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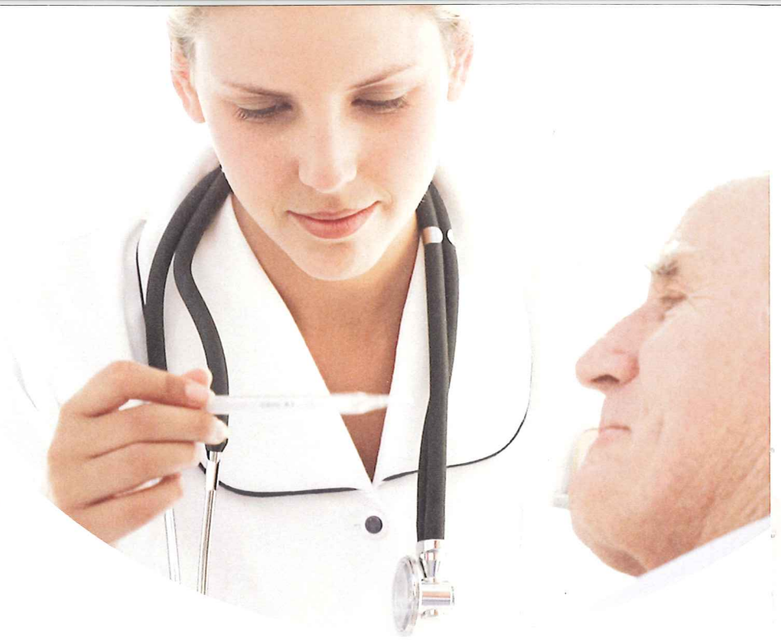
Pain –

The Fifth Vital Sign

Studies estimate that 64-82 percent of leg ulcers, 48 percent of diabetic foot ulcers and 59 percent of pressure ulcers are painful.[1,2,3]

Blood pressure, pulse, respiration and temperature have been defined for many centuries as the four basic "vital signs" that are monitored and managed.



Pain is now considered the "fifth vital sign" that should also be monitored and managed.[4,5,6]

The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage."

Pain is, of course, undesirable because it causes dissatisfaction in the patient, reduces the quality-of-life for the patient, and can lead to poor compliance with treatment.[7,8,9,10] But, pain also alters the physiology of the body by producing a stress reaction, which creates a catabolic reaction (breaking down of fat, protein and carbohydrates for immediate energy use).[8] This catabolic response inhibits healing because, instead of building tissue, the body is breaking it down.[8] The energy used in this "breakdown" process, along with the sleep deprivation and the suppression of the immune function caused by unrelieved pain, weaken the body, making it more susceptible to infection both at the wound site and systemically.[8] The relationship between poor wound healing and pain is well documented.[7,8,9]

PolyMem formulation dressings belong to an innovative class of adaptable wound care dressings called QuadraFoam, which are ideal for virtually all wound types.

QuadraFoam dressings effectively cleanse, fill, absorb, and moisten wounds throughout the healing continuum. No other single wound dressing combines these four key healing capabilities like the PolyMem formulation found in all PolyMem and Shapes by PolyMem® dressings.

PolyMem formulation of QuadraFoam dressing:

CLEANSES Contains a mild nonionic, nontoxic, tissue friendly cleansing agent, activated by moisture, that is gradually released into the wound bed. The built-in, continuous cleansing capabilities usually eliminate the need to cleanse the wound during dressing changes so you can avoid disrupting the growth of healthy tissue as the wound heals.

FILLS Gently expands to fill and conform to the wound, which helps maintain a moist wound healing environment.

ABSORBS Wicks up to ten times its weight in exudate, to help provide long wear time.

MOISTENS Keeps the wound bed moist and soothes traumatized tissues, reducing wound pain and providing comfort at the wound site. The moisturizer also keeps the dressing pad from adhering to the wound so it removes with virtually no pain, improving the caregiver-patient interaction and overall care experience.

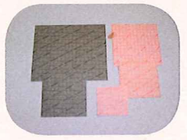
Built right into a QuadraFoam dressing, these four capabilities are ready when you need them–without incurring extra costs or needing additional supplies.

SUGGESTED DRESSING OPTIONS

Shapes by PolyMem Adhesive Film Border Island – water-resistant for long wear time and shaped to conform to the natural shape of the wound, also available in silver

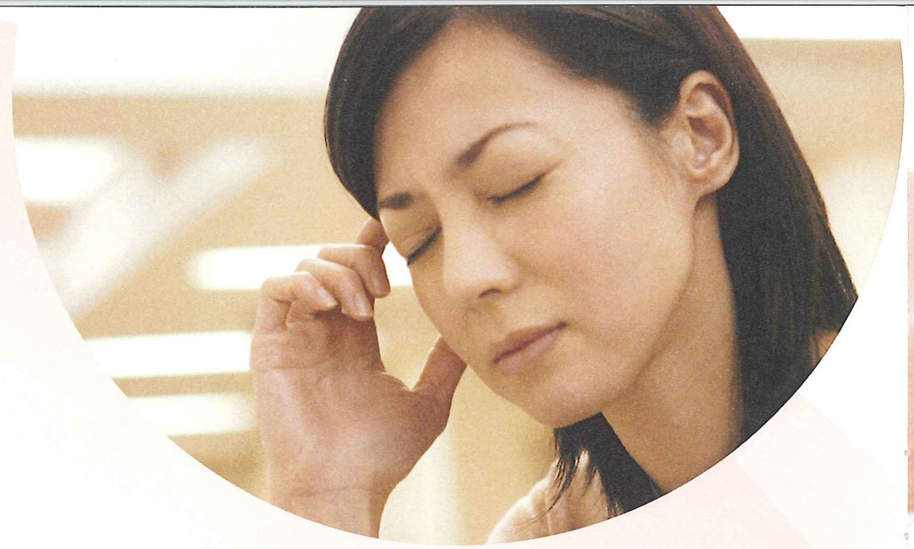
Adhesive Film Border Island – water-resistant for long wear time

Cloth Adhesive Border – highly breathable border for locations where water-resistance is not required



Non-adhesive – ideal for use when held in place with non-adhesive application methods

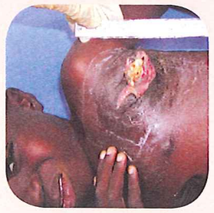
PolyMem formulation incorporating Silver is also available.



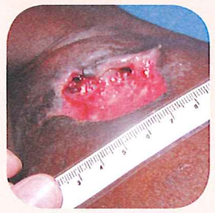
olyMem QuadraFoam formulation, as demonstrated by xtensive animal studies and supported by clinical case tudies, provides the following to wounds:

- ignificant reduction in pain[16,17,19,20,21]
- ignificant reduction in the spread of the inflammatory eaction into the uninjured surrounding tissues[16,20]
- ignificant reduction in edema[16,20]
- ignificant reduction in bruising[16]
- educed injury healing time[16,20]

EXAMPLE OF ACTUAL CLINICAL RESULT[21]



Initial assessment



Example of 6cm debridement

Example of the use of PolyMem Silver for wound care

is patient presented with a chronic, continuously painful infected wound surrounded by significant inflammation d erythema.

e patient's wound pain was completely eliminated within 24 hours after initiation of the use of PolyMem QuadraFoam, hout use of analgesia. The patient's wound remained pain-free during the entire healing process except when aggressively chanically debrided (up to 6 cm deep) in this very sensitive area of the body.

is experience is typical of the pain relief reported by patients to clinicians who use PolyMem QuadraFoam mulation dressings.[21]

STEPS involved in pain and activation of local inflammatory mediators with the resulting spread of inflammatory response as a result of tissue damage.[9,10,11,12,13,14,15,16,17]

STEP 1

Injury occurs causing tissue damage. Contents of the damaged cells are released into the wound area. These substances activate the nociceptor nerve endings and also initiate a local inflammatory reaction.

STEP 2

Local activation of the nociceptor systems, with the release of Substance P, CGRP (Calcitonin Gene-Related Peptide), hormones and the inflammatory mediators causes the recruitment of additional nociceptor fibers in the area of the injury to release and activate the inflammatory reaction, so it spreads into surrounding, undamaged tissues.

STEP 3

Nociceptors respond by activating inflammatory cells, such as mast cells, which then release histamine into the damaged area. The release of histamine increases the spread of the inflammatory reaction.

STEP 4

At the same time, the inflammatory reaction created by the cells' contents and the activation of the nociceptor system causes immune cells to be drawn to the site and activated, which further activate the sensory nerves through the local release of bradykin, histamine, prostaglandin, growth factors and cytokines into the wound area.

STEP 5

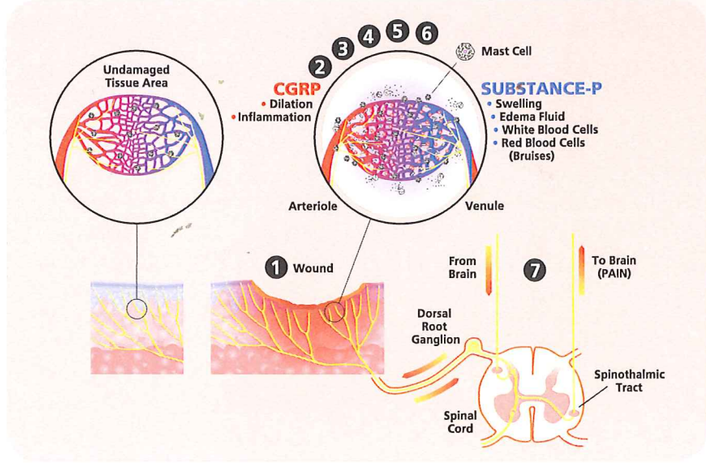
The edema causes further damage by initiating the release of additional inflammatory mediators and reducing the blood profusion of the damaged tissues, which causes activation of more nociceptors and continued spread of the inflammatory response.

STEP 6

CGRP and Substance P cause dilation of the blood vessels and leakage of blood cells, platelets and protein into the capillary bed, causing edema.

STEP 7

Injury message is transmitted to the brain where it is perceived as pain. Brain response can cause either reduction or increase of local inflammatory response.



PolyMem® QuadraFoam® dressings help reduce wound pain associated with dressing changes:

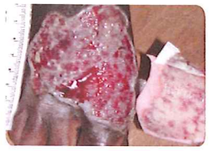
PolyMem QuadraFoam dressings are non-adherent to the wound bed.[18] Dressings which stick to the wound bed cause wound pain and trauma when they are removed during dressing changes and are also associated with delayed healing.[7,18]

The combined actions of the integral glycerin, wound cleanser, polymer matrix and starch copolymer in the dressing prevent PolyMem QuadraFoam from sticking to the wound bed. These dressing components act together to create a soft-gelled, continuously moist, non-adherent wound contact layer, which is atraumatic during removal.

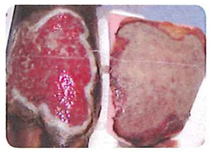
- **PolyMem QuadraFoam dressings usually eliminate the need for wound bed cleansing during dressing changes. Cleansing wounds is known to cause wound pain during dressing changes.[7]**

The PolyMem QuadraFoam formulation continuously cleanses the wound through the combined actions of the integral wound-friendly cleanser, glycerin and the wicking actions provided by both the polymer and the starch copolymer.

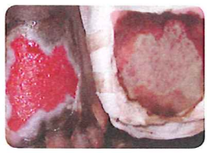
EXAMPLE OF ACTUAL CLINICAL RESULT[19]



Day 3: 7.0cm x 7.0cm x 0.3cm



Day 7: 7.0cm x 7.0cm x 0.2cm



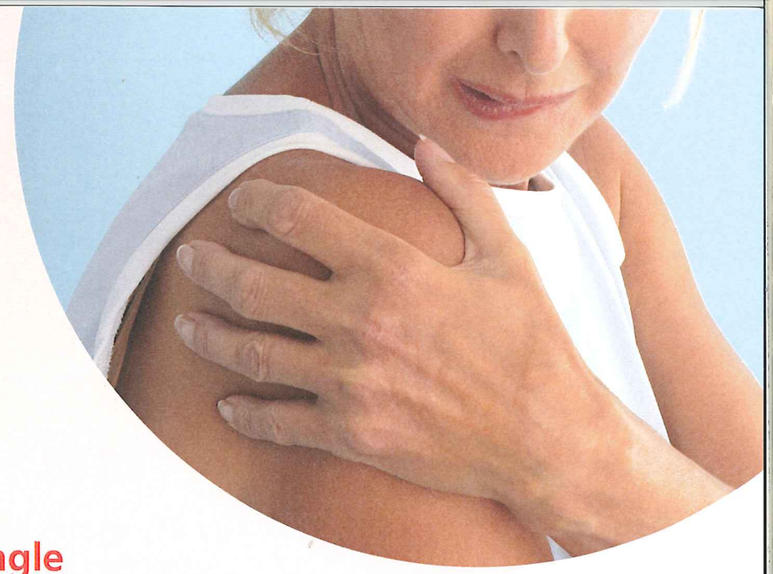
Day 14: 6.7cm x 5.8cm without depth

PolyMem QuadraFoam dressings did not adhere to the wound during removal. Additionally, the wound bed became clean through only the use of the PolyMem dressings; the wound was not manually cleansed during dressing changes. Note that the slough and other wound debris was absorbed into the dressing and was therefore discarded with the dressing.

PolyMem also helps reduce wound pain by altering the actions of certain pain sensing nerve endings.[20]

The most common cause of pain in chronic wounds is tissue damage, which is referred to as nociceptive pain or inflammatory pain.[9,10] Nerve damage is the other cause of wound pain and is called neuropathic pain.[9,10] Neuropathic pain is often experienced after chronic unrelieved nociceptive pain.[9,10]

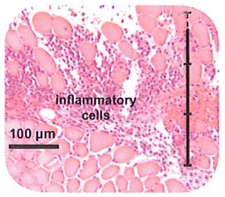
PolyMem formulation dressings help to inhibit the action of some of the pain sensing nerve fibers (nociceptors) which carry some of the pain messages after tissue damaging injuries and inflammation.[20] These nerve endings transmit information that can result in 1) allodynia (pain caused by normally non-painful stimuli, such as lightly brushing the skin); 2) primary hyperalgesia (increased sensitivity to pain at the site of injury), and 3) secondary hyperalgesia (pain caused by touching an uninjured area surrounding the injured site).[10,11,13] These populous nerve endings, found in the epidermis, dermis, muscle, joints and viscera, are also responsible for spreading the inflammatory reaction into surrounding uninjured tissues.[9,10,11,12,13] The spreading of the inflammatory reaction is often clinically evidenced by increased temperature, pain, bruising and swelling beyond the immediate zone of injury.[10,12]



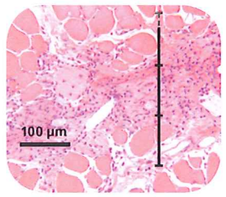
Inflammation is the single greatest cause of wound pain.[10,12]

Extensive animal research demonstrates that PolyMem dressings significantly reduce the spread of the inflammation response into the surrounding uninjured tissues by altering the nociceptor response.[20] This reduction in the nociceptor response occurs without interfering with the robust localized inflammatory response required for healing the injury.[20]

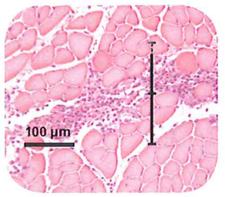
POLYMEM HELPS REDUCE SPREAD OF INFLAMMATORY REACTION INTO SURROUNDING, UNINJURED AREAS



(A) Incision only



(B) Incision with gauze



(C) Incision with PolyMem

This series of images shows the width of the spread of the inflammatory cells, in muscle, around an incision. The dark portion of the scale in each image (each segment is 100µm) represents the spread of the zone of the inflammatory reaction around the center line of the incision. In images A and B, there is no difference in the spread of the inflammatory reaction around the center of the injury. In image C, notice how PolyMem reduces the spread of the inflammation into the surrounding, uninjured tissues by approximately 40 percent when compared with gauze. Statistically, PolyMem reduces the spread of the inflammatory reaction into the surrounding undamaged tissue by approximately 25 percent.[20]

By interrupting this cycle, PolyMem QuadraFoam dressings help interrupt the ever-widening, self-perpetuating cycle of pain and swelling often associated with both chronic and acute injuries.[12,13,14,15,16]

Suppression of the spread of the inflammation and swelling cascade into the surrounding uninjured tissues helps accelerate the healing process.[16,20]

It is currently unclear how the PolyMem QuadraFoam dressings reduce the nociceptor activity. However, there is evidence suggesting that the dressing might absorb sodium ions, by capillary action, from the skin and from the subcutaneous tissues.[17] If this is true, then this local decrease in sodium ion concentration would result in reduced nociceptor nerve conduction, which could account for the observed pain relief. [17, 20]