MEDICAL INNOVATION: NEGATIVE PRESSURE WOUND THERAPY (MEDICAL DEVICE: THERAPEUTIC)

Physician: Dr. Lou Argenta and Michael Morykwas at Wake Forest Industry: Kinetic Concepts, Inc.

Situation

An enormous burden to society

Chronic wounds, or injuries to the skin that fail to heal in a matter of weeks, if ever, represent an enormous burden on society.

Five to seven million Americans are afflicted with chronic wounds annually, including leg ulcers, pressure ulcers and burns, and the total direct cost of chronic wounds amounts to \$20 billion each year in the U.S. This doesn't include the indirect costs of chronic wounds, such as lost work time and impaired quality of life, that are difficult to quantify. Chronic wounds represent a particular threat to older patients and those with poor circulation and diabetes.

Until recently, physicians had very few tools – often just antibiotics and fresh dressings – to manage chronic wounds, which in many cases can lead to severe bacterial infection and even amputation.

Physician-Industry Collaboration

Sub-atomic pressure as a wound healer

In the mid 1990s, two plastic surgeons at Wake Forest University School of Medicine in Winston-Salem, N.C., Dr. Louis Argenta and Dr. Michael Morykwas, began to research the effect of treating hard-to-heal wounds with sub-atmospheric pressure created by a localized vacuum system.

Their early animal research studied the effect of sub-atmospheric pressure on blood flow to the wound area, removal of bacteria from the wound site, and rates of healthy tissue formation. In 1997, the doctors published three landmark articles based on this research, and described a promising new therapy – delivering sub-atmospheric pressure directly to the wound site using a sealed polyurethane foam dressing attached by a tube to a vacuum pump.

Following the publication of the articles, Dr. Argenta looked for an industry partner who could help him make their concept a reality. He worked with Kinetic Concepts, Inc. (KCI), a leader in wound management therapies, to develop a range of products that have become to be known as Negative Pressure Wound Therapy (NPWT).

NPWT uses a series of machines that apply vacuum pressure to a special dressing positioned in the wound cavity or over a flap or graft. This pressure-distributing wound packing helps remove fluids from chronic wounds and promote the normal healing process, by providing continuous or intermittent negative pressure selected to meet the needs of the wound being treated. The pressure can be adjusted within a range demonstrated to provide optimal fluid removal without placing the delicate wound tissue at risk of injury.

Innovation Benefits

38% reduction in wound-associated costs

Today, NPWT represents one of a number of new medical technologies that have dramatically improved chronic wound care and healing, providing enormous benefits to patients and the healthcare system. The KCI NPWT product alone has treated more than 3 million patients worldwide.

Also, <u>a recent study found that more than 1,000 Medicare beneficiaries who failed to respond to conventional wound treatments had more than twice as great a reduction in the size of their wounds when using NPWT, with a treatment cost that was 38% less.</u>

Patient Benefits

A soccer game almost leads to amputation

As described in AdvaMed's <u>Profiles in Progress You Can See</u>, what started out as a typical soccer game quickly turned into a painful nightmare for 19-year-old Chris B. During an aggressive move for the ball, an opponent's kick landed squarely on his leg, breaking it below the knee and requiring immediate orthopedic surgery.

Chris was worried that he might never play soccer again, but his broken leg would end up being the least of his worries. One of the calf incisions from his surgery refused to heal, and, months later, developed into a chronic wound that almost led to amputation.

Chris was unable to walk for months as he underwent several procedures to try to heal his calf wound. Finally, after the fifth failed procedure, his plastic surgeon decided to treat him with NPWT, a new wound management technology at the time.

His physicians used the controlled vacuum system to remove infectious materials carefully and systematically from Chris' wound. A few days later, he returned home and switched to a smaller, battery-powered NPWT unit. His wound began to heal rapidly, dramatically improving in appearance and size. A few months later, he no longer needed the NPWT system and was soon able to walk again. While he cannot yet run or play soccer, he knows that without the device, he would have had to endure more pain and surgeries, including possible amputation.

Chris is making progress every day and has been able to return to work and get back to doing the things he loves to do – above all, he looks forward to playing soccer again soon.