Evaluating All Available Evidence Pertaining to Using PMDs for Pressure Injuries

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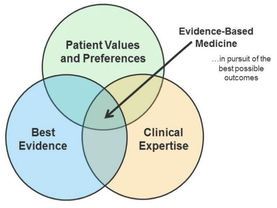
Purpose: Evidence informs us of what is actually happening in the world, and helps us predict what is likely to happen in the future. Evidence can lead to truth. The Information Age has facilitated locating online research results so that clinicians can evaluate it. Adding the best evidence from others to our clinical expertise and our knowledge of our individual patients improves practice.[2,3] This paradigm (The Evidence-Based Practice Triad, above) should be rooted in a foundation of biological plausibility.[4]



The Fundamental question addressed by ranking studies into Levels of Evidence is: What is the likelihood that the results will reliably translate to similar patients? The answer is largely determined by study design. A strong design minimizes the influence of bias (see chart, below) and can overcome many imperfections in implementation. However, Cochrane reviews, which favor double-blinded Randomized Controlled Trials (RCTs) have been criticized because they completely omit most studies from real-world settings.[3-5] In addition to problems with results not translating into practice, when the conclusion is, "insufficient evidence," (as it has been in every evaluation of dressing effectiveness studies),[4] the default is that expert opinion (the GOBSAT method, "Good Old Boys Sitting Around Table") prevails.[4,6-8] A more transparent, inclusive, system was needed.[6,8]

The Joanna Briggs Institute (JBI), a collaborator with the Cochrane Group and over 70 other entities globally, promotes and supports the synthesis, transfer, and utilization of evidence to improve outcomes by identifying feasible, meaningful, effective healthcare practices.[9] In 2014, ~13 years of work reached fruition and the JBI published new guidelines for evaluating clinical effectiveness, including descriptive and qualitative studies that had been brushed aside in previous systems into a hierarchy with very specific definitions.[6,9] Studies are pre-ranked into Levels **1** – **5** based upon design, then adjusted up or down a maximum of two levels using GRADE quality standards.[6,9] These guidelines are quickly becoming the standard for evaluating the best *available* evidence for informing health decisions.[6]

The JBI LEVELS of EVIDENCE, with PROS & CONS for EACH LEVEL

#	Study Design Type	Advantages	Disadvantages
1	Systematic Reviews w/ RCTs Randomized Controlled Trials Pseudo-Randomized CTs	Results are most likely to be unbiased The only difference between groups is the focus of the study	Systematic reviews may be overly selective RCTs often eliminate pts with comorbidities Pseudo RCTs not 100% random; potential bias
2	Reviews of lower level studies Quasi-Experimental Studies Historic Control Studies*	Usually every patient is included (all consecutive pts for a period of time) Includes defined comparison group	Patients not randomly allocated – bias possible Unknown factors may have changed over time, influencing the results
3	Cohort (big population) Study Observational Studies	Every qualifying patient is included, limiting bias	No comparison group in observational studies Correlations may be caused by an untested factor
4	Case Series Case Studies	Actual human results; real life setting Rich in details & insights; relatable Unique patient situations described	Authors tend to report best examples; failures may be omitted; usually numbers of pts are small No comparison group in case studies or series
5	Systematic Expert Guidelines Expert Consensus Single Expert Opinion In Vitro & Animal Studies	Useful when more robust data is not available No human is harmed Comparatively inexpensive	Experts are wrong at least 50% of the time In vitro and animal studies often do not translate well to real human patients PMDs work with the body; in vitro = no body!

Methods: Guided by the question, "Does available evidence support using polymeric membrane dressings* (PMDs) for pressure injuries?" the researcher searched PubMed, with no date or language limits, and over 100 pages of Google Scholar. Colleagues searched CINAHL and SCOPUS. The manufacturer's records were reviewed. Following JBI search guidelines,[10] the researcher attempted to include ALL published articles, book chapters, and major conference posters (electronically searching abstracts and walking conference halls) which included PMDs, including studies sponsored by competitors. All pertinent references were obtained. This data is current through 31 Jan 2018.

Documents simply including the brand name of a PMD* in a list or table alongside conventional foam dressings were eliminated. The author summarized ALL other research in a table and categorized it using the JBI's Evidence Levels for Evaluating Product Effectiveness.[9] The documents were then filtered for those which included using PMDs on tissue damaged by pressure or to prevent such damage. Evidence for damage occurring on the foot of a diabetic was included only if the author stated that the primary mechanism of injury was pressure, or if the damage was on the heel or ankle.[11]

Experts note that clinician authors often mistakenly call their studies case series even when their design is more robust.[12] If a study included a comparison group, it was correctly identified as a Level **1** or **2** study. To avoid bias in favor of PMDs, Level **1** pseudo-randomized controlled trials were down-graded to Level **2** if the comparison documentation was vague or if the overall study time-frame was long. The literature search and pre-ranking portion of the JBI process was completed. However, the more subjective GRADE standards must be applied by independent evaluators.

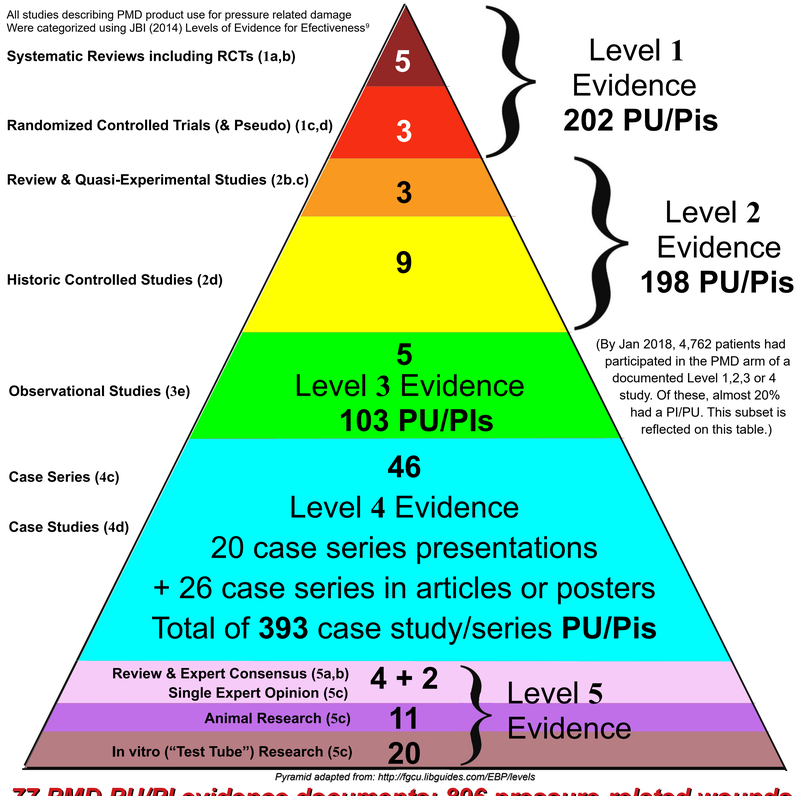
Rationale: Confidence in the findings of a meta-analysis requires that the evidence have a strong foundation (higher level study designs) AND that it includes studies from real-life situations.[4,5,13] This apparent conflict is resolved by two studies which show that results from randomized trials and observational studies are usually consistent.[4,14,15] Selection bias can be minimized by including consecutive patients.[13]

Study methods can have built-in bias, which may explain why results of corporate-sponsored studies favor the sponsor 96.5% of the time.[16] Research conducted by independent clinicians is far less likely to be biased.[13] However, independent clinicians are less likely to formally publish their work as a journal article.[16,17] To help overcome publication bias, The JBI recommends including conference posters and the grey literature in literature searches.[10]

Results: 20 Level 1 & 2 reviews and studies + 51 descriptive studies + 6 expert appraisals

Polymeric Membrane Dressings (PMDs): How the Evidence Stacks Up for Use on Pressure Ulcers/Injuries

PMD products have been tested by independent clinicians and other wound experts worldwide for over 30 years.



Pyramid adapted from: http://fgcu.libguides.com/EBP/levels

77 PMD PU/PI evidence documents; 896 pressure-related wounds.

72 completely independent authors produced most of these studies; 16 additional authors were compensated by Ferris Mfg. Corp. or distributors, usually via an unrestricted grant. 5 researchers were Ferris Mfg. employees.

**When the brand of polymeric membrane dressings (PMDs) in this evidence was identified, it always came from the PolyMem® family of polymeric membrane dressings. PolyMem is made by Ferris Mfg. Corp., Fort Worth, TX, USA, who sponsored this study and presentation.*

Summary of Research Findings: The researcher found 77 evidence documents informing the decision to use PMDs on pressure injuries, including some articles and posters about which PMDs' manufacturer was previously unaware. 896 patients were included in the PMD arm of these studies. The authors, most of whom conducted completely independent studies, consistently found PMDs superior to comparators, which included a variety of conventional foams, antibiotic ointments, hydrofibers, alginates, hydrocolloids, thin films, collagens, silicone, negative pressure wound therapy, acetic acid, petrolatum and bismuth tribromophate, enzymes, hydrogels, maltodextrin dressings, carboxymethylcellulose, Dakins, paraffin gauze, silver sulfadiazine, betadine, various silver-containing modern dressings, and electrical stimulation.

PMDs proved cost effective due to the continuous cleansing system, which reduced dressing change times, decreased pain, and facilitated family participation in patient care. PMDs effectively balanced moisture, decreasing dressing change frequency while keeping wounds moist. Eschar and slough resolved without any other forms of debridement. Persistent wound pain consistently decreased. Wounds closed quickly.

Conclusion: Independent clinicians produced by far the majority of evidence pertaining to PMDs, including evidence pertaining to using PMDs on pressure injuries. The evidence demonstrates that when PMDs are recognized as a unique dressing type, they consistently outperform conventional foams and all other advanced wound management methods.

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