

More Pressure Relief



Following up on how a fine white powder is transforming wound care, from pressure ulcers to bone infections, for people with SCI.

In the early days of 2021, as the rest of the world hunkered down for what would be the first full winter of the COVID-19 pandemic, Vernon resident Dwight Negraiff had an infection of a different kind on his mind. For the past two years, Negraiff, who is quadriplegic, had struggled with a stubborn pressure ulcer that just wouldn't heal.

"My doctors and nurses, they tried every type of medicine and vacuum pump and everything that they could think of, to try to get it to heal, and it just would not heal," recalls the 57-year-old.

It wasn't until his wife was flipping through the Winter 2020 edition of *The Spin* that the couple learned about an innocuous white powder, developed in the UK, that showed serious potential for the treatment of pressure ulcers. The cover story (titled 'Pressure Relief') introduced readers to Amicapsil (also available as Amicapsil-SCI with use information specific to SCI), a compound that uses Micropore Particle Technology, or MPPT, to "pump" the toxins and enzymes secreted by infectious bacteria to the surface of the wound, where it can be removed. The result is an optimized immune system response and a more balanced microbiome, allowing healing to occur.

Soon after, Negraiff sent an email to Willingsford Healthcare, the company that produces Amicapsil. Following a brief exchange, during which he shared a short description and photos of his wound, the company estimated how much Amicapsil he would need and shipped it to his home in Vernon. It didn't take long for him to see results.

"My wife administered [the Amicapsil] and after two weeks, we saw significant improvements. By the time we ran out of the product, the wound was basically gone. My doctors and the nurses were all completely shocked," says Negraiff. "I'd had that pressure ulcer for over two years. [Amicapsil] healed it, and it's never come back."

How Pressure Ulcers Cost Us

If you've had an experience like Negraiff's, then you know that pressure ulcers are a serious concern for the SCI community. Globally, about one in three people with SCI live with pressure ulcers, and the costs are staggering—for both the person with the pressure ulcer, and the healthcare system. Pressure ulcers are difficult to heal, often resulting in prolonged bedrest. The experience can be isolating and reduce quality of life, negatively impacting both physical and mental health.

The financial cost is just as astounding. A study published in 2018 put the lifetime cost of a chronic pressure ulcer requiring hospitalization in Ontario at \$98,500 for a single patient. In 2024, that cost would be about \$118,400. Extrapolating from these estimates, the total cost of treating pressure ulcers among patients with SCI in Canada over the course of their lifetime would come in at a whopping \$3.4 billion dollars—and that's not including the cost of community care. Outside of the hospital, pressure ulcers can cost about \$13,500 per month for a single person, with some patients requiring ongoing treatment for months or years at a time.

The reason behind these staggering costs—physically, emotionally, and financially—is that standard treatments for non-healing chronic wounds like pressure ulcers just aren't working. Standard treatments often include gels and absorbent dressings for non-infected ulcers and topical antibiotics or antiseptics for infected ulcers. Bodies such as the UK's National Institute for Health and Care Excellence (NICE) and the US Food and Drug Administration (FDA) have explicitly stated that systemic antibiotics and antimicrobials are ineffective for treating pressure ulcers, and NICE has gone so far as to explicitly state that these treatments should not be used. But whether it's dogma, tradition, or a simple lack of alternatives, these treatments remain common practice.



Amicapsil applied to a wound.

An Unmet Medical Need

According to the FDA, wounds not healing naturally constitute an "unmet medical need" due to the lack of effective treatments. That's why technologies like MPPT, or Amicapsil, have the potential to revolutionize wound care, especially for people with SCI.

“People with SCI suffer from immunosuppression because the nervous system is damaged and can’t tell the immune system where to send the immune cells to clean up the damage and start the healing process when an injury occurs,” explain Jeanette and Frank Sams-Dodd, founders of Willingsford Healthcare. “In fact, studies have shown that SCI results in a 50% reduction in the number of immune cells that respond to a wounded area. As a result, it’s much easier for infectious bacteria or anything else to take over control. And so, in practical terms, people with SCI have impaired wound healing and reduced ability to fight infection.”

If pressure ulcers are not healed quickly, they can be particularly dangerous for people with SCI. Osteomyelitis, an infection of the bone, can develop in as little as two weeks in a serious pressure ulcer. On top of the prolonged periods of bedrest and low quality of life accompanying a typical pressure ulcer, osteomyelitis can lead to sepsis and recurring hospitalizations. And once the infection is in the bone, it’s much more difficult to remove.

“The problem is that if a wound is not closed rapidly, it can penetrate into muscle. And once that happens, there’s nothing to prevent it from reaching the bone. Then you have the risk of osteomyelitis, which can only be treated with surgery. And the result is that 10 to 12% of people with SCI die as a direct consequence of the pressure ulcers,” explains Dr. Frank Sams-Dodd. This is why the Sams-Dodds are on a mission to effectively treat pressure ulcers; time is of the essence to close the pressure ulcer and prevent osteomyelitis from developing in the first place.

A New Way Of Doing Things

You might be thinking to yourself, “If Amicapsil has the potential to revolutionize wound care, how come my doctors and nurses aren’t using it?” The short answer is: Amicapsil isn’t approved for professional use in Canada—at least, not yet. But it can be imported to Canada for personal use, and it’s been approved for professional use in several other countries,

including the UK, Australia, New Zealand, and the EU.

These approvals are supported by a large (and growing) body of research evidence supporting the use of Amicapsil (and SertaSil, a form of MPPT used for veterinary wound care) in humans and animals across a variety of wound types, from trauma and surgical wounds to diabetic foot ulcers, venous leg ulcers, and, of course, pressure ulcers. For those of you that would like to take a deeper dive into this research, you can find the highlights in the Winter 2020 edition of *The Spin*. The bottom line: MPPT heals wounds significantly faster than other treatments.

However, until recently, a limitation of the existing research supporting the use of Amicapsil was that, aside from case studies, people with SCI had yet to be studied. But new clinical research published in the journal *Frontiers in Medicine* shows just how effective Amicapsil is for treating wounds and pressure ulcers in people with SCI.

The study, a joint effort of the Willingsford Healthcare, the National Spinal Injuries Centre at Stoke Mandeville Hospital, and the Duke of Cornwall Spinal Treatment Centre at Salisbury Hospital, examined the use of Amicapsil as a treatment for 44 wounds and pressure ulcers in 25 people with SCI. Given the lack of effective treatments to serve as comparators and the risks involved with leaving a wound untreated (as would be the case in a placebo group), the study investigated Amicapsil use under real-world conditions.

“You’re not allowed to use placebo or comparators if you know that you are exposing the person in the study to irreversible morbidity or death,” explain Jeanette and Frank, who are study co-authors. “We knew that the existing treatments were not considered effective in treating pressure ulcers, so we could not ethically ask a patient to be in the comparison group.”

Delivered via telemedicine in community care, the researchers simply observed the effects of the Amicapsil and compared the findings against outcome data available in other published studies. “We didn’t put in



any extra parameters or measurements, we simply just recorded when people were using Amicapsil, what happened to the wound—did it close, did it not close—how long it took, and how much Amicapsil was needed,” says Frank.

A Treatment That Works

Because Amicapsil functions in part by harnessing a person’s own immune cells to promote healing, there was a possibility that Amicapsil might not work well in people who are immune compromised, including people with SCI. But the results of the study showed that this was not the case. In fact, daily use of Amicapsil closed all acute and chronic pressure ulcers in the study.

“The results of our study show that the number of days to close [the wound] simply depends on the severity and age of the wound, but the important part was we had the 100% closure rate. As long as we [treated the wound] before osteomyelitis was present, we were able to close the wound,” says Frank.

What’s more, in wounds acting as a draining fistula from an underlying source of infection, such as osteomyelitis, Amicapsil was able to remove the soft tissue infection in as little as 2.5 months, significantly reducing the size of the wound and the risk of sepsis. As a result, patients spent less time in hospital, required less bed rest, and reported greater wellbeing.

“What Amicapsil does is to reduce the overall level or quantity of infection in your body. And an infection in your body releases toxins into your blood. So, the smaller you can keep any infection that’s

chronic, the less toxins you will have in your blood. Toxins in your blood is called toxemia and it takes away your energy and makes you feel miserable,” explains Jeanette. “And while a draining fistula resulting from osteomyelitis won’t completely close, what we’re getting back from people is that [the Amicapsil] makes a very, very big difference because they don’t need bed rest and they get their energy back. They can exercise, they can go out, they can play an active part in the family, or maybe hold a job. You still need to treat the draining fistula every day, but it gives a completely different quality of life.”

The effects of Amicapsil on soft tissue infections may also have diagnostic value when it comes to identifying the presence of osteomyelitis. Research shows that current diagnostic tools, including MRI, CT, and X-ray scans, are not very effective for diagnosing osteomyelitis in people with SCI. But if a wound that is being treated with Amicapsil refuses to close, it could indicate an underlying source of infection. Visible markers on the wound surface could also be used to indicate if osteomyelitis is present.

According to Frank, there isn’t a downside to using Amicapsil for pressure ulcers, whether or not osteomyelitis lies underneath. “If someone comes in with a pressure ulcer, you want to treat it immediately because it may still just be a wound. You don’t want to spend too much time getting an MRI because by that time it could already have developed osteomyelitis. And if it is osteomyelitis, you would want to use the Amicapsil anyway to reduce the soft tissue infection and risk of sepsis.”

While still in the preliminary stages, the Sams-Dodds are working on new research to better understand how Amicapsil can be used to support the treatment of osteomyelitis, and how it might serve as a diagnostic tool.

Cheaper And Easier

Another important highlight from the study published in *Frontiers in Medicine* showed that, in addition to being safe and effective, Amicapsil can considerably re-

duce the cost of pressure ulcer care for people with SCI. Compared with standard care, per-wound cost savings of 51% to 94% per wound (depending on wound severity and age) resulted from successful wound closures and controlling soft tissue infection linked with osteomyelitis.

The telemedicine approach also lowers costs by reducing the demand placed on nurses and other healthcare providers. Amicapsil can be administered independently at home and does not require bed rest, enabling self-care. “The fact that it can be delivered by telemedicine means that you don’t have to wait. If you have someone who can help you or you can apply it yourself, you don’t have to wait at home for the nurse to come. You can choose your own schedule,” explains Frank.

“It provides a huge change towards equal access because anyone can help to treat the wound. We’ve even had a patient who had help from his 10 year old daughter, she did it better than anyone else,” adds Jeanette. “You don’t need to be a wound expert.”

In fact, the telemedicine approach takes place entirely over email. All you need is phone, tablet, or computer with a camera and an internet connection. “Normally, what happens is that people contact us, we ask them to send a picture of the wound and information on the wound age, how it has been treated, and whether there are underlying issues. Then based on that, we tell them what to expect. And then we can send [the Amicapsil] to them. And then if they wish we can help them use it correctly so that they get the maximum benefit from it,” says Frank.

Treatment consists of first rinsing the wound with tap water, preferably in the shower or otherwise with a squeeze bottle. Excess water is removed and, while still moist, Amicapsil is applied directly to the wound in an unbroken layer. The wound can be left uncovered, or covered with a piece of woven, cotton gauze, which will allow airflow and evaporation. The duration of treatment depends on the severity of the pressure ulcer and the healing progress.

“And people know that their wound is being looked after,” says Jeanette about the telemedicine approach. “And that’s one of the reasons why they keep sending pictures, because it also gives them the peace of mind that, ‘Okay, these people are actually checking my wound every single day, ensuring things are moving in the right direction.’”

Real World Evidence

While Amicapsil use has yet to become commonplace in Canada, satisfied clients like Vernon’s Negraiff say it’s a no-brainer for anyone dealing with a pressure ulcer. “Don’t be afraid to try it. Every pharmaceutical drug out there has side effects. And everybody’s body is different. I mean, just the quality of life has changed for me not having a nurse come over every two days, changing bandages on my butt, having a vacuum pump attached to my butt, having to go to the hospital and see the plastic surgeon and all the other BS,” he says.

In the UK, where Amicapsil is more widely used, the British Spinal Injuries Association surveyed people with SCI about their experiences using Amicapsil to treat pressure ulcers. Independently confirming the findings of the *Frontiers in Medicine* study, the survey results showed that every respondent—a total of 41 people reporting on 49 pressure ulcers—reported that their pressure ulcer(s) closed following MPPT treatment, and 95% of respondents rated their experience using Amicapsil as positive or highly positive and 0% negative. Likewise, respondents with a draining fistula reported that Amicapsil effectively

Susan Ormsby



controlled soft tissue infection resulting from osteomyelitis.

Among the UK-based clients whose lives have been impacted by Amicapsil are Susan Ormsby and Steven Parry. Both Ormsby and Parry are managing open wounds with osteomyelitis, and both have reported significant improvements since beginning treatment with Amicapsil.

Sixty-four-year-old Susan Ormsby of Glasgow, Scotland, was born with spina bifida and has been using a wheelchair full-time since the age of 50. She has syringomyelia, a fluid-filled cyst in her spinal cord that causes weakness and loss of sensation. So, when she fell off her wheelchair and dislocated her elbow, she wasn't aware that she'd been injured until much later.

"It wasn't until I became aware that my arm was in pretty bad shape that I went and got an X-ray. And it was too late to do anything with it because osteomyelitis had set into the bone. And a whole lot of pus had formed, and it burst out through the skin," she says.

Ormsby estimates that the open wound on her elbow was about five to six centimeters in diameter. Her doctors told her that if the infection in her elbow couldn't be controlled, the only treatment option would be amputation—which, naturally, she wanted to avoid.

"So, after about nine months of having this terribly leaky arm and I mean, it was very, very leaky, I managed to find out about Amicapsil. And within 12 days, we noticed—now I'm saying 12 days after nine months of a big gaping hole—we noticed that the skin was starting to heal round-

about, and the hole was getting smaller to the point now that is just a very small pin-head," says Ormsby. "And that will never close because they want that to stay open anyway, so that it can drain the fluid from the bone."

Amicapsil not only saved her arm, but it's also improved her overall physical health. "What used to happen was every six or seven weeks, I would end up in hospital getting IV antibiotics, and since I've used the Amicapsil I have not needed to be going into hospital for anything like that. Definitely my whole system is better," she says.

The benefits extend to her mental health and quality of life. "The district nurses used to have to come in three days a week. Now they come in once a month, just to check that I'm happy and that everything's going alright," she explains. "You feel as though you can go on holiday without thinking, 'I might need treatment.' So, it's a big bonus that way too."

Greater Manchester's Steven Parry also has seen how treatment with Amicapsil can change a life. After having surgery for a spinal arteriovenous malformation or AVM (a tangle of blood vessels on or in the spinal cord) and becoming a full-time wheelchair user in 2015, Parry was discharged from hospital with a pressure ulcer on his sacrum that deteriorated rapidly.

"I was having it treated at my local medical center and over a period it started to deteriorate quite rapidly. And I became really poorly and ended up with a pressure sore that was a grade one to two that quickly escalated into a grade four," explains Parry. "And what hap-



Steven Parry

pened was I ended up in hospital with sepsis and osteomyelitis."

He underwent surgery to remove the bone infection, but the wound still wasn't healing. "I was virtually bedbound for close to two years, having nurses come every day to change my dressings," says Parry.

None of the treatments helped to remove the infection or heal the wound, and some treatments, he says, actually made the issue worse. He wound up back in hospital several times as a direct result of the osteomyelitis. That's when he decided to try Amicapsil.

"My wound was horrendous to start with, very deep and infected, and it went from a big hole to more or less a tiny pin-hole using the Amicapsil," says Parry. "My aim was to keep me out of hospital, keep me safe, keep me sepsis-free. You know, reduce the flare ups of the osteomyelitis. And since I've been using Amicapsil I've not been in hospital, I've not had to have constant antibiotics, and I've not had to have any more surgery. It's just changed my life completely."

The Challenges That Remain

Despite the success they've experienced using Amicapsil, a key challenge that Negraiff, Ormsby, and Parry all highlighted is the cost. Amicapsil is approved for use as a medical device, not a pharmaceutical. This means that there is no insurance coverage for the product, and users must pay for it themselves.

"My insurance company wouldn't cover [the \$600 cost] because it wasn't approved. But they said in two years or three years,



Susan's open wound before (left) and after (right) using Amicapsil.

The Science Behind Amicapsil

If you missed our last article about Amicapsil, you might be wondering, “How does Micropore Particle Technology (MPPT) actually work?” To explain, we need to take a closer look at our skin—or, more specifically, what’s living on our skin.

In healthy skin with a naturally healing wound, there is an established, well-functioning population of microbes. They live inside a protective biofilm where they collaborate as a microcommunity. This is called a microbiome. The microbiome collaborates with the body’s immune system to keep the skin and wound healthy.

“When you look at a wound that is healing, you have this diverse, rich population of different types of bacteria, fungi, and viruses that directly help the immune system in order to prevent infection. And infection occurs when one or a few species have taken over control of the wound,” explains Frank Sams-Dodd.

“You have to think of it as a synergy. So, in healthy skin and healthy wounds, the bacterial population is constantly communicating with your immune system, and the immune system is policing the population so that everybody keeps at the right levels and the right composition, and nobody takes over control. So, the immune system is in control, but it’s always in synergy with the microbes,” adds Jeanette Sams-Dodd.

When a small number of microbes “take over” control of the wound, they secrete toxins and enzymes that prevent the immune system from doing its job. This includes both disarming the immune cells and reinforcing the “protective” biofilm so that the immune cells can’t access the wound’s microbiome. The infectious toxins and enzymes exist in the tissue, exudate (fluid from a wound), and pus.

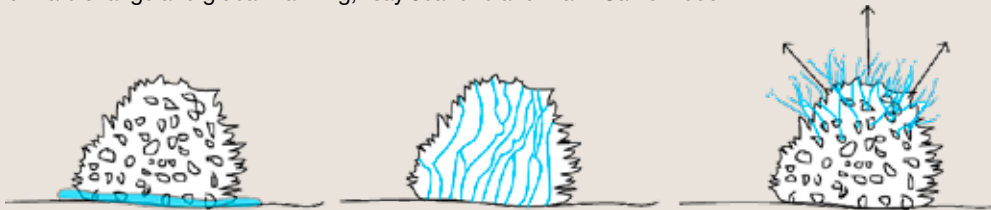
What happens when you apply the Amicapsil is that it draws the exudate to the wound’s surface, where it evaporates, through tiny pores. The pores are so tiny that they can produce a very strong capillary force. It’s the same thing that happens when you leave a straw in a glass of water—the force of adhesion holding the water molecules together and to the straw is stronger than the force of gravity, and forces the water up the straw. The smaller the pores, the stronger the forces.

These capillary forces do two things at the same time: They create holes in the biofilm that allow the immune cells to access the microbiome, and they suck away the harmful toxins and enzymes. The result is that the immune cells are now working and have access to the biofilm, where they can restore the diversity of the microbiome and promote healing.

“It’s a very different mode of action compared to antimicrobials, which try to kill everything,” says Jeanette Sams-Dodd. “When you use antiseptics, for example, iodine and silver, they don’t just kill the bacteria, they also kill the immune cells and the new tissue cells that the body are making in order to heal the wound. Whereas MPPT works in tandem with the immune system to support it without killing anything.”

And because there are no antimicrobials involved in Amicapsil, there are other benefits as well. For example, Amicapsil is effective against antimicrobial-resistant wound infections, but it won’t contribute to antimicrobial resistance. And unlike antimicrobials, the components of Amicapsil are non-toxic and will not cause pollution or contribute to climate change.

“It’s about more than antibiotics that stop working—those resistant microbes end up in nature, where they can actually contribute to climate change and global warming,” say Jeanette and Frank Sams-Dodd.



MPPT acts via capillary evaporation.

if it gets approved, then they’ll reimburse me,” says Negraiff.

While smaller wounds can be healed in as little as one bottle, more complex wounds (including draining fistulas) could require much more and may require lifetime treatment. But for people like Negraiff, Ormsby, and Parry, it’s a small price to pay for the value it provides.

“If you’ve got a pressure sore, which can take months and months to heal, or

even sometimes they don’t heal, definitely use [Amicapsil]. You know, it might cost you a bit of money initially, but in the long run your whole quality of life will improve because you don’t have that infection that you have with the normal dressing,” advises Ormsby.

Another challenge lies in the level of awareness and response to the product among healthcare providers. Amicapsil is not approved for professional use in Can-

ada, so doctors and nurses aren’t allowed to administer it. But in the UK, where it has been approved, some healthcare providers refuse to use it.

“When I first started using Amicapsil, my nurses down at the medical center wouldn’t touch it because I bought it privately. They didn’t want any liability, which was understandable,” says Parry.

Whether it’s concerns about liability, personal beliefs, or a lack of understand-

ing about the product, research shows that it takes time—an average of 17 years—for research evidence supporting a treatment like Amicapsil to make its way into clinical practice.

Advocating For Change

The same challenges existed four years ago when we first reported on Amicapsil in *The Spin*, but there's one important difference: A mounting body of research evidence and a growing number of people who've seen the difference it can make. And with more evidence and more people voicing their support, there's a possibility that healthcare policymakers might see its value too.

While Ormsby has reached out to the Health Secretary of Scotland for support, Parry is petitioning the UK government to make Amicapsil freely available to people with pressure ulcers through the UK's publicly funded healthcare system, the National Health Service (NHS).

"People who haven't suffered from pressure sores, they don't know the full impact," says Parry. "And when you've been a sufferer yourself, and I'm still an ongoing sufferer, I know the impact that pressure sores have on people's lives. And I think if this powder was readily available through the NHS, a lot more people could have a better lifestyle."

While it may take time for healthcare providers and policymakers to come around, the potential for treatments like Amicapsil to transform wound care and enhance the lives of people with SCI is not lost on the Sams-Dodds.

"From the research perspective, this is the first time you've been able to treat an infection in a wound or skin without the need for antimicrobials," says Frank. "And from the clinical and patient perspective, there's a huge unmet medical need in wounds, all types of wounds, not just SCI. And Amicapsil is the first treatment that can close and heal ulcers consistently. The potential to save lives is huge."

Trying It For Yourself

If you'd like to try Amicapsil for yourself, it can be purchased directly from Willingsford Healthcare. To ensure that Amicapsil fits with your other treatments and healthcare concerns, it's a good idea to consult with your medical team first. If your team is reluctant to support it, you always have the option of trying it by yourself. 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 email. For more information, visit willingsford.com or email contact@willingsford.com.

And 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.

For more information about pressure injuries, check out the Skin Health section of our LivingwithSCI.ca website, and be sure to have our Pressure Injury Prevention wallet card handy. ■

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