Can a Drug-Free Dressing Decrease Inflammation and Wound Pain? What Does the Evidence Say?

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PURPOSE

Persistent wound pain not only decreases the quality of life for the patient, but it also directly inhibits healing by producing a stress response. which promotes a catabolic state. 1,2 In addition. wound pain predisposes the patient for wound infection through depression of the immune system.² Patients with multiple comorbidities and the elderly are often poor candidates for systemic pharmaceutical pain relievers. Even when they are prescribed, systemic products do not always address wound pain well.

Topical pharmaceutical pain relievers such as ibuprofen and lidocaine have local sideeffects that can increase infection risks and/ or directly impair wound healing.3-9 Studies indicate that inflammation often plays a critical role in the etiology of many wound types, but anti-inflammatory drugs such as prednisone inhibit wound healing. Can any intervention truly promote wound healing while decreasing inflammation and persistent wound pain?

RATIONALE

Pain and trauma associated with dressing changes (procedural pain) can be minimized by using a non-adherent dressing, 10 such polymeric membrane dressings. \$\frac{\pmathrm{1}}{11,12}\$ Components of these sophisticated dressings also work synergistically to provide continuous cleansing of the wound bed, usually completely eliminating the need for manual wound bed cleansing or even rinsing at dressing changes. 12-16 Wound bed cleansing is an often overlooked source of procedural pain.1

But this study focuses on persistent wound pain, including examining the scientific physiological explanation for claims that polymeric membrane dressings inhibit the nociceptor response, even through intact skin. 12-16,18 The resulting decreased pain and inflammation should dramatically improve wound healing. 1,2 In addition, any drug-free persistent wound pain relief would avoid negative side-effects inherent in the use of currently available systemic and topical pharmaceutical agents.

METHODOLOGY

A thorough search of the peer-reviewed published data discussing this dressing's possible effect on inflammation and wound pain was performed to determine the robustness of the evidence for its ability to decrease inflammation and persistent wound pain. We identified four scientific studies: a 72-patient controlled study of pain and comfort level on burn and split-thickness skin graft patients a 24-patient controlled study of pain and inflammation following arthroscopy and two rigorous animal studies performed by independent laboratories. We also examined the four published large facility-based product evaluations. Finally, we did a meta-analysis of every published peer-reviewed patient case study or series (187 individual patients) to identify how polymeric membrane dressings may influence persistent wound pain in clinical practice.

- 1. Recognize that side effects of many pharmaceuticals currently available for wound pain can hinder healing.3-5
- 2. Review the evidence found in patient case studies and in rigorous scientific studies, for polymeric membrane dressings' ability to influence the nociceptor response, which can often decrease wound pain.
- 3. Consider the advantages of using a drug-free dressing over using systemic or topical medications for the relief of wound pain.

Laboratory research unequivocally concludes that polymeric membrane dressings achieve significant pain relief by inhibiting the nociceptor response both locally and centrally. 19-21 appears that the dressing is also influencing other receptors, resulting in additional analgesia beyond that anticipated by its antinociceptive properties (see data, below), 20-21

The facility-based evaluations found decreased pain, spasticity and bruising and increased patient mobility when polymeric membrane dressings were used. The decrease in persistent wound pain provided by polymeric membrane dressings was one of the critical factors influencing the choice to use polymeric membrane dressings (see map) in each of the four large evaluations. 13,16, 23, 24

Persistent wound pain was mentioned as a problem for 88 of the 187 case study/series patients. The independent clinician authors attributed a reduction in persistent wound pain to polymeric membrane dressings in 83 of these patients (94%). In 67 cases (76%), the pain reduction was described as dramatic, very significant, etc. (see

CONCLUSION

Polymeric membrane dressings definitely inhibit the nerve conduction that normally leads to pain and the inflammatory response, not only on wounds, but also when applied to intact skin. This reduction in the nociceptor response occurs without interfering with the robust localized inflammatory response required for healing the injury. These insights into the actions of this dressing formulation have exciting implications for persistent wound pain relief and wound healing in both chronic and acute wounds.

CASE STUDY META-ANALYSIS

A WOCN consultant

evaluated various modern dressings for skin tears at

nine long-term care facilitie

in the Chicago area:
"...polymeric membrane
dressings reliably and

reproducibly relieve the pain

associated with skin tears both

No Data: 3 Same Pain: 1 Worse: 1

INCISIONAL STUDY ON A RODENT MODEL^{20,21}

specialists hypothesized that polymeric membrane

dressings use the same mechanisms as acupuncture and

nitrous oxide administration. But polymeric membrane

dressings are non-invasive and do not have systemic

ANALGESIA WITH NO INCISION

FACILITY-BASED EVALUATIONS

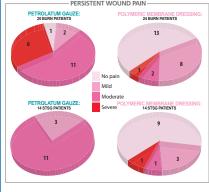
Rehab Station, Stockholm, a leading research center for Spinal Cord Injured (SCI) wound dressings over provide significant wound pain relief (or in SCI cases, decreased spasticity)... All of our Plastic surgeons at Sheba the quick healing and dressings for all skin graft donor 800 cases:
"...the use of pain medication in the ward was significantly When over 180 USA-based Long-Term-Care reduced after polymeric facilities compared polymeric membrane dressings using an evidence-based Skin Tear Protocol to their previous treatmen

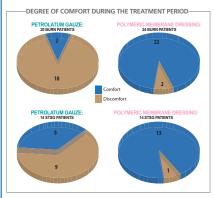
71% switched to polymeric membrane dressings. Statistics wea. A reduction in both episodes of bruising with injury and swelling in the area of injury. Patients using the polymeric membrane dressings skin tear protocol also reported decreased pain during dressing changes and decreased pain overall."

introduced. An additional benefit was faster mobilization of our tients...The dramatic reduction

BURN AND GRAFT PATIENT STUDY¹¹

A Korean group investigated the effects of polymeric membrane dressings on wound healing and pain in 1999. Their work was published in a peer-reviewed journal, but since it was in Korean, it went largely unnoticed. Later, the authors directed a translation into English, from which this information was obtained. Using anesthetized rabbits, the authors determined that epithelization was significantly increased with polymeric membrane dressings (p<0.05) They went on to test polymeric membrane dressings in a 72-patient controlled study of pain, healing time and comfort level on patients with burns and on patients with split-thickness skin graft (STSG) donor sites. Polymeric membrane dressings were significantly superior to standard care for each of the three parameters (p < 0.01). The authors reported that the dressings were also easy to use and economical





BLUNT TRAUMA ANIMAL MODEL¹⁹

A woman fell from a ladder, leaving a significantly painful area with a very slight abrasion. She placed a polymeric membrane dressing on the area, hoping that it would alleviate the pain.

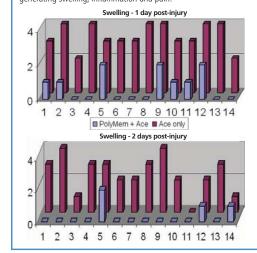
The woman experienced a complete absence of tenderness. swelling and bruising in the area covered by the dressing, but the injured area that was left exposed exhibited the expected response note the line of ecchymosis (photo,



The surprising dressing-shaped area without ecchymosis exhibited by the woman who fell in the office, coupled with amazing results when polymeric membrane dressings were used post-arthroscopic knee surgery on a 65-year-old man, led Dr. Kahn of the University of Minnesota to do studies using the dressings over intact skin. The results were presented at the World Pain Conference in 2000.

- Uniform blunt trauma was applied to both legs on 14 anesthetized animals
- A polymeric membrane dressing plus a compression wrap were applied to one leg
- Only the compression wrap was applied to the other leg Two independent blinded observers evaluated swelling on a 0 - 4 scale at 24 and 48 hours

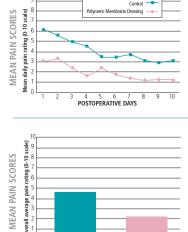
The author concluded: "Preliminary experimental evidence suggests that this cutaneous dressing inhibits the activity of the nociceptive neurons in the epithelium which, in turn, blocks the response of the spinal dorsal root mechanism that is responsible for generating swelling, inflammation and pain," 19



ARTHROSCOPIC KNEE SURGERY²²

A 24-patient randomized controlled study of pain and inflammation using polymeric membrane dressings following arthroscopy was performed. The results were published in the Medline indexed journal, Orthopedics, in 2003.

Pain and skin temperature (an indicator of inflammation) were compared in 24 patients randomized to the use of polymeric membrane wraps or standard dressings following minor arthroscopic knee surgery over a ten day period. The treating surgeon, who performed the post-operative evaluation on day 10, was blinded. Despite equal use of pain medication, pain scores were significantly lower for the polymeric membrane group on each of the ten days, when compared to the controls. The polymeric membrane group demonstrated lower overall pain scores (p=0.03) and also lower temperatures (p=0.02) than the control group.





Preliminary findings (graphs below) showed a statistically significant decrease in spinal cord Fos labeling when animals with incisions

wrapped with polymeric membrane dressings were compared to those wrapped with a placebo foam[†] (p=0.005), gauze (P<0.0001) and no dressing at all (p=0.0017). Since the performance of the placeho foam[†] on the animals receiving incisions was not statistically different from that of gauze (p=0.1740) or no wrap (p=0.8397), it was not included in the main study (histological slides, below, and graphs, far right).

the same foam substrate found in polymeric membrane dressings, but without the added components

PAIN PERCEPTION WITH INCISION Placebo Foam[†] Dressing

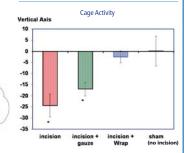
The vertical lines (photos, right) on the histological slides measure the extent of the inflammation (purple stained cells) at the incision site. The inflammatory cells are dramatically more localized with polymeric membrane dressings.

Polymeric membrane dressings help reduce the spread of the inflammatory reaction into surrounding, uninjured areas. But there is no reduction in the robust localized inflammatory response required for healing the injury. Suppression of the spread of the inflammation and swelling cascade into the surrounding, uninjured tissues helps accelerate the healing process.

Surprisingly, when polymeric membrane dressings were applied to animals without incisions in the preliminary study, they showed significantly more Fos labeling than animals wrapped in the placebo $foam^{\dagger}$ (n<0.0001) or no dressing at all (n=0.0042) The authors suggested that, while clearly the incised animals were exhibiting decreased nociceptor activity, polymeric membrane dressings must be activating non-nociceptive peripheral nerve fibers in the animals Surpery and dressing without incisions At the conclusion of the main study, the pain 1 Hour 3 Hours 5 Hours 24 Hour

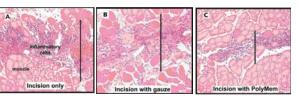
Withdrawal response due to hyperalgesia is the same with or without gauze, but it is much less with polymeric membrane dressings in place. indicating pain relief.

* Statistically significantly different (p<0.0001) from polymeric membrane dressings



Polymeric membrane dressings (Wrap) also reverse the decrease in cage activity, which is caused by wound pain, much more dramatically than covering the wounds with

*Statistically significantly different from rats with no incision



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This research analysis was funded by Ferris Mfg. Corp.

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