what



prevents dangerous bacterial infections by ensuring no single species of bacteria can become dominant.

In a serious pressure ulcer, the skin's microbiome can be compromised, allowing one or a few bacterial species to take over. This constitutes an infection, which slows or even stops healing. Our immune system tries to prevent this, but rampant bacteria secrete toxins and enzymes to thwart immune cells and attack other beneficial types of bacteria. And the infectious bacteria also secrete a biofilm that creates a slime wall "fortress" around themselves that our body's immune cells can't penetrate to do their job.

Simply put, attempting to "carpet bomb" the infection in and around a pressure ulcer with a topical broad-spectrum antibiotic or antiseptic might kill the culprit bacteria—but also all the other tiny living things essential for healing that make up our skin microbiome. In the case of antiseptics, even new cells at the wound site can be killed. There's also growing concern about drug-resistant bacteria. Today, most of us are carrying at least one resistant strain of bacteria on our skin. The risk is that, with antimicrobial treatment, the resistant type will not be harmed, but the non-resistant types will be killed. So antimicrobial treatment can actually provide the resistant bacteria with ideal conditions to aggressively multiply and infect the wound.

Rebalancing the Microbiome

All of this suggests that a better approach to healing difficult pressure ulcers would be supporting the immune system as it attempts to regain some balance in the microbiome at the wound site. This is exactly what MPPT does, according to the company that developed it, the UK's Willingsford Healthcare. The company describes MPPT and its MPPT product, Amicapsil, as "passive immunotherapy that disrupts the weaponry bacteria and fungi use to inhibit the immune system, allowing the immune system to recover."

According to Dr. Frank Sams-Dodd, co-founder of Willingsford Healthcare with his wife Jeannette, Amicapsil is

composed of "fine, highly porous particles that absorb wound exudate into a micropore structure." He says that the micropores act as pumps, which are powered by evaporation—the exudate, or pus, which contains the toxins and enzymes secreted by infectious bacteria as weapons against the immune system, is drawn from inside the wound to the surface, where it evaporates. The removal of these toxins and enzymes allows the immune system to recover and regain control to balance the microbiome—necessary for healing. He adds that Amicapsil also has the ability to create holes in the biofilm protection erected by dangerous bacteria, allowing immune cells to penetrate and do their job. All of this is achieved with mechanical action rather than antimicrobial action.

"Amicapsil was part of a 10-year early research effort specifically aimed at identifying improved treatments for wounds, followed by 10 years of development," says Sams-Dodd, a neuroscientist with 25 years of experience in the pharmaceutical and medical device industry. "The interest and idea came from the frustration of being unable to heal difficult wounds."

We pressed Sams-Dodd for some more details about the composition of Amicapsil, but his responses were a little vague—likely necessary to protect valuable intellectual property.

"Amicapsil is fully patented for use and composition," he offered. "Amicapsil does not contain any antimicrobials and is non-polluting. It consists exclusively of natural non-toxic ingredients. It is readily biodegradable and can go directly back into the biological cycle. Its manufacture is a complicated process."

Treatment consists of first rinsing the wound with tap water, in the shower or with a squeeze bottle. Once dry, Amicapsil is applied directly to the wound. Only clean procedures are required. The wound can be left uncovered, or covered with a piece of gauze, providing it's breathable to allow airflow and evaporation. The frequency of treatment depends on the severity of the pressure ulcer and the healing progress.



A pressure ulcer treated with Amicapsil

In 2016, Amicapsil was approved for use by professionals in the UK and throughout the European Union. In 2017, approval was extended for use by individuals. It has similar approvals in Australia and New Zealand. These approvals are for use as a medical device, not a pharmaceutical, and they don't extend to providing financial coverage for the powder—users must pay themselves (more on the cost later). There are no formal approvals in Canada or the US, but there's nothing to stop people in North America from importing it for personal use.

What the Science Says

There's a surprising amount of research evidence to support the use of MPPT and Amicapsil—in humans, and in animals (wound care is a big problem for veterinarians as well). Amicapsil has been evaluated in variety of wounds beyond pressure ulcers, including trauma and surgical wounds, diabetic foot ulcers, and venous leg ulcers.

In fact, there's way too much research to attempt to summarize it in detail here. But we'll provide a few highlights.

In a 266-patient randomized clinical trial in the UK, Amicapsil was compared to the antibiotic gentamicin and the common antiseptic iodine in abscesses, surgical wounds, venous leg ulcers and diabetic foot ulcers. The study showed that it removed wound infections 60 percent faster than both the antibiotic and the antiseptic, and reduced the number of hospitalization days by 31 percent.

In a clinical case-series performed at Bristol University Hospital in 2017, Amicapsil was able to advance the healing of infected surgical wounds to the same stage in four to five days that would have taken three or more weeks with the hospital's standard procedure of using vacuum assisted closure, or VAC.

Perhaps most relevant is a case-series study of 40 acute or chronic wounds and pressure ulcers in people with SCI that's taken place in the last couple of years in the UK.

According to Sams-Dodd, Amicapsil closed all the pressure ulcers, regardless of whether they contained resistant bacteria or not, as long as the person started treatment before the wound was two months old. The older the pressure ulcer was, and the more antimicrobial and anti-septic approaches that had already been tried, the longer healing took. In many wounds over six months old, the infection had spread to the bone, but even with these, Amicapsil was able to remove the infection in the soft tissue above.

We decided to take a deeper dive into the results from one of these case studies. We chose the most recent, which

was led by Dr. Oliver O'Sullivan at the Defence Medical Rehabilitation Centre (DMRC), the UK's national rehab facility for injured military personnel.

"We have found, similar to many other rehabilitation centres, that our management of chronic wounds has prevented optimal rehabilitation," says O'Sullivan. "So when we heard about MPPT, we felt it was worth trying."

O'Sullivan's case study subject, a service man in his 30s, had sustained a complete SCI in 2016. In early 2019, he developed an abscess. Despite several aggressive interventions including surgery, the abscess turned into a serious non-healing wound over the course of seven months. That, of course, took an enormous toll on the physical and mental health of the patient, who eagerly agreed to the Amicapsil treatment.

There was a dramatic improvement in the wound after one month—it no longer produced a foul odour, and it had reduced in size significantly. "We were surprised by the progress, especially at first," says O'Sullivan. "It was clearly making a difference. After a month, we, and the patient, really felt it was worth pursuing

as it was clearly improving this chronic wound, and enabling him to undergo more rehab and improve holistically."

Treatments were reduced from twice daily to once daily. After three months, only a small open area remained. And by six months, the wound had achieved almost full resolution.

The results of the case study were published in the August 4, 2020 issue of the journal *BMJ Military Health*. "Amicapsil has the potential to improve the management of chronic wounds at DMRC with its ability to heal wounds quicker," wrote O'Sullivan in the article's conclusion.

Amicapsil in the Real World

Amicapsil has been approved to purchase since 2017, so it's not surprising that many people with SCI have tried it and reported success.

One of them is 42-year-old Peter Hamilton, a software developer who lives in Salisbury in the southwest of England. Shortly after his C5/6 injury in 2011, he developed a pressure ulcer on his sacrum. It was the bane of his existence for years, with all conventional treatments including surgery failing to resolve it.

PRESSURE ULCERS: CARRY YOUR CARD!

You've got your AD wallet card. You've got your UTI wallet card. Now you can add the pressure injury wallet card. As with all SCI BC wallet cards, the idea is to keep this resource in your wallet or purse. The card was developed as a collaboration with GF Strong clinicians Regina Colistro and Shannon Sproule with a specific use in mind: to alert your caregiver or healthcare professionals in the hopes that you can avoid a pressure injury completely. Print your own at sci-bc.ca/PressureCard, or contact InfoLine at info@sci-bc.ca or 1.800.689.2477 to get yours by mail.

Note for Patients

Give this card to your community health team, caregivers, nurses, physicians or BP team upon admission.

Use the space below and the diagrams inside to communicate your history of pressure injuries. Share this information on this card with your health professionals.

Learn more about pressure injury and SCI from Spinal Cord Injury BC:

SCI BC helpline: 1-800-689-2477
 Email: info@sci-bc.ca
 Download an online version of this card: sci-bc.ca/PressureCard

Note for Health Team

I have a history of pressure injuries.
 Location(s) and date of history: _____

I have an active pressure injury.

MEDICAL ALERT

PRESSURE INJURY PREVENTION

Please attach this card to any chart.

I have a spinal cord injury. I am at extremely high risk for developing an injury due to pressure, shear and/or insulいた mattress or padding practices. This can quickly become life threatening. I require:

- skin check on admission
- priority use of a pressure redistribution mattress
- regular turns and repositioning
- head of bed no more than 30° to prevent shearing
- avoidance of sling left in place while sitting

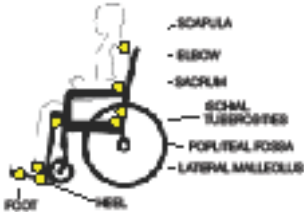
To obtain a pressure redistribution mattress in hospital, please contact the POC/Charge Nurse. Review this card for more details on pressure injury.

Produced in partnership with:




Pressure Injury Information

Pressure injuries are common after SCI. They can affect as many as one third of people with SCI each year and almost every person with an SCI experiences at least one pressure injury in their lifetime. The risk of pressure injuries increases over time when living with an SCI long-term.



SCAPULA
 ELBOW
 SACRUM
 SCAPULA
 SCAPULA
 TUBEROSES
 POP/ITREAL TUBOSA
 LATERAL MALLEOLUS
 FOOT
 HEEL

Common Locations of Pressure Injury



HEEL
 SACRUM
 ELBOW
 SCAPULA
 SCAPULA

HEEL
 MEDIAL & LATERAL MALLEOLUS
 GREATER TROCHANTER
 HEEL
 SACRUM/ON PROXIMA

Note: If you have a history of pressure injuries, or currently have active injuries, use the diagrams to circle the locations where your pressure injuries occur.

More info on pressure injury:
sciproject.com/pressureinjurysummary
livingwithsci.ca/in-health

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Satisfied Amicapsil users Peter Hamilton and Raquel Sigantoria

"The wound rarely stayed healed for more than six months at a time, and each time it broke down again it proved harder than the last to re-heal," says Hamilton. "I'm a trustee of the Spinal Injuries Association (SIA), one of the national SCI charities here in the UK. One of the other trustees brought (Amicapsil) up at a board meeting, and having had a chronic pressure sore for the best part of four years, I figured I had little to lose."

Hamilton purchased Amicapsil. Given his reduced hand function and the pressure ulcer location, he was unable to treat himself, but with daily consultations with Willingsford Healthcare, his wife and personal assistant were easily able to do the treatment. Over the course of several months, the wound closed to a tiny hairline opening—and finally resolved completely. Since then, Hamilton has successfully used Amicapsil for another pressure ulcer.

"Compared to anything else on the market, it is not far short of miraculous," says Hamilton. "I have very sensitive skin and have always been at risk of skin breakdown elsewhere. Now I just don't worry about it any more, because I know that with Amicapsil, a wound will just heal. Amicapsil has a refrigerated, unopened shelf-life of at least a year, so I can foresee me keeping some in my fridge for the next time my skin breaks down."

Another satisfied user is 38-year-old Raquel Sigantoria, a personal injury lawyer based in London who sustained a T6/7 injury 27 years ago.

She first used Amicapsil two years ago for a small, open breakdown in the IT

area (the two bones that are the lowest point of the pelvis when you're sitting). Amicapsil helped this heal in 24 hours.

"However, the biggest test was a skin breakdown following a misjudged transfer where the skin on the back of my thigh broke," says Sigantoria. "The hospital advised treating with dressings, but I had an allergic reaction to the dressing and the wound then became infected. Within three weeks of using Amicapsil, the wound was no longer infected, and within four days of the eschar and slough both being removed, the wound had virtually healed. It took about another week for the wound to be strong enough to withstand me sitting up 16 hours on it. In total, it took six weeks for Amicapsil to fully heal the pressure ulcer, which was about five cm long and 2.5 cm wide. If I had been left to follow the NHS advice I would have been on bedrest for several months with it possibly worsening."

Like Hamilton, Sigantoria needed assistance from a family member to carry out the daily treatments, which were monitored by Sams-Dodd.

"I have no doubt that using Amicapsil sped up my recovery and substantially reduced the amount of time I had to spend on bedrest compared to how long it has taken for other skin breakdowns in the past," she says. "Amicapsil is life-changing, and I now keep a bottle in my fridge for whenever I might need it."

The Challenges Ahead

Will Amicapsil revolutionize the treatment of pressure ulcers? We think it's too early to say. But if it's to do so, we believe

there are three major hurdles that need to be addressed: no insurance coverage combined with what could be perceived as high cost, lack of awareness, and perhaps most importantly, the need for more research and conclusive evidence.

Let's start with cost. At first glance, it is expensive—about \$100 for a 750 mg bottle. Sams-Dodd says that smaller wounds can be healed with one to three bottles, with more complex wounds needing more. For many, this might simply be too much. But conversely, for anyone who has ever experienced a non-healing wound and the weeks and months required to heal, the cost might not seem that high. Naturally, health care coverage would remove any hardship, and the company has applied for NHS coverage in the UK. Approval wouldn't immediately help anyone living here in BC, but it would set an important precedent.

Then there's the issue of lack of awareness globally about Amicapsil.

"It unfortunately always takes a long time for new treatments to be well introduced, particularly if it's a fundamentally new way of treating a condition, and if you're a small company with a limited marketing budget," concedes Sams-Dodd.

The two end users we introduced you to above both believe that it's successes like theirs that will turn the tide and lead to increased awareness and acceptance by national health programs.

"To my mind, this is an issue that will be driven by patients and results," says Sigantoria. "The proof will be in the pudding: if the product works, speeds up wound healing, reduces time spent on bed rest and reduces the financial spend and time spent in a hospital bed, then Amicapsil will become a no-brainer."

"Although expensive, by healing wounds faster, Amicapsil may save money in the long run," adds Hamilton. "The cost of conventional dressings and nurses' time—especially on chronic, non-improving wounds—could be significantly reduced for the serious cases that can lead to expensive, repeat hospitalizations and surgical interventions over many years."

We agree, but it also seems likely that the third challenge—completing more conclusive research—will be necessary for health policy-makers to get on board. O’Sullivan, the principal investigator of the most recent SCI case study of Amicapsil, agrees. “Whilst we have seen good effects in our handful of patients, and have seen a few papers describing its success elsewhere, I think that more evidence is required before the NHS can fund it,” he says. “I think further studies need to be done before it will be widely adopted, and we are at the early part of this new developments journey.”

One possible issue is that most of the research on Amicapsil to date has been funded and overseen by the company that makes it, Willingsford Healthcare. We’re not suggesting the research is flawed or compromised, but we do think more independent research may remove any suggestion of conflict of interest.

Another issue may be that the bulk of the research specific to SCI involves case studies. Approving bodies such as the UK’s NHS and the USA’s FDA may wish to see these case studies augmented by large-scale RCTs, or randomized clinical trials. RCTs compare the experimental treatment with another treatment or no treatment at all (placebo), with participants randomly selected to each group.

For his part, Sams-Dodd is aware of the need for more research—but he points out that RCTs are difficult to design for products like Amicapsil.

“We have discussed an RCT with the major SCI centre in the UK, but the choice of comparator has turned out to be the main challenge for everyone because it raises serious ethical questions,” he says. “In accordance with FDA guidance, an RCT only has a purpose if there is a gold standard treatment that is known to work, or you are able to include a placebo control group. You must then demonstrate superiority to this gold standard treatment or to the placebo treatment. The justification for an RCT is, however, highly questionable in the absence of an effective gold standard, and even more so when it is predictable that the patients

are highly likely to deteriorate if they use the common or standard approach.”

Sams-Dodd also thinks it would be difficult to find RCT participants. “In one treatment group, you have a product that has shown to have 100 percent efficacy in acute wounds, and in the comparator group you have something that has been shown to be ineffective and that everyone in the community knows this. Who would consent to participating?”

He also points out that the high costs of RCTs are often recouped by raising the cost of treatment.

For these reasons, Sams-Dodd says the company will continue to focus on systematic baseline studies for acute wounds, given that this is a scientifically-accepted method of evaluating new treatments in areas without a gold standard. “However,” he adds, “Amicapsil can also be used to control soft tissue infection and regenerate the tissue in chronic grade four ulcers prior to osteomyelitis surgery in order to improve the success rate, and here more traditional RCTs are appropriate. We are actively looking for collaborators for both.”

Getting Your Hands On It

No doubt, some of you have been reading this and thinking, “OK...I need to try some of this!” The good news is that you can reach out to the company, which would be happy to not only sell you some, but also consult with you about your treatment.

However, we know it’s likely that, if you’re suffering from a serious pressure ulcer, you’re working with your own medical team towards resolution, and you’ll want to ensure any treatments

are supported and approved by them. The problem is that it’s highly unlikely that more than a few health professionals here in BC have heard of Amicapsil, let alone any experience with it. So if you’re determined to try it within the context of your medical treatment and with your medical team’s blessing, you might have to take the lead in terms of encouraging members of your team to learn about Amicapsil.

If your team is reluctant to support it, you always have the option of trying it by yourself—remember, it’s considered a medical device, not a medicine; and to the best of our knowledge, it’s been found to be safe. If you move forward with this, Willingsford Healthcare is willing to review daily photos and offer guidance to you, or to your family member or carer who is handling the treatment, via e-mail.

“This has developed into a more formalized telemedicine approach, which we currently are pursuing, because it allows anyone to use Amicapsil independently of where they are in the world,” says Sams-Dodd. “This has gained extra relevance and attention during these COVID-19 times, where individuals even with severe wounds were left to mend for themselves. Everyone who has used the approach has been extremely positive because it allowed them to control when and where to do the treatment.”

Amicapsil can be purchased directly from Willingsford Healthcare. For more information, visit willingsford.com or email contact@willingsford.com.

A final request to readers: if you decide to try Amicapsil, please let us know about your experiences with it so that we, in turn, can let other peers know. ■

“If I knew then what I know now...”

What do you wish you’d done differently earlier in your post-SCI life? What do you realize now that you didn’t back then? In the spirit of peers supporting peers, we’d like to share your hard-won wisdom with more recently-injured readers in the next issue of *The Spin*. We’re not looking for a shopping list; we’re looking for THE ONE THING that you wish you would have known about or have done differently. Write us a short email, and describe the one thing you’d do differently if you had a time machine, and why. Please send your emails to Jocelyn Maffin, SCI BC Resource Centre Manager, at jmaffin@sci-bc.ca.