

## Wounds that can take you out

A scratch on your finger and a scrap on your knee are "every day" wounds. This issue we are focusing not on the "every day" wound but the deep tissue wounds that afflict thousands of people. These deep tissue wounds are also known as pressure ulcers, decubitus ulcers, bed sores or pressure sores. They develop primarily from pressure in a concentrated area of the skin or from shearing of the skin. These wounds surface in hospitals, nursing homes and among people with disabilities in the community. Persons with paralysis, users of prosthetic limbs, people with peripheral nerve disorders, those living with diabetes and the elderly are at high risk of developing pressure sores. In a study published in 1998 by Dr. Gilcreast, et al, it is estimated that the failure of foot wounds to heal results in 54,000 people with diabetes having to undergo extremity amputations annually in the U.S. A pressure sore can take a person out of his/her daily life for six months to a year and cost an estimated \$100,000 in health care. The prevalence of pressure sores in hospital patients is high and even higher for those in nursing homes. So what part can technologies play in this? There are two areas that we will cover in this issue, the role of neurotechnology in the area of healing a wound and the role of prevention.

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## Educate: Pressure Sore Healing & Prevention

### *Healing the Chronic Wounds*

The most common areas on the body where pressure sores develop are the sacrum (buttocks), ischium (hip area), trochanters (the upper thigh), and around the ankles and heels. They occur primarily due to extended periods of immobility or irritant chafing of the skin. The process of healing a wound is a dynamic repair method. It consists of three defined phases 1) inflammatory, 2) proliferation and 3) maturation. To progress normally, each phase consists of a unique cellular interaction. There has been much progress in the treatment of pressure ulcers. According to Dr. Kath Bogie, a prominent researcher in this area, "as multidisciplinary research and care increases, so, too, will the evidence base required to address these common and complex, chronic wounds." Progress has been made in dressings, creams, gels and technology. One prevalent area of technology is the use of electrical stimulation.

Alternative therapies such as ultrasound, ultraviolet light, superficial heating, pulsed electromagnetic fields, and electrical stimulation have all been studied in the treatment of chronic wounds. Let's focus on the last treatment mentioned, electrical stimulation. Over the past decade, much research has been conducted in the use of electrical stimulation to treat pressure ulcers. Research published by Luther Kloth of Marquette University explains the basis of using electrical stimulation for the treatment of chronic wounds. "The treatment goal for electrical stimulation is to attract negatively or positively charged cells into the wound area, such as neutrophins, macrophages, epidermal cells and fibroblasts that in turn will contribute to wound healing processes by way of their individual cellular activities."<sup>1</sup> The application of electrical stimulation for wound healing has been found to significantly increase the healing rate and be effective in a large number of cases.

Several studies seek to prove the effectiveness and safety of electrical stimulation in the treatment of chronic wounds. In essence, external stimulation may serve to mimic the failed natural bioelectric currents which allow wound healing to proceed. It has also been proven

treatment of chronic wounds. In essence, electrical stimulation may serve to mimic the natural bioelectric currents which allow wound healing to proceed. It has also been proven that given daily, electrical stimulation is effective for enhanced healing rates. However, the success of electrical stimulation is not for every wound. It is dependent to diagnosis, depth of lesion, and severity of infection.

As a treatment option electrical stimulation is easy to apply and can be used by a person at home following instruction from a medical doctor or therapist experienced with electrical stimulation and the treatment of pressure ulcers. To consider this treatment, discuss it with a medical professional prior to beginning any treatment. In addition, practical issues such as cost, time, required training, and patient and therapist safety concerns need to be discussed and addressed. Local or regional insurance coverage may be available however nationally the Center for Medicare and Medicaid does not cover electrical stimulation for wound healing.

As of this writing, we have not been able to find many devices yet approved by the FDA specifically for wound healing, although several devices approved for other indications are being applied for this purpose via off-label use. One device (the Staodyn Dermapulse) has undergone controlled animal and human testing, and an application requesting approval for treating dermal ulcers has been submitted to FDA. There is also an "electric bandage" offered by Biofiscia; however, it is only available for commercial use in Europe and Canada. With this in mind, there are several clinical trials and devices in development supported by the many years of research.

<sup>1</sup> Kloth L.C. (1995) *Physical modalities in wound management: UVC, therapeutic heating and electrical stimulation. Ostomy. Wound. Manage.* 41, 18-4, 26.

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## Educate: Pressure Sore Healing & Prevention

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### *How to prevent them?*

There are two areas of neurotechnology for the prevention of pressure sores, electrical stimulation to build healthier tissue and sensing devices to alert of potential problem areas. Preventive efforts have focused on the relief of pressure via frequent repositioning and the use of pressure-relieving devices. Accordingly, pressure ulcers may be prevented not only by reducing external pressure but also by increasing the resistance to pressure, that is, by directly influencing tissue oxygenation. Physiotherapists recommend strategies to relieve or redistribute pressure for those confined to bed, using a wheelchair or ambulatory individuals with an insensate foot. Again, according to Dr. Kath Bogie of Case Western Reserve University, "healthier tissue can be achieved through increased blood supply or vascularization."

Electrical stimulation makes the muscle move and is the only tool currently available to achieve this in a paralyzed muscle. However, if surgery has been conducted in the treatment of a pressure ulcer, electrical stimulation may not be effective due to potentially altered anatomy of the treatment area. An electrical stimulation regime may be combined with other methods of pressure sore prevention such as frequent position changes, mattresses and cushions to effectively distribute pressures, or custom wheelchair or prosthetic fittings. Regular skin inspection must be continued and the user must stay off any areas of reddened skin, if they appear, until the skin is no longer pink.

Electrical stimulation can be applied in either implantable or external applications. Surface stimulation studies have shown that electrical stimulation can produce positive short-term changes in tissue health such as regional blood flow and pressure distribution. The use of TENS systems, exercise protocols or standing can prevent sores and build healthy tissue. Implanted systems are currently being studied. One study using a system of intramuscular electrodes with percutaneous leads has found to produce additional long-term changes such as gluteal muscle thickness increased by 50% and significant increases in tissue oxygen levels. These findings suggest that an implantable system may have potential for pressure sore prevention, particularly for individuals who lack sensation or who are physically unable to perform regular independent pressure relief. In essence, this modal of electrical stimulation focuses on the contraction of the muscle which in turn allows the body to create healthy tissue. Clinical trials are being conducted to study implanted and external electrode protocols, wireless devices, exercise treatments.

Neurosensing is the other area of development toward the prevention of pressure sores. According to Dr. Chester Ho of the V.A. Hospital in Cleveland, "the use of pressure mapping can help fit devices of daily use such as wheelchairs, beds and prosthetics." This mapping uses sensors to view key pressure points and develop or alter devices to help prevent sores from occurring in those identified areas. For those using orthotics, prosthetics and those living with diabetes, there are wireless sensing devices available to measure pressure and weight-bearing time inside a shoe or artificial limb. This again, can help in the prescription and design of customized equipment. Finally, one novel treatment still in development is based on research conducted by Dr. James Collins of Boston University. He conducted two experiments which indicated that either mechanical vibrations or electrical stimulation can be used to enhance tactile sensation. With this in mind, the use of implanted electrodes to boost sensorimotor function is being development for people with severe sensory loss or motor dysfunction. Clinical trials are also being conducted in such areas as implanted pressure sensing devices for prosthetic users, shear and pressure sensing foot insoles and computerized sensory substitution systems.

### *Summary*

Studies are abundant and commercial products are few. Reimbursement for treatments has been sketchy. Still, thousand of people either have had or do have a pressure ulcer and yet more are in the at risk populations. Technologies being developed can help reduce the amount of time to heal a wound and more importantly help to prevent one all together. With the average cost of a wound at \$100,000 in medical care, treatment and lost wages, a reduction can not only ease the health care burden but improve quality of life. Resources and clinical trial search terms are available in the Resources section of this newsletter.

For more resources, visit the Educate section of our website, [www.NeurotechNetwork.org](http://www.NeurotechNetwork.org)

## Personal Experience: Dr. Martyn Butcher

In this issue of *The Current*, we have experience from a clinician who is using a new electrical stimulation device for chronic wound healing. His experience is supported by many years of published research.

published research.

Dr. Martyn Butcher, MD is a wound specialist practicing in the United Kingdom for over 25 years. He is also the Clinical Director for a neurotech company, [Biofisica](#). He became interested in the treatment of wounds using electrical stimulation from the years of research supporting the treatment but no products to properly deliver the treatment to his patients. He finds the wounds treated with electrical stimulation tend to be those chronic in nature with a grade III or IV classification and have been present for more than six weeks while using conventional dressings. The device he is using is an "electrical bandage" from Biofisica called POSIFECT<sup>®</sup>

The treatment is applied around the wound periphery and delivers a low level electrical current to the skin. It is designed to encourage new blood vessels to form and attract fibroblasts to the wound site. The device comes in one size. In the event that the wound is larger than the size of the device, it is repositioned at intervals around the wound site. When actively stimulating, the device also has a microprocessor to monitor the wound and adjust the level of stimulation. It is powered by a battery with an optimum range of two to four days. The typical treatment protocol is three weeks of stimulation followed by a one week break and another three weeks of stimulation; however, treatment protocols may vary by the needs of the individual patient. The device may be used with other wound dressings but not with silver-based dressing and not while there is an active infection.

This new treatment has been available in the United Kingdom for approximately one year under a European CE Mark and just recently gained approval in Canada. Consequently, it is not yet approved by the U.S. Food and Drug Administration. This device is supported by years of research and can bring wound healing into the electronic age.

## Resources For Chronic Wound Healing and Prevention

There are many resources available for those to treat chronic wounds and prevent pressure sores. The following is a listing of support organizations and neurotechnology organizations offering solutions for this condition. Note there are no surface stimulation systems FDA approved for wound healing. They are used on an off-label basis.

### Support Organizations

FDA Consumer Information: Helping Wounds Heal [http://www.fda.gov/fdac/features/2002/302\\_heal.html](http://www.fda.gov/fdac/features/2002/302_heal.html)

Wound Care Information Network <http://www.medicaledu.com/estim.htm>

Age and Ageing: The Cost of Pressure Ulcers in the UK <http://ageing.oxfordjournals.org/cgi/reprint/33/3/230>

UAB Spinal Cord Injury Information Network: Pressure Ulcers <http://www.spinalcord.uab.edu/show.asp?durki=21622&site=1021&return=21874>

IFESS Consumer Information <http://www.ifess.org/Services/ConsumerEd.htm>

Trials search at <http://www.clinicaltrials.gov/>  
Potential search terms include: pressure sore, pressure ulcer, wound healing, decubitus ulcer, deep tissue wound, bed sore. Understand the risks of clinical trials before participating.

### Neurotechnology Organizations

Afferent Corp. <http://www.afferentcorp.com/>

Biofisica <http://www.biofisica.com/>

CleveMed [http://www.clevemed.com/products/prod\\_all\\_p\\_pressorestep.php](http://www.clevemed.com/products/prod_all_p_pressorestep.php)

Compex Technologies <http://www.compextech.com/>

Dynatronics <http://www.dynatronics.com/>

Empi <http://www.empi.com>

RS Medical <http://www.rsmedical.com/>

Zynex Medical <http://www.zynexmed.com/>

Information regarding these devices and organizations is available in the Educate section of our website at [www.NeurotechNetwork.org](http://www.NeurotechNetwork.org)

*\*\*Surface stimulation systems have not been FDA approved for wound healing. Most use is via off-label and not recommended by companies*

## On the Horizon: Updates in the World of Neurotech

- ♦ [The Center for Adaptive Neural Systems](#) at Arizona State University is currently pursuing several research projects that may have commercial applications in neuroprosthetics and neurorehabilitation. One project involves adaptive electrical stimulation for locomotor retraining, which seeks to improve outcomes for locomotor therapy following spinal cord injury.
- ♦ [St. Jude Medical, Inc.](#), the St. Paul, MN manufacturer of neurostimulation systems, announced U.S. Food and Drug Administration and European CE Mark approvals of a 10-year battery longevity claim for the Eon neurostimulator, a rechargeable device used to treat chronic pain. For patients, this means the Eon device can provide sustainable therapy and maintain a reasonable recharge interval for 10 years, potentially resulting in fewer battery replacement surgeries.
- ♦ [EnteroMedics Inc.](#), the St. Paul, MN manufacturer of neuromodulation devices for obesity and other gastrointestinal disorders, announced that the FDA has granted approval for the expansion of its pivotal clinical trial, known as the EMPOWER study, from 220 patients to 300 patients. Full enrollment is expected in the first half of 2008. The EMPOWER study is a randomized, double-blind, placebo-controlled study to evaluate the safety and effectiveness of investigational VBLOC vagal blocking therapy using the Maestro system in obese patients. VBLOC therapy is designed to empower weight loss by promoting earlier feelings of fullness and reduced hunger while minimizing the side effects and complications associated with existing surgical options and preserving the individual's normal anatomy.
- ♦ Cochlear implant recipients experience a significant improvement in their quality of life, quality of life of 56 cochlear implant recipients using the Nijmegen Cochlear Implant Questionnaire, a self-administered assessment that asks responders about sound perception, speech, self-esteem, and social interaction. Responders reported significant improvements in all areas, with especially large gains observed in the areas of sound perception and social interaction.
- ♦ [Medtronic, Inc.](#), the Minneapolis, MN manufacturer of neurostimulation systems, announced it has received FDA approval to market the RestoreULTRA neurostimulation system for the treatment of chronic intractable pain of the trunk and/or limbs. The patient programmer used with this includes a new feature called TARGETmyStim. This feature allows users to make appropriate and immediate adjustments in their stimulation in order to best address normal fluctuations in pain, including changing pain patterns. By using the remote control programmer, users can fine-tune their stimulation to specific sites up and down the spinal cord and increase or decrease the intensity of the electrical impulses. These adjustments allow the user to customize their pain therapy in a way that was previously only possible with a physician programmer during an office visit.
- ♦ [Neurotech Awareness Coalition](#) is a collaborative effort to change public policy, increase public awareness and directly reach out to disability and frontline clinician groups. Learn more and join the coalition.
- ♦ The [National Spinal Cord Injury Association](#) is working with Neurotech Network to update their resources. NSCIA offers Fact Sheets on various areas important to SCI. Together the organizations are creating a new resource of neurotechnology for spinal cord injury. When completed the resource will be posted on both organization's websites.

Cochlear implant recipients experience a significant improvement in their quality of life, and have improved speech recognition, according to new research published in the March 2008 issue of Otolaryngology-Head and Neck Surgery. The German study evaluated the

Updates are available on our website. Stay updated by signing up for email notifications too. Visit our website at [www.NeurotechNetwork.org](http://www.NeurotechNetwork.org).

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Search the web and raise money for Neurotech Network without forking out a dime. How is that possible? [GoodSearch.com](http://www.GoodSearch.com) is a search engine which donates 50-percent of its revenue to the charities designated by its users. You use GoodSearch exactly as you would any other search engine. Because it's powered by Yahoo!, you get proven search results. The money GoodSearch donates comes from its advertisers — the users and the non-profit organizations do not spend a dime. Search and support Neurotech Network. Go to <http://www.goodsearch.com/>, under "Who do you Goodsearch for?" type "Neurotech Network". Search away! It's that easy.

### *Raise money while you shop*

We went one step further to register with [GoodShop.com](http://www.GoodShop.com). GoodShop is an online shopping mall of world-class merchants dedicated to helping fund worthy causes across the country. Each purchase made via the GoodShop mall results in a donation to Neurotech Network – averaging approximately 3% of the sale, but going up to 20% of the sale. More importantly, there is no cost to you! Visit [www.goodshop.com](http://www.goodshop.com). Select Neurotech Network, then shop for what you want from thousands of merchants.

## Neurotech at Working 2 Walk

Neurotechnology was a featured session during the Working 2 Walk Conference in Washington, DC. On Monday, April 14, Neurotech Network lead a collaborative effort to increase awareness of this growing field. The session began with an introduction to neurotechnology presented by Jennifer French. This was followed by five interactive demonstrations. This included Kelly Emmett for [Medtronic ITB therapy](#), Caitlin Smith for [Control Bionics NeuroSwitch](#), Dr. Beverly Walters, MD for [Cyberkinetics Andara OFS](#), Jody Feld with user, Duane Morrow for the [Bioness L300](#) and Judy Kline with user, Josh Basile for the [Restorative Therapies RT300](#). Many questions and comments came from the engaged audience. A blog of the session is available on the [Working 2 Walk website](#).

Look for Neurotech Network presenting at more conferences. Upcoming events will be the Frontiers of HealthCare Conference in Providence, RI on June 9 and the American Physical Therapy Association (APTA) meeting in San Antonio, TX on June 14.

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## Neurotech Executives Descend on Washington

Nearly 40 executives from neurotechnology companies and organizations came to Washington, DC early in March for the 2008 Public Policy Tour sponsored by the Neurotechnology Industry Organization. The second annual event enabled representatives from the neurotech industry to interact with legislators and regulators and gain a better understanding of how decisions are made in the nation's capital.

After a briefing by representatives of the lobbying firm K&L Gates, participants headed to Capitol Hill for meetings with congressional staffers, and in some cases, members of Congress themselves. NIO encouraged participants to push legislators to support a newly drafted National Neurotechnology Initiative (NNTI), which would authorize about \$200 million in new funding for neurotech-related projects.

Rep. Patrick Kennedy (D-RI) announced he would introduce the legislation in the House on March 12, and Sen. Pete Domenici (R-NM) was expected to introduce it in the Senate. "The current mousetrap of federal initiatives isn't working, and needs to be changed," Kennedy said in a press conference. "We've worked on a bipartisan basis to help make federal research much more effective, to make sure the right hand knows what the left hand is doing."

Kennedy pointed to Neurotech Network executive director Jennifer French as an example of what can be accomplished. French, who suffered a spinal cord injury several years ago, was one of the first users to be implanted with a functional electrical stimulation system that lets her stand up out of her wheelchair. "Her experience is an example of how this technology can be applied to others," he said. In response to a question from Neurotech Business Report concerning the Centers for Medicare and Medicaid Services' refusal to reimburse for FES systems such as French's, Kennedy reacted strongly, contending that people with disabilities have a constitutional right to treatments such as this. "The next administration will need to make a lot of changes with CMS," he said.

On the second day of the tour, participants met with representatives from the CMS and the Food and Drug Administration. Although the meeting was somewhat unwieldy with more than a dozen CMS officials in addition to the NIO delegation, it was worthwhile for these individuals to meet face to face with so many neurotech executives and it was insightful for the industry representatives to get even a vague idea how things get done at the agency. Among the CMS personnel in the meeting were Barry Straube, Director of the Office of Clinical Standards and Quality, and Jeffrey Rich, Director of the Center for Medicare Management. Rich advised participants to design clinical trials broadly, and include cost components. Straube stressed the agency's renewed reliance on evidence-based medicine for national coverage decisions. The CMS representatives seemed to welcome input from the neurotech community with regard to "horizon scanning". We were also encouraged to hear of CMS' openness to more interagency collaboration and town hall-style meetings with affected parties. We were a little discouraged, however, to hear CMM Director Jeff Rich caution vendors against "cherry-picking" the enrolled population in a clinical trial. It is our belief that biomarkers and other selection tools that help a vendor hone in on its most appropriate target population will save the government money in the long term by allowing clinicians to choose from among several alternative therapies the one that is most effective for the patient.

FDA representatives spoke of the agency's new critical path initiative, which involves patients, industry, caregivers, and researchers. The representatives seemed open to input from neurotech executives but cautioned that there wouldn't be time for multiple meetings. They cited as a positive example a recent orthopedic device forum as an effort to help train CDRH staff. They suggested it might be acceptable for the neurotech industry to propose a draft guidance document that might indicate acceptable endpoints.

For the most part congressional staffers seemed to express interest in the NNTI, though there was private speculation that it might be difficult to secure funding on the first attempt. There is currently considerable sensitivity on the hill to servicemen and women returning from Iraq with brain injuries and post-traumatic stress disorders and several members are concerned that there might be an underestimation of the number of cases of TBI. Many of the staffers met with during the two days were not aware of the neurotechnology industry and appreciated the opportunity to meet directly with executives.

The \$200 million sought for the NNTI is a scaleback from last year's first cut at the initiative. Among the key components are \$5 million for the establishment of a coordinating office within the Department of Health and Human Services to serve as the unified voice of federal neurotech efforts; \$80 million to authorize the NTH Blueprint for Neuroscience Research, a collaboration between the 16

Department of Health and Human Services to serve as the unified voice of federal neurotech efforts; \$80 million to authorize the NIH Blueprint for Neuroscience Research, a collaboration between the 16 NIH institutes involved in brain and nervous system research; \$75 million to increase NIH funding for SBIR and STTR programs, with an emphasis on translational neurotechnologies; \$30 million to increase neuroscience-related staffing and training at the FDA; and \$10 million to establish a research center to conduct studies on the ethical, legal, and social implications of neurotechnology.

Neurotech device-oriented organizations participating in the two-day event included [Cyberkinetics](#), [Boston Scientific](#), [Medtronic](#), [Advanced Neuromodulation Systems](#), [Neurotech Network](#), [PhotoThera](#), [International Neuromodulation Society](#), and [NeuroNexus Technologies](#). Neuropharma firms Accera, Adlyfe, Pfizer, Alseres, and Sound Pharmaceuticals also participated.

*Commentary provided by Jim Cavuoto, Neurotech Reports*

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