Appendix G. Overall Strength of Evidence

**Table G-1. Overall strength of evidence**

| **Key Question** | **Number of Studies** | **Number of Subjects** | **Quality**  **(Good, Fair, Poor)** | **Consistency**  **(High, Moderate, Low)** | **Directness**  **(Direct or indirect)** | **Precision**  **(High, Moderate, Low)** | | **Strength of Evidence (High, Moderate, Low, or Insufficient)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?** |  |  |  |  |  |  | |  |
| ***Support Surfaces*** |  |  |  |  |  |  | |  |
| Air-fluidized beds superior to other surfaces | 4 randomized trials, 1 observational | 908 | Fair | High | Direct | Low | | Moderate |
| Alternating pressure surfaces similar to each other | 4 randomized trials | 369 | Fair | High | Direct | Low | | Moderate |
| AP beds versus other surfaces | 2 randomized trials, 1 trial, allocation unclear, 1 retrospective cohort | 368 | Poor | Moderate | Direct | Low | | Low |
| AP cushions versus other cushions | 2 randomized trials | 77 | Fair | Low | Direct | Low | | Insufficient |
| LAL beds similar to other surfaces | 4 randomized trials; 1 observational | 329 | Poor | Low | Direct | Low | | Low |
| ***Nutrition*** |  |  |  |  |  |  | |  |
| Protein-containing nutritional supplements superior to standard diets or placebo | 10 randomized trials  2 observational | 562 | Fair | High | Direct | Imprecise | | Moderate |
|  |  |  |  |  |  |  | |  |
| Vitamin C similar to placebo | 1 randomized trial | 88 | Good | NA (one study) | Direct | Imprecise | | Low |
| Zinc supplementation versus no zinc supplementation | 1 randomized trial | 70 | Fair | NA (one study) | Direct | Imprecise | | Insufficient |
| ***Local Wound Applications*** |  |  |  |  |  |  | |  |
| Hydrocolloid superior to standard care | 10 randomized trials | 560 | Poor | Moderate | Direct | Low | | Low |
| Hydrogel versus standard care | 4 randomized trials | 156 | Poor | Low | Direct | Low | | Insufficient |
| Foam versus standard care | 3 randomized trials | 118 | Poor | Low | Direct | Low | | Insufficient |
| Transparent film versus standard care | 3 randomized trials | 106 | Poor | Low | Direct | Low | | Insufficient |
| Hydrocolloid versus hydrogel | 3 randomized trials | 167 | Poor | Low | Direct | Low | | Insufficient |
| Hydrocolloid equivalent to foam | 8 randomized trials | 508 | Fair | Moderate | Direct | Moderate | | Moderate |
| Radiant heat similar to other dressings (complete wound healing) | 4 randomized trials | 160 | Good | Moderate | Direct | Moderate | | Moderate |
| Radiant heat superior to other dressings | 4 randomized trials | 160 | Good | Moderate | Direct | Moderate | | Moderate |
| Debriding enzymes versus hydrocolloid/standard care | 5 randomized trials | 218 | Fair | Low | Direct | Low | | Insufficient |
| Phenytoin versus hydrocolloid/standard care | 3 randomized trials | 154 | Fair | Low | Direct | Low | | Insufficient |
| Dextranomer paste inferior to hydrogel/alginate dressings | 2 randomized trials | 227 | Fair | Moderate | Direct | Low | | Low |
| Collagen applications similar to hydrocolloid/standard care | 3 randomized trials | 169 | Fair | Low | Direct | Low | | Low |
| Maggot therapy versus standard care | 3 observational | 129 | Poor | Moderate | Direct | Low | | Insufficient |
| Platelet-derived growth factor superior to placebo | 3 randomized trials | 196 | Fair | Moderate | Direct | Low | | Low |
|  |  |  |  |  |  |  | |  |
| Fibroblast growth factor versus placebo | 2 randomized trials | 60 | Poor | Low | Direct | Low | | Insufficient |
| Nerve growth factor versus placebo | 1 randomized trial | 36 | Good | NA | Direct | Low | | Insufficient |
| Macrophage suspension versus standard care | 2 observational | 299 | Poor | Low | Direct | Low | | Insufficient |
| ***Surgery*** |  |  |  |  |  |  | |  |
| Cutaneous versus fasciocutaneous versus myocutaneous flaps | 4 observational | 560 | Fair | Low | Indirect | Low | | Insufficient |
| ***Adjunctive Therapies*** |  |  |  |  |  |  | |  |
| Electrical stimulation superior to sham | 9 randomized trials | 397 | Fair | Moderate | Direct | Moderate | | Moderate |
| Electromagnetic therapy equivalent to sham | 4 randomized trials | 112 | Fair | Moderate | Direct | Low | | Low |
| Ultrasound similar to sham or standard care | 3 randomized trials | 148 | Fair | Moderate | Direct | Low | | Low |
| NPWT similar to standard care or topical gel | 2 randomized trials  1 observational | 52  86 | Fair | High | Direct | Low | | Low |
| Light Therapy similar to sham or standard care (complete wound healing) | 1 randomized trials  1 observational | 489 | Fair | Low | Direct | Low | | Low |
| Light Therapy superior to sham or standard care in (wound surface area reduction) | 4 randomized trials  1 observatonal | 489 | Fair | Low | Direct | Low | | Low |
| Laser Therapy similar to sham or standard care | 4 randomized trials | 157 | Fair | Moderate | Direct | Low | | Low |
| Hydrotherapy superior versus sham or standard care | 2 randomized trials | 128 | Fair | Moderate | Direct | Low | | Insufficient |
|  |  |  |  |  |  |  | |  |
| **1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?\*** |  |  |  |  |  |  | |  |
| ***Surgery*** |  |  |  |  |  |  | |  |
| Ulcer recurrence rate after surgery lower for sacral versus. ischial ulcers | 4 observational | 560 | Fair | Moderate | Indirect | Low | | Low |
| ***Adjunctive Therapies*** |  |  |  |  |  |  | |  |
| Electrical stimulation vs. sham, by ulcer stage | 5 randomized trials | 197 | Fair | Moderate | Direct | Moderate | | Insufficient |
| Electromagnetic therapy versus sham, by ulcer stage | 1 randomized trial | 30 | Fair | NA | Direct | Low | | Insufficient |
| **1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age; race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? \*** |  |  |  |  |  |  | |  |
| ***Surgery*** |  |  |  |  |  |  | |  |
| Ulcer recurrence rate greater after surgery for patients with spinal cord injury versus others | 1 observational | 158 | Fair | NA | Indirect | Low | | Low |
| ***Adjunctive Therapies*** |  |  |  |  |  |  | |  |
| Electrical stimulation versus sham in spinal cord injured patients versus others | 4 randomized trials | 138 | Fair | Moderate | Indirect | Low | | Low |
| Electromagnetic therapy versus sham | 2 randomized trials | 60 | Fair | Moderate | Direct | Low | | Insufficient |
|  |  |  |  |  |  |  | |  |
| **1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training? \*** |  |  |  |  |  |  | |  |
| ***Key Outcomes: Adjunctive*** |  |  |  |  |  | |  |  |
| Electrical stimulation versus sham | 9 randomized trials | 397 | Fair | Moderate | Direct | | Low | Low |
| Electromagnetic therapy versus sham | 3 randomized trials | 72 | Fair | High | Direct | | Low | Insufficient |
| **2. What are the harms of treatments for pressure ulcers? \*** |  |  |  |  |  | |  |  |
| ***Support Surfaces*** |  |  |  |  |  | |  |  |
| Unclear harms of support surfaces | 6 randomized trials; 1 observational | 2,399 | Fair | Low | Direct | | Low | Insufficient |
| ***Nutrition*** |  |  |  |  |  | |  |  |
| Unclear harms of nutritional supplementation | 5 randomized trials  2 observational studies | 448 | Fair | Low | Direct | | Low | Insufficient |
| ***Local Wound Applications*** |  |  |  |  |  | |  |  |
| Dressings and topical therapies associated with skin complications | 25 randomized trials  5 observational studies | 3,728 | Fair | Moderate | Direct | | Low | Moderate |
|  |  |  |  |  |  | |  |  |
| Dressings/topical therapies vs. other dressings/topical therapies | 6 randomized trials  1 observational | 2276 | Poor | Low | Direct | | Low | Insufficient |
| Biological agents not associated with significant harms | 4 randomized trials  1 observational | 332 | Fair | Low | Direct | | Low | Insufficient |
| ***Surgery*** |  |  |  |  |  | |  |  |
| Ulcer recurrence from flap failure 12 to 24 percent | 2 observational | 3 | Fair | Moderate | Indirect | | Low | Low |
| ***Adjunctive Therapies*** |  |  |  |  |  | |  |  |
| Local skin irritation with electrical stimulation | 3 randomized trials | 146 | Fair | Low | Direct | | Low | Low |
| Unclear harms of electromagnetic therapy | 1 randomized trial | 30 | Fair | NA | Direct | | Low | Insufficient |
| Unclear harms of therapeutic ultrasound | 3 randomized trials | 101 | Fair | Low | Direct | | Low | Insufficient |
| Unclear harms of negative pressure wound therapy | 2 observational | 77 | Fair | Low | Indirect | | Low | Insufficient |
| Light therapy not associated with significant harm | 4 randomized trials | 327 | Fair | Moderate | Direct | | Low | Low |
| Short-term laser therapy not associated with significant harm | 4 randomized trials | 137 | Fair | Moderate | Direct | | Moderate | Low |
| **2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline? \*** |  |  |  |  |  | |  |  |
|  |  |  |  |  |  | |  |  |
| ***Surgery*** |  |  |  |  |  | |  |  |
| More harms with ischial versus sacral and trochanteric surgical repairs | 2 observational | 376 | Fair | Low | Indirect | | Low | Low |
| Wound dehiscence more common when bone removed at time of surgery | 1 observational | 148 | Fair | NA (one study) | Direct | | Low | Low |
| ***Adjunctive Therapies*** |  |  |  |  |  | |  |  |
| Harms of electrical stimulation, by ulcer stage | 3 randomized trials | 146 | Fair | Low | Direct | | Low | Insufficient |
| **2b. Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity; body weight; specific medical comorbidities; and knows risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? \*** |  |  |  |  |  | |  |  |
| ***Adjunctive Therapies*** |  |  |  |  |  | |  |  |
| More adverse events with electrical stimulation versus sham in frail elderly vs. younger (mostly spinal cord injured- patients | 3 randomized trials | 146 | Fair | Moderate | Direct | | Low | Low |
| **2c. Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training? \*** | No studies | - | - | - | - | | - | - |

Abbreviations: NA+ not applicable.

\* Overall strength of evidence ratings are displayed for key questions and comparisons for which our review included a body of evidence that could be rated. Key questions and comparisons for which there were no studies, or single poor-quality studies, were not rated for strength of evidence. Strength of evidence domains were adapted from Owens et al.