Biomedical Innovations: Changing Wound Care One Doctor, One Patient At A Time

University of Georgia
University of Georgia Research Foundation

Imagine the anguish that comes from receiving a severe wound, burn or skin ulceration. Aside from the pain, the mind will struggle with quality-of-life issues in the near future.

These worries are very real for millions throughout the world (see sidebar) who, without proper wound care, will suffer from devastating scars, disfigurement, amputation and/or social rejection. This problem is most acute in a wide variety of resource poor settings, including sub-Saharan Africa, rural Asia, much of South America and areas impacted by natural disaster where there is a very high risk of infection — the primary obstacle to optimal wound care.

Open skin wounds such as burns, neuropathic ulcers, pressure sores, venous stasis ulcers and diabetic ulcers routinely heal via a complex multistep cellular-based process. But healing is often impaired when components in the process — individually or as a whole — fail to function properly for a variety of reasons, primarily infection.

Young Girl's Hand Is Saved

This is the very position a young girl in Haiti found herself in after the hurricane of 2010. She received severe burns on her hands and arms from a cooking mishap. By the time she saw a medical professional, her hands had become badly infected. She likely faced a life without digits or possibly her hands due to the prevailing belief that amputation was the only solution.

> *As luck would have it, two new topical applications, with antimicrobial agents and marketing clearance from the U.S. Food and Drug Administration, were undergoing evaluation in Haiti as part of a multidrug therapy regimen for leprosy.*

Using compounds based on licensed academic research conducted at the University of Georgia (UGA) in Athens, the innovative topical technology "potentiates" — increases the effectiveness of microbial killing — in available antibiotics to fight dangerous infections, even drug-resistant microbes such as methicillin-resistant Staphylococcus aureus, vancomycin-resistant Enterococcus faecalis, multidrug-resistant Pseudomonas aeruginosa and multidrug-resistant Acinetobacter baumannii.

These products work by generating physical holes in the microbe's cytoplasmic membrane, or antibiotic-resistant biofilm, which provides a shield that effectively protects the integrity and functionality of the microbe's cellular membrane. The holes reduce the bacteria's ability to remove classes of clinically relevant antibiotics and result in the death of the microbe.

"Microbes function very much like a boat because both are dependent on differential pressure," says co-developer Branson Ritchie, D.V.M., Ph.D., a distinguished research professor at UGA and president and chief executive of the academic startup company founded in 2002, Molecular Therapeutics LLC of Athens. "If you punch holes in a boat or a microbe, they can't work anymore."

In Haiti, health care providers decided as a last resort to apply Molecular Therapeutics' innovative topical treatments, Silvion and Silvaklenz, on the young girl's severely burned hands. Remarkably, the pain rapidly diminished, the spreading microbial infection was stopped in a matter of days and the prospect of a future with the use of two hands became a reality.

This dramatic example is just one of many in which this biomedical technology is producing similar results, not only for those living in undeveloped areas, but also for those with access to wound-care gold standards practiced by the urban hospitals of major cities in the developed world.

"These products are just incredible. I see patient outcomes that are astronomically better than what I've seen using methods approved by WOCN [Wound, Ostomy and Continence Nurses Society]," says Donna Howarth, director of nursing, Medside Healthcare home-care agency in Sandy Springs, Ga. "Traditional wound care is focused at the tissue level, while these products work at the cellular level, which I think makes the difference."

Academic Research Provides Biomedical Foundation

Developed at the UGA College of Veterinary Medicine, these biomedical technologies are licensed to UGA startup Molecular Therapeutics by the University of Georgia Research Foundation Inc. (UGARF), which manages intellectual property developed by UGA employees. The startup company markets three antibacterial products based on the UGA portfolio: Silvion, a moisturizing solution, and Silvaklenz, a wound cleanser, both for humans; and Tricide, a veterinary treatment to prevent infection and promote healing in nonfood fish, such as koi.

"The wound-care market is quite crowded, but these products appear to be unique in their ability to significantly

enhance the killing activity of a topical antimicrobial," says Derek E. Eberhart, Ph.D., a senior licensing manager in the Technology Commercialization Office (TCO) at UGARF.

Eberhart was one of many in the business support team, including the university's Georgia BioBusiness Center incubator, to help protect the innovations, prepare the technology for licensing opportunities and enable the eventual spin out of the academic startup company. The research was supported in part by UGARF's Animal Health Fund, which fosters selected research initiatives in the UGA College of Veterinary Medicine. In addition, Molecular Therapeutics received seed funding from the Georgia Research Alliance, a partnership of state government, local industry and academia focused on facilitating new science and technology efforts with the potential to help people and have significant economic impact.

Two patents are issued to UGARF — one in the United States for aquatic applications and another in Canada for medical/human applications — and additional patents are pending in the United States and Europe. The inventors involved in various aspects of these technologies included Ritchie and his colleagues at UGA: Richard Wooley, D.V.M, Ph.D., a professor in the UGA College of Veterinary Medicine who is now retired; Victoria Burnley Vaughan, formerly in the department of Small Animal Medicine and now owner/director of Koi Lab LLC; Douglas T. Kemp, Pharm.D. formerly of the College of Veterinary Medicine; and Anthony Capomacchia, Ph.D., associate professor in the College of Pharmacy.

Ritchie embarked on antimicrobial research in 1998 with his mentor and colleague Wooley in an attempt to resolve the problems associated with multidrug-resistant microbes in burn patients. The compound that enhances the effectiveness of antibiotics became the underlying foundation for the biomedical technologies for humans and animals that Molecular Therapeutics is using.

"This technology, which helps kill drug-resistant bacteria and fungi with compounds that cleanse wounds while also being gentle on the tissue, is a beautiful example of translational medicine," Ritchie says. "We started with burn patients as our target, but it just so happens that it also works with wound care in companion animals."

Veterinary and Pharmacy Sciences Come Together

A real breakthrough came when potentiated antibiotics were combined with a bioadhesive following collaboration between Ritchie and Capomacchia on a nontoxic ointment to help burn victims. Capomacchia specializes in the formulation of drug delivery systems.

Veterinarians soon successfully used the Tricide nonpetroleum ointment treatment on a burned dog in a high-profile animal cruelty case, followed shortly by Gasper, a beluga whale at the Georgia Aquarium in Atlanta.

These animal trial applications were soon followed by the first human patient — a firefighter involved in an explosion that caused first- and second-degree burns on his face and arms. Within 12 days of treatment with Silvaklenz and Silvion, the results were astounding. His skin is now back to normal.

In a short period of time, the researchers had come full circle: from designing a nontoxic ointment to help burn victims, to developing drug-delivery applications for aquatic animals and back to treating skin problems in humans.

Translation of Basic Research to Effective Products

Initial attempts to license the basic science research by UGA failed to identify any companies that could translate it into effective clinical products.

"Our intent was to license these technologies for use with people and animals, but we couldn't find anybody

interested," says Ritchie, who feels the existing licensing environment is "quite challenging" for academic biomedical research. "So, it came down to a decision: We either do this ourselves or let down the constituents who could most benefit and who we wanted to help."

The self-described "entrepreneur by necessity" says it isn't so much what he intended to do, but what he had to do.

Eberhart in the TCO at UGARF says existing companies that consider in-licensing academic opportunities — research that is often in the concept stage — tend to focus on risk assessment and the pathway to commercialization.

"Most inventions arising from university research are early stage and, thus carry a high level of risk and uncertainty," Eberhart says. "Most academic labs are not set up to perform the extensive proof-of-concept experiments that many companies would prefer to see before licensing a technology. Sometimes, a startup company is a necessary step in the commercialization process."

Today, both Eberhart and Ritchie say that Molecular Therapeutics is starting to get some traction with nine independent sales representatives under a national sales director who are introducing more health care providers to the company's Silvion and Silvaklenz products. "We're making headway — one doctor, one patient at a time," says Ritchie. "We're OK with this approach because we're helping patients who can really benefit from these products."

People Are the Real Beneficiaries

Even though Ritchie says he didn't start out with entrepreneurship as a goal, he says he is "honored" to have worked with colleagues who started with a problem, developed a viable solution and now sees better quality-of-life prospects for people suffering from burn wounds, neuropathic ulcers, pressure sores, venous stasis ulcers, diabetic ulcers and even acne.

"I look at this as a blessing because we're in touch with the user base," says Ritchie, who sees merit in building connections between caregivers and the patients, such as those that exist between the young girl in Haiti and about a dozen patients under Director of Nursing Howarth's care at Medside Healthcare.

"One of our patients suffering from cellulitis (a noncontagious spreading bacterial skin infection) was looking at having his legs amputated," Howarth relates. "I'll admit I was skeptical, but we used the topical applications on Day One. On Day Four, we took the bandages off and his toes were no longer black and he was pain free.

"We had been treating him for three months with traditional methods and little progress. Imagine, in four days seeing measurable progress. It was out of this world. It was so Star Trek."

To see available technologies from research institutions, click here to visit the AUTM Innovation Marketplace.