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Infection Rate Reporting:

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12%

34%
1.71428

560
12

STERILANT FOR HUMAN WOUNDS IS CHANGING PATIENTS' LIVES

In this article, I'd like to relate how a number of leading physicians, including myself, have utilized this new super-oxidized water technology called Microcyn in the treatment of diabetic foot ulcers, venous stasis ulcers, and burns.

Based on my experience, I can arguably say that Microcyn technology is the world's first and only pH-neutral sterilant product that sterilizes wounds, ulcers and burns while simultaneously inducing wound healing. This is welcome news to a profession that truly has not seen a significant advance in either disinfectant or antiseptic technologies in many decades.

And unlike traditional antibiotics and antiseptics, Microcyn technology does not facilitate the mutation of resistant strains of bacteria, damage cellular elements, or restrict the microcirculation of the wound, thus ensuring the wellbeing of surrounding healthy tissue.

My homeland, Mexico, was the first country to obtain the Microcyn technology, receiving regulatory approval from our Ministry of Health in July 2003 as a disinfectant and antiseptic, and then as a sterilant in November 2003. As a point of continuing validation, Microcyn received its first two CE Mark approvals in Europe in early 2004 as a disinfectant, and the manufacturer expects its first Food and Drug Administration (FDA) approval in the United States as a wound dressing as early as 2004. As of this writing, I understand that EPA approval is anticipated shortly for use as a hospital disinfectant in the United States this year.

I first learned of the Microcyn technology last year when I attended the annual meeting of the Mexican Diabetic Foot Association in Veracruz, Mexico. As president of this society, I'm constantly in search of new treatment options for one of the most devastating and common outcomes of diabetes, that being diabetic foot ulcers.

Unfortunately, diabetes is a malady that is growing in incidence, rather than declining. Worldwide, there are 120 million Type 2 diabetics, with that number projected to increase to 220 million by 2010. In the United States alone, more than 6 percent of the population is afflicted with diabetes, with diabetic foot ulcers being the leading cause of morbidity, mortality, and excessive care costs. In 2000-2001, there were 82,000 lower-limb amputations performed just on U.S. diabetics. Diabetics are prone to foot ulcerations due to both neurological and vascular complications. These ulcers are the primary port of entry for infections in diabetic patients and it is believed that early detection and appropriate treatment of these ulcers could prevent up to 85 percent of the amputations.

In my quest to find alternative modalities, I have pursued more than my share of dead ends and unfulfilled product promises. So I must admit that when I was first introduced to the Microcyn technology, I was most skeptical. However, one of the other physicians in my clinic approached me one day and told me they had used the Microcyn on a diabetic foot ulcer and that something quite unusual had occurred. The horrendous odor associated with these ulcers had completely disappeared. Knowing that the odor was, in large part, the result of bacteria, this led me to believe that there might be something to the antimicrobial claims they were making for this product.

I decided to investigate further by implementing a comprehensive treatment regimen with Microcyn as the core technology. The case study results were impressive and worthy of peer review, so we began a randomized, single-blind, clinical investigation in our Veracruz clinic, La Clinica del Pie Diabetico, beginning in November 2003. That 20-week clinical study, in which we enrolled 45 patients, showed an important clinical benefit when using Microcyn technology with respect to reduction of fetid odor, cellulitis and cytotoxicity (defined as the advancement from infection to the formation of granulation tissue in the wound and development of healthy tissue peri-wound when compared to patients treated with conventional therapy alone).

Patients in the study received similar treatment regimens with the exception that soap and Microcyn were used in place of the povidine-iodine and saline rinses. That clinical study was completed in June and has been submitted for peer review in the United States.

As an example of a typical case study we see at the clinic, the pictures at right, which span a four-month period, chronicle the progression of a moderately severe foot ulcer in a 58-year-old male who presented himself to our clinic in November 2003. His treatment consisted of full immersion of his foot ulcer in Microcyn one to two times per week, using between one and three gallons of Microcyn per week. After full immersion, the wound then received a dressing, consisting of an application of Italdermol (gel used in providing a moist wound environment), gauze, and adhesive covering. In addition, the patient was then instructed to avoid weight bearing as much as possible. Patients are provided with off-weight-bearing, custom-molded inserts to relieve pressure at the ulcer site, if the ulcer is on a weight-bearing area. This patient has recovered without complications and he indicates his quality of life, due to elimination of pain and cessation of odor, has vastly improved.



Diabetic foot ulcer treated with Microcyn™ over a four-month period.

Based upon my experience with the Microcyn technology, I have concluded that this super-oxidized water relies on two different modes of action that are key to the successful treatment of foot ulcers. The first is the antimicrobial nature of the formula. Significantly, it achieves this kill rate within minutes yet remains non-toxic, non-flammable and non-irritating to skin, eyes and throat.

Microcyn has been tested against a variety of organisms, including the five most common bacteria found in hospitals: *Staphylococcus aureus*, Coagulase-negative *Staphylococcus* spp. (such as *Staphylococcus epidermidis*), *Enterococcus* spp. (such as *Enterococcus hirae*), *Escherichia coli*, and *Pseudomonas aeruginosa*. Microcyn demonstrated a 106 reduction after 15 seconds of exposure against all five organisms.

Additionally, Oculus has conducted several bactericidal tests using Association of Analytical Communities (AOAC) test methods. Using these methods, Microcyn was shown to kill *S. aureus*, *P. aeruginosa*, *S. choleraesuis*, in one to 10 minutes. Lastly, Microcyn has been shown to be effective against mycobacterium *M. bovis*, HIV-1 and Canine Parvovirus. Microcyn also is effective against resistant strains of bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) and *vancomycin-resistant Enterococcus* (VRE).

Thus, Microcyn technology is designed to reduce the bacterial counts in the infected diabetic foot ulcers, thereby improving the wound conditions, which may then stimulate the wound healing process and closure of the wound. Wounds that remain infected cannot proceed to the granulation tissue phase of wound healing.

Therefore, Microcyn truly does represent a breakthrough solution, both disinfectant and wound healing antiseptic in a single formula, but without the toxic effects of either disinfectants or antiseptics that are commonly used today. And due to the phenomenal results we have achieved in our clinic, and in my role as president of the Mexican Diabetic Foot Association, I have taken to the road to bring this innovative news to my colleagues around the globe. Most recently, I presented to surgeons in France, Italy, Netherlands, Ireland, Spain, United Kingdom, Czech Republic and Germany. As a result, there will be clinical studies underway in a number of research and medical institutions by the end of this year.

Early on, I also realized that if we were able to achieve these impressive results with diabetic foot ulcers, then Microcyn could certainly have an impact on other wounds including venous stasis ulcers, pressure ulcers, ischemic ulcers, burns and possibly even dental infections.

Dr. Cuauhtemoc Ramirez, a specialist in phlebology with a clinic in Matamoros, Tamaulipas, subsequently heard of the success we were having. He deals with patients afflicted with chronic venous stasis ulcers or what are oftentimes referred to as "varicose vein leg ulcers."



Dr. Cuauhtemoc Ramirez

"Frankly, I was both astonished and excited when I heard of Dr. Martinez's work with Microcyn," Ramirez said. "Infection is the most frequent complication associated with an ulcer of the foot or leg. And bacterial infection simply prevents the ulcer from healing." Ramirez

THE DEGREE OF ULCERATION IS OFTENTIMES EXACERBATED BY A GENERAL NEGLECT OF THE WOUND THAT CAN BE THE RESULT OF POVERTY, LITTLE TO NO EDUCATION, INABILITY TO ACCESS MEDICAL CARE, AND POOR NUTRITION. COMPOUNDING THIS IS THE FACT THAT INVADING BACTERIA CAN GROW RESISTANT IN REACTION TO ANTIBIOTICS OR TOPICAL ANTISEPTICS THAT ARE USED TO TREAT THE ULCER.

The second mode of action is Microcyn's wound healing capability. There is strong evidence to suggest that oxygen is essential for maintaining cellular integrity, function, and repair when tissues are injured. In order to promote fibroblast proliferation and the production of collagen, oxygen must be present in sufficient quantities. But glucose metabolism is mainly anaerobic (Embden-Meyer-Hoff) and oxygen is essential for metabolism only at the mitochondrial level during the oxidative process and respiratory chain.

Our bodies are continuously exposed to an autooxidation-related aging process that could be harmful if the primary and secondary anti-oxidative barriers fail to protect us from the oxidative stress damage. Reactive Oxygen Species (ROS) are produced as result of the last aerobic metabolism of glucose inside the mitochondria. Super-oxide dismutase and catalase are antioxidants that, in this current biochemical pathway, prevent damage and generate CO₂ and water.

When ROS are produced in the final step of glucose metabolism within a balanced aerobic environment, super-oxide anion, hydrogen peroxide, OH radicals and others interact; signaling and promoting the inflammatory response, killing bacteria and promoting angiogenesis through Vascular Endothelial Growth Factor gene expression.¹⁻² Microcyn is a super-oxidized solution containing most of this ROS and mimicking endogenous production of neutrophils, macrophages and endothelial cells.

N. Yahagi hypothesized that ROS, shown to be the electron spin resonance spectra present in the anode chamber of super-oxidized water, might trigger early wound healing through fibroblast migration and proliferation.³ Microcyn is a pH-balanced super-oxidized water with this "active oxygen" species and yet stable to the point of providing a minimum shelf life of one year.

Traditional antiseptics, such as chlorhexidine, providine-iodine, alcohol, hydrogen peroxide (as conventionally used in higher concentrations) and triclosan are toxic to fibroblasts and epithelial cells and should not be used on open wounds and ulcers.

has patients with venous stasis ulcers who have endured these non-healing wounds for up to 50 years. Patients with 20- and 30-year-old ulcers are not uncommon at all in his practice, or in the clinics of his peers.

"It is a devastating lifestyle," Ramirez shares. "The pain is constant. The odor associated with these ulcers is horrific. And yet, these patients live with both the pain and decaying stench 24 hours a day, seven days a week ... many for the greater part of their lives."

The degree of ulceration is oftentimes exacerbated by a general neglect of the wound that can be the result of poverty, little to no education, inability to access medical care, and poor nutrition. Compounding this is the fact that invading bacteria can grow resistant in reaction to antibiotics or topical antiseptics that are used to treat the ulcer.

"From my experience, seldom will conventional antiseptics kill all the bacteria and fungi," Ramirez continues. "And to the contrary, many antiseptics actually end up damaging the healthy tissue surrounding the ulcer." It's been a real dilemma since what is typically used in an attempt to heal, actually may end up causing even greater harm to the patient. But to do nothing has not been a humane answer, either.

"I was very excited," Ramirez enthuses. "I knew within two weeks after treating my first patients with Microcyn that I was beginning to see healing in these decade-old ulcers and this was absolutely something I had never experienced in my nearly 20-plus-years of practice."

Ramirez's comprehensive treatment program includes the use of Microcyn applied two times a day via a spray application and left for 15 minutes during the first four days of the regimen. This is followed by application of Microcyn and a topical ointment, and the wound is then covered with bandages. This is left on for four days and then the cycle is repeated.

The photos below graphically illustrate the significant results achieved on these ulcers when treated with a Microcyn-based regimen.



10-year-old leg ulcer before and after three months of treatment with Microcyn



22-year-old leg ulcer before and after three months of treatment with Microcyn



35-year-old leg ulcer before and after three months of treatment with Microcyn

This regimen can on occasion be combined with a surgical approach that may include an ambulatory phlebectomy as well as tying of the saphenous vein.

Ramirez has undertaken a clinical study with 44 of his patients, half of whom are in a control group treated with a traditional protocol and the other half administered the Microcyn-based regimen. All those in the Microcyn group, though in various stages of treatment, are responding positively.

"My patients say that the Microcyn at first stings a bit," said Ramirez, "but they are very happy because it relieves them of the pain, and the odor disappears almost immediately." After seven to 10 days, dramatic visual improvement of the ulcer is typically noted. Ramirez intends to continue the clinical until 60 patients in total have completed treatment at which time he will submit his study for peer review.

Another type of wound that is highly susceptible to infection is that of burns. In fact, infection is the primary complication in burn victims, oftentimes to the point of being life threatening.

Dr. Ariel Miranda, a plastic and reconstructive surgeon, and chief of the pediatric burn unit at the Guadalajara Civil Hospital, first became interested in Microcyn's potential to accelerate healing in the adolescent burn victims he treats in early 2004.



Dr. Ariel Miranda

"In addition to the high risk of infection due to the fact that the skin is no longer a barrier to bacteria," Miranda says, "We are also challenged by the complications associated with skin grafts."

A graft "takes" or is successful when new blood vessels and tissue form in the injured area. Sometimes, skin grafts do not take because of early complications such as infection, which is the most common cause of graft failure.

"We debride and treat our patients' burns with Microcyn using a proprietary spray method," Miranda continues. "Based on our preliminary results, the healing of the burns is accelerated, the levels of pain and infection reduced and the patient hospital stay, on average, is reduced from 10 days to six."

In addition to these promising results, Miranda and his burn unit team are also able to more easily treat facial burns, since Microcyn can be used freely about the face, eyes and mouth without concern about toxicity. Miranda expects to submit his first clinical study of the use of Microcyn on burn patients by the end of 2004.

As one might imagine, our respective successes are generating a great deal of interest from physicians and other health professionals around the world. This includes the use of Microcyn to treat dental infections such as advanced periodontal

disease, maxillofacial head and neck infections and abdominal surgical procedures, among others. I firmly believe that Microcyn will become the standard for treating diabetic foot ulcers as regulatory approvals are received.

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First day of treatment with Microcyn. Burns are sprayed using a proprietary high-pressure spray device.



Second day of treatment with Microcyn. Wound is improving without local signs of infection and initial scar contraction is observed. There is also improvement of tissue surrounding the wound.



Fifth day of treatment with Microcyn. Scar contraction is progressing without infection and tissue around the burn remains healthy.

Fermin Martinez, MD, a leading authority on diabetic foot ulcers and president of the Mexican Diabetic Foot Association, is pioneering the use of the Microcyn super-oxidized water for the treatment of chronic wounds.

