THAT'S A WRAP

A LOW-COST, ANTIBACTERIAL INNOVATION AIDS IN BURN TREATMENT

The first out-of-laboratory tests of a novel treatment for burn wounds took place in the trauma unit at University of Florida Shands Hospital system in Gainesville, Florida, in 2009. Nurses placed standard silver dressings on two wounds and then Quick-Med Technology's FDA-approved BIOGUARD gauze over the silver dressing on one wound and Brunswick gauze over the other.

Director of the Institute for Wound Research at the hospital, Dr. Gregory Schultz, remembers the test. "Basically, when the nursing staff took down the dressings, the Brunswick gauze was green with Pseudomonas [bacteria]," Schultz said. "In contrast, the BIOGUARD dressing was essentially sterile—just pure white."

When the nurses changed the contaminated Brunswick gauze dressings, he added, "a huge amount of bacteria was aerosolized—onto the patient, the nurses, the bed, and the floor. But there were no bugs growing on the BIOGUARD dressing—it killed all of them. It took the nursing staff about three patients to say, 'Enough—no more conventional gauze in the trauma unit.'"

The tests were enabled through a Small Business Innovation Research (SBIR) contract that addressed the U.S. Army's need for better treatment of vesicant, or chemical-weapon burns. Although outlawed by two international agreements, sulfur mustard agent—a particularly cruel method of chemical warfare used in WWI—surfaced in the late 20th century among terrorist groups, and has been used in Middle East conflicts. Effects of the gas are slow to emerge, severely wounding but not killing its victims, and forcing the affected force to retrench to treat its wounded.

In 2005, in response to escalated incidents of sulfur mustard use, and aware of Quick-Med's progress with a technology known as NIMBUS (Novel Intrinsically Microbicidial Utility Substrate), the U.S. Army awarded an SBIR contract to Quick-Med.

The NIMBUS technology centers on an active antimicrobial agent, a large polymer called polyDADMAC. When bonded to a gauze dressing and placed over a burn injury, polyDADMAC displaces stabilizing calcium ions on the cell membrane of bacteria. Basically, it creates holes in the cell wall. And because the polyDADMAC molecule is so large, it cannot enter the cell where mutation might create bacterial resistance.

Tests have shown that polyDADMAC, incorporated in the BIOGUARD dressings, is 99.99 percent efficient in killing Methicillin resistant *S. aureus* (MRSA), *Psuedomonas aeruginosa*, and *Escherichia coli* (E. coli), among other bacterial strains.

Burn victims face many challenges. Wounds discharge fluid at a high rate and bandages need to be changed frequently. The warmth and moisture of the wound can nurture bacterial populations, which can double in number in a little over 20 minutes. Sometimes bacteria form biofilms that protect the bacteria from antibiotics and the patient's immune system. Burn victims die more frequently from the results of infection than from the burn itself, according to Quick-Med President Dr. Bernd Liesenfeld.

In this context, NIMBUS addressed several major issues related to burn treatment. NIMBUS-treated fabric kills bacteria rapidly without the risk of creating resistant bacteria. NIMBUS can also be made with a superabsorbent quality that doubles or triples the time needed between bandage changes. There is also less odor in the wound dressings.

The technology was featured in TIME magazine's 2006 annual issue on innovation, and received Food and Drug Administration (FDA) clearance in 2009.

Liesenfeld noted that the SBIRs "helped us to really better understand what we could do with the technology ... It was a validation and a really good showpiece—and definitely helped with our research and commercialization."

Liesenfeld, a materials engineer at Quick-Med when the SBIR was awarded, developed the system that allowed for commercial application of the NIMBUS polymer, polyDADMAC, on a fabric. Schultz, who contributed research to the SBIR contract, remembers that the process of bonding was amazingly simple—they simply soaked the fabric in a bath containing a solution of polyDADMAC.

When treated and dried, the polymer was permanently bonded to the fabric—what the engineers referred to as dehydration bonding. At the time, Schultz noted, silver dressings were becoming popular, but were many times more expensive than Quick-Med's BIOGUARD.

Quick-Med was in a position to commercialize BIOGUARD in 2009, licensing it to Derma Sciences, Inc., which was acquired by Integra Life Sciences in 2018. Liesenfeld noted that the SBIRs "helped us to really better understand what we could do with the technology and show some fantastic research results. It was a validation and a really good showpiece—and definitely helped with our research and commercialization."

Dr. Bernd Liesenfeld

Since that time, Quick-Med has distinguished itself with another, possibly more far-reaching, innovation. Using an approach similar to NIMBUS, Liesenfeld used hydrogen peroxide—a common, natural antimicrobial

Creative Commons: WillMcC

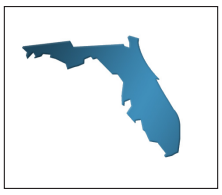
University of Florida Shands Hospital provided the first out-of-laboratory tests for Quick-Med's revolutionary burn treatment technology. Dr. Gregory Schultz, inset, is the hospital's director of the Institute for Wound Research.

agent—in its Stay Fresh™ technology, sequestering hydrogen peroxide into a dry phase and then applying it to a fabric with a binding agent. This treatment inhibits the growth of bacteria and fungi on the textile, and also eliminates odors.

As to bacterial resistance, peroxide in the body is a biogenic process and has been functioning for thousands of generations, Liesenfeld said, "so we don't see any resistance to it. We feel very secure in saying that the chemistry doesn't engender resistant species. That's the binding thread that goes through our research."

In 2018, the clothing conglomerate Phillips Van Heusen licensed Stay Fresh for manufacture of a series of garments.

Schultz is very impressed with the potential for the use of the technology in hospitals. "When you get a hospital-acquired infection, it's usually not from the surgeon's hands in the OR," he said. "It's usually from all the contaminated surfaces that surround the patient— bed linens, drapes, privacy curtains."



According to Schultz, they tested Stay Fresh fabrics through 50 industrial launderings. "It absorbed peroxide used in the industrial washing cycle, effectively recharging its antimicrobial activity," he said, and maintained a sterile surface through all the washings. Other informal studies were conducted in the operating room with clothing made from Stay Fresh fabric. "We cultured the bugs from treated and non-treated scrubs," Schultz said. "The anesthesiologist's pants or shirts, especially if they got splattered with blood, urine, or spit, could be hugely contaminated if the fabric was not treated with a microbicide. On scrubs treated with Stay Fresh, however, there were almost no bugs. That was when we realized this was going to have a big impact."

Quick-Med Technologies, Inc.

Modernization Priority: Biotechnology
Gainesville, FL • SBIR contract: W81XWH-06-C-0024 • Agency: ARMY • Topic: A05-131, Chemical Casualty Care: Wound Dressings Designed to Speed Wound Closure Following Debridement of Cutaneous Vesicant Injuries