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Methods used in the study, *Evaluation of a polyurethane foam dressing impregnated with 3% povidone-iodine (Betafoam) in a rat wound model*, led to unreliable results

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Dear editor,

I eagerly read the recent article, *Evaluation of a polyurethane foam dressing impregnated with 3% povidone-iodine (Betafoam) in a rat wound model* [1], expecting to find a solid independent research study comparing 6 dressings. I was disappointed. Blinding and randomization were not discussed, leaving readers to wonder if the healthiest rats with the most promising wounds were (perhaps not even consciously) chosen for the preferred (Betafoam) dressings. Fig. 3B is missing the data for one of the comparator dressings (Medifoam) and some of the significant differences are omitted. Further, the investigators used one of the comparator dressings (PolyMem Silver, Ferris Mfg. Corp., Ft Worth, TX, USA) completely contrary to their instructions for use (IFUs). Study results will not translate into real world settings when a comparator is used inappropriately. For example, when negative pressure is compared with conventional dressings, researchers would not omit suction from both arms of the study and use the same dressing change intervals, because adding uniformity in these aspects of the study methods would yield meaningless results [2].

The value of the findings is also brought into question by other serious problems with the study design, most due to the investigators' failure to distinguish between polymeric membrane dressings (PMDs) and conventional foam dressings. Despite this, the comparator dressing that performed the best (after the test dressing) in this study is PolyMem Silver (PolyMem-Ag), a PMD that has been called an Ideal Dressing [3,4].

Basic knowledge of PMDs is needed to understand why the study design was not suitable for this dressing type. PMDs release a nontoxic surfactant cleanser [5] to break the chemical bonds between the wound bed and substances that impair healing [3,6-12]. Glycerol pulls nutrient-filled, enzyme-rich fluid from the body into the wound bed, enhancing both healing and autolytic debridement [6,8-10,13-15]. The now-loosened and floating undesirable substances are drawn by the superabsorbent into the PMD substrate [4,6,10,16]. This continuous wound cleansing system is so powerful that routine rinsing is not recommended at dressing changes [6,15-17].

PMDs placed on either intact skin or on wounds alter the nociceptor response to concentrate inflammation at the site [10,18,19], and decrease secondary inflammation, which can facilitate healing and prevent infection by increasing circulation to damaged areas [14,20-22]. For this reason, their IFUs include covering the periwound as well as the open wound area with PMDs. Limiting inflammation to the specific area of injury has another benefit: wound closure with PMDs is reported to result in a stronger, more pliable, less noticeable scar [13,23,24].

PMDs balance moisture using several simultaneous mechanisms [6,8,9,15,20,25]. The one that is important to this research study design is that the "intelligent" backing adjusts the moisture vapor transmission rate to allow excess fluid to evaporate while retaining the fluid needed to keep dry wounds moist [8].

The configuration of the PMD tested in this study, PolyMem Silver, is designed to keep the silver locked in the dressing, where it acts on microbes that are pulled from the wound bed by the above-described continuous cleansing system without

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the toxic effects to human cells that may be a problem for conventional foam dressings with silver [10,26-29]. Even in the artificial conditions of the study by Zou et al. [30], cited by the authors, PolyMem Silver was the least toxic of all the silver dressings tested.

Specific problems with the study, *Evaluation of a polyurethane foam dressing impregnated with 3% povidone-iodine (Betafoam) in a rat wound model* [1], include:

(1) PolyMem Silver's "intelligent" backing cannot maintain optimal moisture throughout the wound bed if it is covered with an additional moisture barrier such as Op-Site, as was the case in this study.

(2) The investigators in this study did not follow PolyMem Silver's Instructions for Use. Instead of changing the dressings when indicated, the investigators changed the dressings every 2 to 3 days, regardless of saturation.

These 2 failures to use PolyMem Silver as designed would have had additive effects, causing the wounds to be oversaturated in the first few days of use and preventing the PMDs' continuous cleansing system and control of inflammation from performing optimally to promote healing.

(3) The quality of the scar was not tested directly by checking tensile strength or cosmetic features. Instead, the total quantity of collagen deposited was measured. However, more is not always better: although deficient collagen deposition leads to a weak scar, excess collagen deposition is also undesirable, leading to hypertrophic scars in humans. PolyMem Silver limits the inflammation that causes this excess collagen deposition; this well-balanced inflammation is reported to result in a higher quality scar [13,23,24]. Histology showed that although Betafoam had a significantly better arrangement of collagen fibers than the other four comparator dressings, PolyMem Silver performed as well as Betafoam on scar histology.

(4) Tissue invasion into the dressing was not tested by evaluating the wound bed after dressing removal, but rather, residual DNA in the dressings was used as "proof" that a dressing had adhered to the wound bed, causing mechanical trauma and tissue damage. However, PMDs are designed to atraumatically pull slough, cellular debris, and other wound contaminants, including DNA-containing cell fragments, into the dressings through the previously described continuous wound cleansing system. This beneficial function of PMDs would cause PolyMem Silver to test as if it was adherent to the wound bed, even though hundreds of independent clinicians have reported [6] that PolyMem is completely nonadherent and dressing changes are trauma-free.

In conclusion, several of the tests used in this study were inappropriate for measuring the desired outcomes, particularly when using PMDs. And, the methods used in this research specifically undermined the effectiveness of PolyMem Silver (the IFUs were not followed). However, despite these limitations, PMDs still performed quite well in this study, which demonstrates the adaptability of the PMD design. Future studies comparing Betafoam with other dressings should be designed to allocate dressings randomly, and to use each dressing according to its manufacturer's Instructions for Use. Finally, study results are meaningful only if the methods take into account the unique characteristics of all study comparators.

Sincerely,

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CONFLICTS OF INTEREST

Dr. Benskin discovered PolyMem dressings while working for 5 years in a remote clinic in northern Ghana, West Africa. As a result of her extensive experience using PolyMem on well over one thousand patients, Dr. Benskin became so passionate about the benefits of these unique dressings that she is currently an employee of Ferris Mfg. Corp., the makers of PolyMem.

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