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THE VALUE OF MEDICAL TECHNOLOGY IN WOUND TREATMENT

Improving Quality of Life and Saving Costs

MEDICAL TECHNOLOGY
life changing
innovation

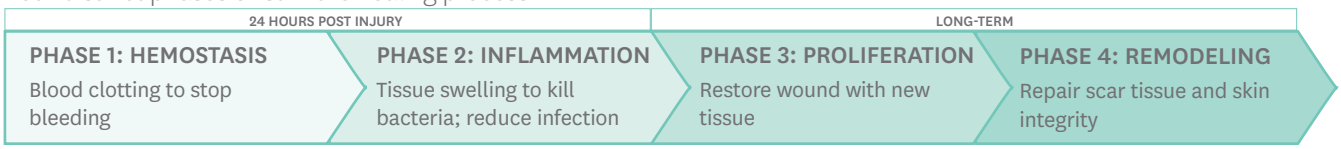
the disease

Wounds are breaches in the structure of the skin that compromise skin function. They can be painful and lead to additional medical complications. Wounds become chronic when they have not completed the healing process (restoring tissue loss and skin function) in the expected time frame, usually within 30 days.[1] Typically, wounds are classified as chronic because they don't respond to initial treatment, or they persist despite appropriate care.[2]

- Chronic wounds typically occur on complex patients with multiple co-morbidities.
- The presence of an open, unhealed wound increases the patient's risk of infection and additional complications.
- Standard wound care may not be sufficient to jump start a stalled wound; advanced wound therapies can help reduce the total cost of care and help restore a patient's quality of life.

There are five to seven million episodes of non-healing cutaneous wounds each year in the United States, with an estimated cost of $20 billion annually to the U.S. health care system.[3]

Four distinct phases exist in the healing process:[4]



Wounds may stall in the healing process due to many reasons, including restricted blood flow, poor nutrition, diabetes, immunosuppressive drugs, or poor mobility. Increases in scientific understanding of the cellular and biochemical steps involved in wound repair have spawned multiple new, advanced medical technologies that may be applied to manage non-healing wounds by addressing the underlying defect that has caused the wound to stall. Diabetic foot ulcers, venous leg ulcers, and pressure ulcers are the chronic wounds most often managed with advanced therapy intervention.

DIABETIC FOOT ULCERS

Diabetic foot ulcers (DFUs) are one of the most common complications of diabetes. Patients with diabetes have a 15 percent risk over the course of their lives for developing a diabetic foot ulcer. Foot ulceration is the precursor to approximately 85 percent of lower extremity amputations in persons with diabetes.[5] Within five years, 45 to 55 percent of patients with neuropathic (complex, chronic pain) and ischemic (restriction in blood supply to tissues) DFUs, respectively, will die.[6]

VENOUS LEG ULCERS

An estimated two and a half million Americans are affected by venous leg ulcers (VLUs) each year at a cost of $14.9 billion to the health care system.[7] 13 to 29 percent of venous leg ulcers take more than two years to reach complete healing,[8] and of those, healed ulcers return at a rate as high as 60 to 70 percent.[9]

PRESSURE ULCERS

There are more than three million patients diagnosed with pressure ulcers (formerly known as bedsores, pressure sores, or decubitus ulcers) in the United States each year. The estimated cost of managing a single full-thickness pressure ulcer is nearly $70,000.[10] Vulnerable patients include the elderly, stroke victims, diabetics, dementia patients, patients in wheelchairs, and those who are bedridden or suffering from impaired mobility or sensation. U.S. expenditures for treating pressure ulcers have been estimated at $11 billion per year.[11]

the treatment: medical technology

"Medical technology has helped to evolve wound treatment dramatically over the past 15 years."

Wound healing is a complex process relying on advanced medical technology to enhance results and improve patient care. Medical technology has helped to evolve wound treatment dramatically over the past 15 years from simple dressings to sophisticated, evidence-based options that treat and promote wound healing.[12]

Today, several types of wound treatment exist that are tailored to the specific type of wound and the unique needs of the patient.

CELLULAR AND/OR TISSUE BASED PRODUCTS FOR WOUNDS

Cellular and/or Tissue Based Products for Wounds (CTPs) contain various combinations of cellular and acellular components intended to stimulate the host to regenerate lost tissue and replace the wound with functional skin. Acellular products (e.g., cadaveric human or animal derived with cellular material removed or bioengineered matrices) contain a matrix or scaffold composed of materials such as collagen, fibronectin, hyaluronic acid, and chondroitin sulfate. Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix are typically allogeneic.

The mechanisms by which bioengineered cellular or acellular CTPs aid wound repair may range from maintenance of a biochemically-balanced, moist wound environment to structural support for tissue regeneration and/or the provision of beneficial cytokines and growth factors to the wound bed.[13]

Research has shown that select CTPs:

- Promote rapid closure of DFUs,[14]
- Promote a higher percentage of wounds closed than conventional therapy,[15] and
- Reduce the incidence of osteomyelitis (bone infection) and frequency of amputation.[16]

NEGATIVE PRESSURE WOUND THERAPY

Negative Pressure Wound Therapy (NPWT) is the application of negative pressure to create an environment that promotes wound healing at the cellular level by promoting granulation tissue formation, promoting perfusion, and removing exudate and infectious material.[17]

NPWT has been shown to:

- Reduce incidence of emergent care and hospitalizations for pressure ulcer patients,[18]
- Reduce secondary amputations for patients with DFUs,[19] and
- Reduce healing time for patients with chronic wounds.[20]

MOBILE HEALTH AND TELEHEALTH IN WOUND CARE

The emergence of mobile health and telehealth technologies has created new opportunities for the diagnosis, monitoring, and treatment of wounds. These technologies offer the option of staging and tracking the progression of wound healing in a variety of care settings.[21]

ANTIMICROBIAL DRESSINGS

Antimicrobial dressings are wound dressings that have an antimicrobial agent acting as a barrier to prevent or help manage infection. Topical antiseptics act on multiple sites within microbial cells and reduce the likelihood of bacteria developing resistance.[22] Dressings incorporating these antimicrobials can play an important role in wound healing by providing an antimicrobial barrier and killing micro-organisms contained in the wound fluid absorbed into the dressing.

Innovation of antimicrobial dressings continues at a rapid pace using advanced medical technology. For example, new dressing technologies that control wound biofilm are being introduced. Biofilm is a grouping of bacteria encapsulated in a protective coating that adheres to wound surfaces. Biofilm is resistant to antibiotics and antimicrobial agents and may delay wound healing. Dressing technologies that disrupt biofilm allow antiseptics to more effectively kill bacteria in the wound fluid.

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COLLAGEN DRESSINGS

Chronic wounds trapped in the inflammatory phase will not progress to healing without resolving the inflammation. During the inflammatory phase, a wound attempts to cleanse itself of all non-viable tissue and debris by utilizing digestive enzymes to breakdown non-viable tissue and exudate to wash away the debris. The major classes of enzymes responsible for digesting non-viable tissue are the matrix metalloproteases (MMPs), including several that digest collagen. MMPs also degrade growth factors (i.e., protein chains) that regulate cell populations and activity. Collagen dressings absorb exudates while also providing a sacrificial substrate, which can serve to divert the MMPs from digesting newly formed tissue, thereby tipping the balance towards wound healing.

Collagen components, such as fibroblasts and keratinocytes, are fundamental to the process of wound healing and skin formation. Collagen is known to support the regulation of extracellular components, which can assist in wound healing. There are a number of advanced wound-care dressings available that incorporate collagen. Some are comprised of Type I collagen and may be combined with other ingredients such as alginates or oxidized regenerated cellulose (ORC). In select populations, use of collagen dressings rather than saline-soaked gauze has been shown to reduce frequency of nursing visits and optimize wound healing time, subsequently reducing health care costs.[23]

THERAPEUTIC SUPPORT SURFACES

Pressure ulcers (formerly known as bedsores, pressure sores, or decubitus ulcers) are areas of localized damage to the skin and underlying tissue due to pressure, shear, or friction. Pressure-redistribution beds, mattresses, and seat cushions are widely used as prevention aids in both institutional and non-institutional settings.

Advanced support surfaces allow for pressure redistribution to manage tissue loads and/or microclimate, as well as provide other therapeutic functions such as pulsation and turning.

Select low air-loss and powered pressure redistribution options provide advanced pressure ulcer prevention and have demonstrated a threefold improvement in median rate of healing, compared with foam mattresses.[24]

"Compression pumps also provide advanced technology for patients with insufficient emptying of venous blood flow in the lower extremities."

COMPRESSION THERAPY

Compression therapy is the recognized treatment of choice for venous leg ulcers and chronic venous insufficiency. Non-healing venous ulcers and "mixed" ulcers with venous disease components exhibit varying degrees of lymphedema, which may respond to compression therapy.

Compression therapy systems, including hosiery, tubular bandages, and bandage systems, which are comprised of two or more layers or components, provide graduated compression externally to the lower limb to improve venous return and reduce edema. Bandages are commonly used for the treatment of active venous leg ulcers.

Compression pumps also provide advanced technology for patients with insufficient emptying of venous blood flow in the lower extremities.

Many patients, including those with venous disease and lymphedema, utilize these devices effectively to reduce swelling and to improve comfort. In addition, improved blood flow aids in the prevention of venous leg ulcers.[25]

medtech as a solution

Advanced wound care treatments can reduce the risk of pressure sores, ulcers, and infection; provide improved outcomes for patients; decrease hospitalization times; enhance quality of life; and improve cost savings for the U.S. health care system.

CLINICAL BENEFIT

Wounds are a serious health concern, causing great levels of patient pain, distress, and anxiety. The medical technology used in wound treatment benefits patients on many levels including:

- Lowering incidence of re-admission, additional surgeries, and complications,[26]
- Reducing amputation rates,[27][28]
- Reducing healing times,[29] and
- Reducing incidence of surgical dehiscence and infection.[30]

ECONOMIC BENEFIT

Estimates indicate that wounds account for nearly four percent of health care system costs, and that number is rising.[31] Furthermore, studies show that products used to treat wounds can produce measurable cost savings to the health care system, including:

- Reducing cost of care in acute and post-acute settings,[32][33]
- Reducing the risk of hospitalization and emerged care episodes,[34]
- Reducing total nursing time and wound related costs,[35] and
- Reducing the risk of repeat skin graft and associated length of hospital stay.[36]

the future

Moving forward, advanced medical technology will play an increasing role in developing enhanced treatment and healing options that will ultimately improve the treatment and health of patients with chronic and non-healing wounds. At the annual meeting of the American College of Wound Healing and Tissue Repair, Dr. Amelia Bartholomew of the University of Chicago discussed new data suggesting it may one day be possible for humans to regenerate tissue for healing.[37]

The cost and incidence of chronic wounds is increasing, due in part to an aging population, increased prevalence of diabetes, and rising obesity. Failure of a wound to heal can have a profound effect on a patient's quality of life. Advanced medical technology is a solution.

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The Value of Medical Technology in Wound Treatment: Improving Lives, Saving Costs

Wounds are breaches in the structure of the skin that compromise skin function. They can be painful and lead to additional medical complications. Wounds become chronic when they have not completed the healing process in the expected time frame, usually within 30 days.[1] Standard wound care may not be sufficient to jump start a stalled wound; advanced wound therapies can help reduce the total cost of care and help restore a patient's quality of life.

5 - 7 MILLION

Episodes of non-healing cutaneous wounds each year in the United States.

$20 BILLION

Estimated annual cost to the U.S. health care system.[2]

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treatment

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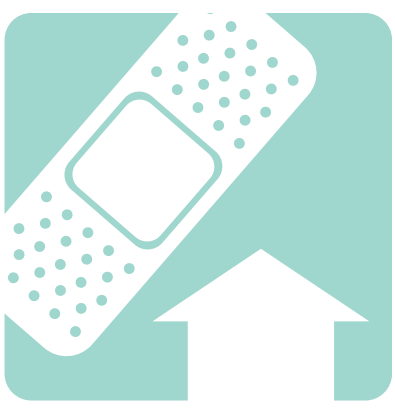
dressings promote rapid healing



Cellular and/or tissue based products for wounds promote rapid closure of diabetic foot ulcers and lead to a higher percentage of wounds closed than conventional therapy.

Antimicrobial dressings act on multiple sites within microbial cells and reduce the likelihood of bacteria developing resistance.[7]

Collagen dressings have been shown to reduce frequency of nursing visits and optimize wound healing time, subsequently reducing health care costs.[8]

vacuum therapy reduces emergent care

Negative pressure wound therapy reduces incidence of emergent care and hospitalizations for pressure ulcer patients, reduces secondary amputations for patients with diabetic foot ulcers, and reduces healing time for patients with chronic wounds.

Therapeutic support surfaces have demonstrated a threefold improvement in median rate of healing, compared with foam mattresses.[9]

medtech as a solution

Estimates indicate that wounds account for nearly **4 percent** of health care system costs, and that number is rising.[10]

clinical benefit

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Reduced amputation rates.[12 13]

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