Evidence Table H-9: Adjunctive

Evidence Table H-9a. Adjunctive trial and observational studies

| **Author, year Country Overall Quality Rating** | **Study Type** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Adegoke, 2001141 Nigeria  Fair | Randomized trial | Patients presenting with multiple pressure ulcers admitted to the neurology wards of the University College Hospital, Ibadan, Nigeria. | Patients that were smokers | NR/NR/7/6 | Age (Mean):44 years Female: NR Race: NR | Adjunctive: Electrical Stimulation vs. sham | Stage: 100% Stage IV Size (mean): 15.8 vs. 15.4 mm2 Location:  greater trochanter - 2 vs. 1 sacrum - 1 vs. 2 |
| Adunsky, 2005142 Israel Fair | Randomized trial | Only in-patients, with stage III degree non-diabetic pressure ulcers lasting 30 days, age>18 years, informed consent, ulcer duration less than 24 months, ulcer size greater than 1 cm2 but smaller than 50 cm2, no recent history (minimum of 30 days) of growth factors or vacuum-assisted treatment. | Patients with ulcers other than 3 degree (stage III), liver function enzymes higher than twice the upper limit of normal values, renal failure with creatinine>2 mg%, anemia (hemoglobin<10 g%), albumin<2.6 g%, and patients having a pacemaker. Patients with significant medical disorder that might interfere with treatment results, patients with recent (2 months) use of steroids, chemotherapy, or other immunocompromising drugs. | NR/NR/63/63 | Age (Mean): 71 years Female: 35% Race: NR | Adjunctive: Electrical Stimulation vs. sham | Stage: NR Size (mean): 7.5 vs. 7.6 cm2 Location:  sacrum – 25  trochanters – 13  legs – 13  buttocks – 4  ischium – 2 |
| Ahmad, 2008(a)143  Ahmad, 2008(b)144 Saudi Arabia  Fair | Randomized trial | Chronic pressure ulcer, Stage II ulcers  (Article uses Yarkony-Kirk grade criteria) | Cardiac pacemaker; peripheral vascular diseases; active osteomyelitis; pregnant; receiving long-term radiation therapy, steroid therapy or chemotherapy. | NR/NR/60/60 | Age (Mean): 39 years Female: 53% Race: NR | Adjunctive: Electrical Stimulation (high voltage pulsed galvanic current (HVPC)) | Stage: II Size (mean cm2): 7.12 vs. 7.12 vs. 7.14 vs. 7.21 Location: NR |

| **Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued** |  |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Study Type** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location** |
| Baker, 1996145 US Fair | Randomized trial | Patients with spinal cord injuries (SCI) and one or more pressure ulcers. | NR | NR/NR/80/80 | Age (Mean): 36 years Female: 18%  Race: White - 43% Black - 29% Other - 28% | Adjunctive: Electrical Stimulation | Stage: NR Size (mean): 6.6 vs. 2.4 vs. 8.5 vs. 8.6 cm2 Location:  foot - 13% vs. 9% vs. 7% vs. 8% thigh - 15% vs. 23% vs. 26% vs. 16% ischial - 30% vs. 33% vs. 24% vs. 40% sacral - 30% vs. 33% vs. 24% vs. 36% other - 5% vs. 5% vs. 14% vs. 36% |
| Burke, 1998\*146 US  Fair | Randomized trial | VA inpatients presenting with either a Grade III or IV pressure ulcer. | NR | NR/NR/18/ 18(42 PU) | Age (Mean): NR Female: NR Race: NR | Adjunctive: Hydrotherapy | Stage: Grade III or IV – 100% Size (mean): NR Location: NR |
| Comorosan, 1993147  Romania  Fair | Trial | Ministry of Health (Romania) in terminal stages of life, chronically ill, or neurologically impaired. Patients had stage II and III ulcers. | NR | NR/NR/30/30 | Age (Mean): 72 years  Female: 56%  Race: NR | Adjunctive: Electromagnetic pulse | Stage: II - 67%  III - 33%  Size (mean): 5.6 cm2  Location:  Sacrum - 23%  Buttock - 30%  Other - 47% |
| Dehlin, 2003148 Denmark Fair | Randomized trial | Patients with stage III (Shea grade II or III score) pressure ulcer, ulcer location on the trunk or foot, ulcer age 2 weeks to 6 months, initial area 1-20 cm2, and patients age >65 years. | Patients with unstable diabetes mellitus (HbA1c >10%), serious or terminal malignancy or terminal illness, treatment with radiotherapy or cytotoxins, suspected or proven osteomyelitis, antibiotic treatment of ulcer within 2 weeks , use of corticosteroids, (>10mg/day of prednisone) significant abnormal blood tests in the month before inclusion, pacemaker, photosensitivity or sensitivity to electromagnetic radiation, life expectancy < 3 months, and participation in any other clinical study during the last month. | NR/NR/201/164 | Age (Mean):84 years Female: 65% Race: NR | Adjunctive: Light Therapy | Stage: (Shea) Stage II - 56% vs. 50% Stage III - 44% vs. 50%  Size (mean): NR  Location:  Foot - 55% vs. 55% Trunk - 45% vs. 45%  Ulcer age (mean):  49 vs. 57 days |
| Dehlin, 2007149  Denmark Fair | Randomized trial | Patients with stage III (Shea grade II or III score) pressure ulcer, ulcer location on the trunk or foot, ulcer age 2 weeks to 6 months, initial area 1-20 cm2, and patients age >65 years. | Patients with unstable diabetes mellitus (HbA1c >10%), serious or terminal malignancy or terminal illness, treatment with radiotherapy or cytotoxins, suspected or proven osteomyelitis, antibiotic treatment of ulcer within 2 weeks , use of corticosteroids, (>10mg/day of prednisone) significant abnormal blood tests in the month before inclusion, pacemaker, photosensitivity or sensitivity to electromagnetic radiation, life expectancy < 3 months, and participation in any other clinical study during the last month. | NR/NR/163/163 (including 87 subjects from 2003 study) | Age (Mean): 84 years Female: 61% Race: NR | Adjunctive: Light Therapy | Stage: (Shea) Stage II/III – 100%   Size (mean): 4.1 vs. 4.7cm2  Location:  Foot - 41% vs. 46% Trunk - 59% vs. 54%  Ulcer age (mean):  41 vs. 46 days |
| Durovic, 2008150 Serbia Fair | Prospective, randomized, single-blind study | Patients with stage I–III ulcer; absence of relative contraindications for using of polarized light; absence of deterioration of a common disease or attack of new disease; and a patient’s agreement to participate in the study. | Patients previously in the study to treat their current pressure ulcer; skin grafting was planned within one week; nutrition was poor, as indicated by albumin levels below 3.0 g/dL; presence of local or general infection, particularly the sacral (pilonidal) sinus or the sacral osteomyelitis; necessity for drugs that can affect the skin and delay in healing, specially steroids, immunosuppressive agents, antineoplastic drugs and anticoagulants. | NR/48/40/40 | Age (Mean):65 years Female: 45% Race: NR | Adjunctive: Light Therapy | Stage: I-III  Size (mean):Surface Area (cm2) - 15.10 vs. 19.15, p=0.18  Location: Low part of back - 0 vs. 5% Right-low part of back 5% vs. 0 Right buttock - 5% vs. 0 Left buttock - 5% vs. 5% Both buttocks - 0 vs. 10% Sacral area - 50% vs. 25% Right sacral-buttock area - 5% vs. 0 Right iliac spine - 0 vs. 5% Left hip - 15% vs. 15% Right hip - 0 vs. 5% Right heel - 5% vs. 20% Left heel - 10% vs. 10% |
| Ford, 2002151 US Fair | Randomized trial | Presence of stage III or IV ulcer for 4 or more weeks; albumin greater than or equal to 2.0; age 21–80; and ulcer volume after debridement = 10–150 ml. | Fistulas to organs or body cavities; malignancy in the wound; pregnant or lactating female; Hashimoto thyroiditis, Graves disease, iodine allergy, systemic sepsis; electrical burn, radiation exposure, chemical exposure; cancer, connective tissue disease, chronic renal or pulmonary disease, uncontrolled diabetes, corticosteroids or immunosuppressive agents; cardiac pacemaker; ferromagnetic clamps; or recent placement of orthopedic hardware. | NR/NR/28/22 | Age (Mean): 41.7 vs. 54.4 years Female: NR Race: NR | Adjunctive: Negative Pressure Wound Therapy | Stage:  Stage II & III – 100%  Size (mean): NR  Location:  Ischial - 25.7%  Sacral - 48.6% Lateral malleolar - 11.4% Trochanteric - 2.9% Calcaneal - 11.4% |
| Gentzkow, 1991152 US and Canada Fair | Randomized trial | Patients with open pressure ulcers at Stage II, III or IV at 9 centers in the US and Canada. | Ulcers were excluded if they were totally occluded by eschar, had bleeding or involved major blood vessels; located presternal, periorbital, or laryngeal/pharyngeal; occurred in pregnant patients; patients with cardiac pacemakers; osteomyelitis or peripheral vascular problems predisposing them to thrombosis; cancerous; patients on long-term steroid therapy, chemotherapy, radiation therapy, or were very obese. | NR/NR/49(ulcers)/40(ulcers) | Age (Mean): 63 years Female: 45% Race: NR | Adjunctive: Electrical Stimulation | Stage: Stage II - 5% vs. 0% Stage III - 73% vs. 76% Stage IV - 21% vs. 24% Size (mean): 12.5 vs. 19.2 cm2  Location: Hip/Ischium - 32% vs. 42% Sacrum/Coccyx - 42% vs. 19% Leg/Foot - 26% vs. 38% |
| Griffin, 1991153 US Fair | Randomized trial | Male, complete/incomplete spinal cord injury (SCI), pelvic pressure ulcer stage II-IV. | Severe cardiac disease; cardiac arrhythmia; uncontrolled autonomic dysreflexia or used a pacemaker. | NR/NR/20/17 | Age (Median): 29 years  Female: 0% (Male:100%) Race: NR | Adjunctive: Electrical Stimulation | Treatment vs. placebo stage II: 25% vs. 22.2% stage III: 62.5% vs. 66.6% stage IV: 12.5% vs. 11.1% Size (mean mm2): 234.1 vs. 271.8 Location: pelvic area |
| Gupta, 2009154 India Fair | Randomized trial | Inpatients with neurological disorders having one or more stage III or IV clean and non-infected ulcers. | Patients with cardiac pacemakers and pregnant women were excluded from the study. Nonischemic ulcers and ulcers with underlying osteomyelitis were also excluded from the study. | NR/NR/12/12 | Age (Mean): 28 years Female: 25%  Race: Non-white - 100% | Adjunctive: Electromagnetic Therapy | Stage: Stage III - 37% Stage IV - 43% Size (mean): NR Location: NR |
| Ho, 2010155 US Fair | Cohort - Multicenter, observational study | Hospitalized inpatients at the SCI centers associated with 10 VA Medical Facilities; male or female inpatients (aged ≥18 years) with SCI and at least 1 Stage III/IV (indicating a severe wound) ulcer of the pelvic region. | Patients elected to have reconstructive flap surgery of the target pressure ulcer; patients with known osteomyelitis who had not been, or refused to be, adequately treated with appropriate antibiotic treatment and/or surgical procedures (as determined by the patients’ physician); no resolution of osteomyelitis after 3 months of antibiotic and/or surgical care; psychopathology that may conflict with study objectives; Previous diagnosis of active malignant disease at any time during the patient’s lifetime; life expectancy <12 months; History of nephrosis, hemodialysis, or chronic ambulatory peritoneal, dialysis therapy; history of AIDS, at immunologic risk of infectious complications within the past 6 months; known hypersensitivity to anabolic steroid medications ,coronary artery disease, significant occlusive vascular disease, or congestive heart failure; or inability/unwillingness to provide informed consent. | NR/NR/86/86 | Age (Mean): 55 years Female: 2% Race: White - 56% African American - 37% Asian - 1%  Hispanic - 5% | Adjunctive: Negative Pressure Wound Therapy | Stage: Stage III (mean) - 1 vs. <1 ulcers Stage IV(mean) - 2 vs. 2 ulcers  Size (mean) - NR Location:  Ischial - 42% vs. 52% Perineal - 2% vs. 0% Sacral - 43% vs. 48% Trochanter - 13% vs. 0% |
| Ho, 2012156  US  Fair | Prospective, randomized trial | Inpatients who had SCI and were receiving standard wound care for stage III and IV pelvic pressure ulcers; aged older than 18 years; No preserved sensory function in the area of the pressure ulcers; Stage III and IV pelvic (coccygeal, ischial, or trochanteric region) pressure ulcers; clinically clean wound area (i.e., no necrotic tissue, no odor, and no exudate or minimal serosanguinous exudate only); No surrounding erythema or other evidence of cellulitis; No tunneling, no actual or possible connection to body cavities, and no fistula; No malignancy or vascular disease associated with the area of tissue breakdown; No significant active systemic disease, such as heart disease, renal failure, diabetes, or end-stage cancer; Pressure ulcers with maximum diameters of 3 to 15 cm at recruitment into the study; No antibiotic therapy for 7 days before recruitment into the study. | NR | 267/28/28/28 | Age (Mean):56 years Female: NR Race: NR | Adjunctive: Pulsatile Lavage | Stage:  Stage II or III - 100%  Size (mean) –  Ulcer volume – 6.54 vs. 10.56 cm3  Location:  Sacrococcygeal - 50% vs. 29%  Ischial - 50% vs. 57% sacrococcygeal  Buttock - 0% vs. 14% |
| Houghton, 2010157 Canada Good | Randomized trial | Patients with paraplegia/ quadriplegia caused by congenital, medical or traumatic SCI, 18 years and older, living in the community, stage II-IV PU, 1-20 cm2 for at 3+ months, able to participate for at least 3 months. | Serious or multiple medical conditions that would limit healing, condition that was contraindicated for EST (cardiac pacemaker, osteomyelitis, pregnancy, cancer). | 67/34/34/31 | Age (Mean): 51 years  Female: 42% Race: NR | Adjunctive: Electrical Stimulation | Stage: stage II: 22.2% vs. 6.2% stage III: 22.2% vs. 37.5% stage IV: 55.5% vs. 43.7% stage X: 0% vs. 12.5% Size (mean cm2): 2.73 vs. 3.38 Location: buttock region, foot, ankle and knee   (NPUAP stage X: unstageable) |
| Iordanou, 2002158 Greece Fair | Observational | Patients with pressure ulcers of 1st, 2nd and 3rd grades (Torrance); pressure ulcers on the buttocks, trochanters, sacrum, shoulders and legs; each patient had to have two pressure ulcers, one of which received the polarized therapy (experimental) and the other acting as comparator; and the larger ulcer of each patient was chosen as the experimental ulcer. | Presence of skin necrosis on the ulcers; previous or planned surgical excision of the pressure ulcer; and patients in palliative care (in very poor clinical status). | NR/NR/55/32 | Age (Mean): 67 years Female: NR Race: NR | Adjunctive: Light Therapy | Stage (Torrance): 1-3 Stages I-III : 100% Size (mean): 2.84 vs. 2.10 cm2 Location:  Buttocks/trochanters/ sacrum/shoulders/legs - 100% |
| Kloth, 1988159 US Fair | Randomized trial | Patients between 20 and 89 years of age, All patients in the study had intact peripheral nervous systems and stage IV ulcers that had eroded into or through muscle. | NR | NR/NR/16/ 16 | Age (Mean): 69 years  Female: NR Race: NR | Adjunctive: Electrical Stimulation | Stage: Stage IV - 100% Size (mean) - 4.08 cm2 Location: |
| Lucas, 2003160 Netherlands Fair | Randomized trial | Consecutive patients with stage III pressure ulcers. | Patients with ulcers other than stage III (full-thickness skin defect extending into adipose tissue). | NR/NR/86/79 | Age (Mean):82 years Female: 63% Race: NR | Adjunctive: Laser Therapy | Stage III - 100% Size (mean): 350 vs. 317 mm2 Location (n= 47 vs. 39): Gluteal - 8 vs. 4 Sacrum/Coccyx - 14 vs. 14 Greater trochanter - 1 vs. 0 Med. Femoral condyle - 0 vs. 1 Calcaneus - 14 vs. 13 Med. Fem. Cond. - 1 vs. 1 Lat. Malleolus - 5 vs. 3 Other - 0 vs. 0 |
| Lucas, 2000(a)161 Netherlands Fair | Randomized trial | Consecutive patients with stage III pressure ulcers. | Patients with ulcers other than stage III (full-thickness skin defect extending into adipose tissue). | NR/NR/20/16 | Age (Median): 88 years  Female: 88% Race: NR | Adjunctive: Laser Therapy | Stage III - 100% Size (mean): 94 vs. 82.5 mm2 Location (n= 8 vs. 8): Gluteal - 1 vs. 3 Sacrum/Coccyx - 2 vs. 2 Calcaneus - 2 vs. 2 Med. Fem. Cond. - 1 vs. 1 Lat. Malleolus - 2 vs. 0 Other - 0 vs. 0 |
| Maeshige, 2010162 Japan Fair | Randomized trial | Treatment naive inpatients who were receiving standard wound care including surgical debridement, topical antimicrobials and pressure redistribution, presence of National Pressure Ulcer Advisory Panel (NPUAP) stage III or IV pressure ulcers. | clinical signs of local wound infection, extensive necrotic tissue, diabetes mellitus type 2 and/or peripheral arterial disease. | NR/NR/5/5 | Age (Mean): 82 years Female: 60% Race: Non-white - 100% | Adjunctive: Ultrasound | 7 ulcers/5 patients  Stage III: 4/7 ulcers Stage IV: 3/7 ulcers  Size (mean): 14.65 cm2   Location:  ilium - 1/7 lateral malleolus - 2/7 sacrum - 2/7 fibula/tibia - 2/7 |
| McDiarmid, 1985163 UK Fair | Randomized trial | Patients over 18 years or age with pressure sores referred by physiotherapy and nursing staff in three Bristol hospitals; pressure sores had not had radiotherapy in the area over the past 6 months. | Evidence of deep vein thrombosis (DVT); sores not limited to superficial tissue not extending beyond the dermis; pressure on the sore not capable of being removed; malignancies in the area to be treated. | NR/NR/40/18 | Age (Mean): NR Female: NR Race: NR | Adjunctive: Ultrasound | Stage: NR Size (mean) NR: Location: NR |
| Nussbaum, 1994164 UK Fair | Randomized trial | Hospitalized patients at Lyndhurst Spinal Cord Centre with a diagnosis of spinal cord injury (SCI) and skin wounds. | NR | NR/NR/20/20 | Age (Mean):41 years Female: 11% Race: NR | Adjunctive: Laser Therapy | Stage: NR Size (mean): 2.1 vs. 1.9 vs. 2.8 cm2 Location: NR |
| Onigbinde, 2010165  South Africa  Poor | Cohort | Absence of previous skin breakdown or wound prior to being admitted, presence of bilateral pressure sores on the lower limbs; a stable regimen of medications during the course of the study including the antibiotic ciproflaxin; a wound duration of at least 8 weeks; and age between 35-55 years. | Patients with diabetes, malnutrition, dermatitis, or with metallic implants | NR/NR/10/10 | Age (Mean): 45 years  Female: 80%  Race: NR | Adjunctive: Light Therapy | Stage: NR  Size (mean):  Treatment A: 76.5 cm2 Treatment B: 43.8 cm2  Location:  gluteal - 60%  heel - 40% |
| Ozdemir, 2011166  Turkey  Fair | Randomized trial | Patients with stage II or III pressure sores due to immobilization as a result of hemiplegic, paraplegic, other neurological disorders, and amputation operations. | Pressure sores that were borderline to surgery and stage IV. | NR/NR/45/40 | Age (Mean): 63 years Female: NR Race: NR | Adjunctive: Electromagnetic Therapy | Stage: NR Stage II – 80% vs. 60%  Stage III – 10% vs. 40%  Size (mean): NR  Location:  Sacrum - 21.05% vs. 20%  Gluteus - 21.05% vs. 15%  Trochanter - 10.52% vs. 15%  Heels - 21.05% vs. 25%  Other - 31.57% vs. 25% |
| Salzberg, 1995167 US Fair | Randomized trial | Spinal cord-injured patients with pressure ulcers admitted to the Veteran's Administration Medical Center at Castle Point, NY over a 2-year period. | Patients with more than 1 ulcer, recent ulcer surgery, with a cardiac pacemaker, intercurrent disease, active cellulitis, sepsis, terminal illness or end-stage renal disease (ESRD), and patients with Stage I or IV pressure ulcers. | NR/NR/30/30 | Age(Mean): 54 years Female: NR Race: NR | Adjunctive: Electromagnetic Therapy | Area: 14 vs. 33 cm2, p=0.089Granulation %: 23 vs. 45, p=0.210 Epithelization %: 8 vs. 10, p=0.222  Stage II - partial thickness skin loss involving epidermis and dermis, superficial presenting as deep crater, abrasion, blister, or shallow crater  Stage III - full thickness skin loss involving damage or necrosis of subcutaneous tissue which may have extended down to, but not through, underlying fascia and presenting as a deep crater with or without undermining adjacent tissue |
| Schubert, 2001168 Sweden Fair | Randomized trial | Elderly patients with Stage 2 or 3 pressure ulcer, newly admitted to an orthopedic or a geriatric ward, were asked to enter the study. | NR | NR/NR/74/59 | Age (Mean): 85 years Female: 64% Race: NR | Adjunctive: Light Therapy | Stage: Stage 2/3 - 100% Size (under 10.0 cm2): 92% vs. 94% Location:  Trunk - 68% vs. 83% |
| Schwien, 2005169 US Poor | Retrospective cohort study | Start of care and end of care between July 1, 2002 and September 30, 2004; one Stage III or one Stage IV pressure ulcer; and primary diagnosis of 707.0 decubitus chronic skin ulcer. | Patients who died at home; enteral or parenteral nutrition therapy; high risk factors of heavy smoking, alcohol dependency, or drug dependency; poor or unknown overall prognosis; or secondary diagnoses of uncontrolled diabetes, cancer, systemic infections, or related to malnutrition/ anemias/ proteinemia. | 1,941,039/ 134,147/ 2,348/ 2,348(60 NPWT) | Age (Mean): 68.2 years  Female: 56% Race: NR | Adjunctive: Negative Pressure Wound Therapy | Stage: Stage III - 7/60(24%) vs. 756/2288 (44%) Stage IV - 14/60(45%) vs. 337/2288(59%) Size (mean): NR Location: |
| Srivastava, 2010170  India  Poor | Prospective longitudinal interventional study  (cohort) | Patients with large to moderate sacral pressure ulcers | NR | NR/NR/55/55 | Age (Mean):NR  Female:NR  Race:NR | Adjunctive: Negative Pressure Wound Therapy | Stage  Size (mean): NR  Location:  Sacral - 100% |
| Taly, 2004171 India Good | Randomized trial | Patients with spinal cord disorders and admitted to the rehabilitation ward with pressure ulcers or who developed ulcers during their stay in the ward were eligible for the study. Pressure ulcers were divided into the conventional 4 stages: stage 1, nonblanching erythema of intact skin; stage 2, partial thickness skin loss; stage 3, full-thickness skin loss; and stage 4, extension into muscle and bone. 7 Pressure ulcers of the conventional stages 2, 3, and 4 were included in the study. | Subjects with photosensitivity, ulcers from other causes, necrotic tissue in ulcers that would interfere with the application of laser, flask-shaped ulcers that cannot be adequately exposed to laser, pressure ulcers with underlying osteomyelitis, or pressure ulcers requiring surgical intervention at the time of first assessment were excluded. | 129/40/35/29 | Age (Mean): 32 years Female: 23% Race: NR | Adjunctive: Laser Therapy | Stage: 2/3/4; 21 (32.8%) on the sacrum, 18 (28.1%) on the greater trochanter, 9 (14.1%) on the gluteal region, 2 (3.1%) on the lateral malleolus, 2 (3.1%) on the elbow, 1 (1.6%) on the ischial tuberosity, 1 (1.6%) on the heel, and 10 (15.6%) on other sites. Size (mean) Location: 55 at stage 2, 8 at stage 3, and at stage 4. Most ulcers evolved after hospitalization: 33 ulcers (51.6%) developed in an acute care facility, 13(20.3%) in a rehabilitation ward, and 18 (28.1%) at home. These ulcers could be attributed to prolonged lying in bed, 49 (76.6%); improper transfers, 10 (15.6%); and prolonged sitting, 5 (6.3%). |
| ter Riet, 1995172 ter Riet, 1996173 Netherlands Good | Randomized trial | Patients with stage II, III, or IV pressure ulcers (i.e., partial-thickness skin loss or worse") from 11 nursing homes and one hospital located in the south of the Netherlands. If a patient had multiple ulcers, we used two hierarchical criteria to choose one ulcer for inclusion in the trial. | Patients with difficulties with swallowing or frequent vomiting (poor compliance with AA regimen); osteomyelitis in the ulcer area (healing very unlikely); idiopathic hemochromatosis, thalassemia major, and sideroblastic anemia (in these three diseases, AA supplementation is contraindicated); and Cushing's syndrome or Cushing's disease, pregnancy, radiotherapy in the ulcer area, and the use of antineoplastic agents or systemic glucocorticosteroids (all because of hormonal alterations in collagen synthesis). Terminally ill patients; patients for whom surgical treatment of the ulcer, other than debridement, had been planned, patients taking vitamin C supplements in excess of 50 mg per day. Patients with stage II ulcers (partial-thickness skin loss) could participate only if deep ithelialization had persisted for at least 7 days without interruption. Patients with leg ulcers had to have a positive history of pressure on that site to be eligible. | NR/NR/88/88 | Age (Mean): 81 years Female: 75% Race: NR | Adjunctive: Ultrasound | Stage: Stage II/III - 80% vs. 83.7% Stage IV - 20% vs. 16.3% Size (mean):  Wound surface area cm2 (%) 0.01-1.00 - 42.2% vs. 34.9% 1.01-5.00 - 40% vs. 44.2% 5.01-10.0 - 15.6% vs. 11.6% >10.0 - 2.2% vs. 9.3% Location:  Trunk - 60% vs. 58.1% |
| Wanner, 2003174 Switzerland Fair | Randomized trial | Patients admitted with a pressure sore of the pelvic region, deeper than stage II (at least a penetration in the subcutaneous fat). | Pressure sores not in the pelvic region; depth of the pressure sore was less than stage III. | 34/24/24/22 | Age (Mean): 51 years Female: 31% Race: NR | Adjunctive: Negative Pressure Wound Therapy | Stage: II+ (Daniel et al.) Size (mean): 50 ml vs. 42 ml Location: Pelvic region |
| Wood, 1993175 US Fair | Randomized trial | Patients with chronic pressure ulcers. | NR | NR/NR/71/71 | Age (mean years): 75 years  Female: 45%  Race: White – 100%  PU stage II-III (article uses grade PU criteria) | Adjunctive: Electrical Stimulation | Stage: Stage III - 100% Size (mean) - NR Location:  leg - 15/31 vs. 16/41 coccyx - 7/31 vs. 9/41 hip - 2/31 vs. 10/41 buttock - 5/31 vs. 5/41 other - 2/31 vs. 3/41 |

| **Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued** |  |  |  |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Treatment A** | **Treatment B** | **Treatment C** | **Treatment D** | **Complete Wound Healing** | **Wound Surface Area** | **Healing Time** | **Infection Rate** | **Osteomyelitis Rate** |
| Adegoke, 2001141  Nigeria Fair | A: IDC plus nursing care - after cleaning ulcers covered with sterile gauze soaked in 0.9% saline. 2 pieces of aluminum plate electrodes were cut to sizes slightly larger than the individual ulcers, wrapped in 6 layers of lint soaked in 0.9% saline. IDC turned on and gradually increased intensity until a "minimal perceptible contraction" was observed, then reduced slightly so no visible contraction could be observed. The rest to surge ratio was 2:1 at 30 Hz with rectangular wave forms for a duration of 45 minutes | B: placebo IDC plus nursing care - after cleaning ulcers covered with sterile gauze soaked in 0.9% saline. 2 pieces of aluminum plate electrodes were cut to sizes slightly larger than the individual ulcers, wrapped in 6 layers of lint soaked in 0.9% saline. IDC turned on and gradually increased intensity until a "minimal perceptible contraction" was observed, then reduced slightly so no visible contraction could be observed. The rest to surge ratio was 2:1 at zero Hz with rectangular wave forms for a duration of 45 minutes | NA | NA | NR | Treatment A: Change in surface area: baseline to week 4 - 22.2%  Treatment B: Change in surface area: baseline to week 4 - 2.6% | NR | NR | NR |
| Adunsky, 2005142 Israel Fair | A:Treatment Group (TG): DDCT treatment, electrical currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20-min sessions daily, reduced to two daily sessions after 14 days.  Ulcers were covered with hydrocolloid or collagen dressings after treatment  Treatment period lasted for 8-weeks | B: Placebo Group (PG): placebo-DDCT treatment, zero currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20-min sessions daily, reduced to two daily sessions after 14 days.  ulcers were covered with hydrocolloid or collagen dressings after treatment   Treatment period lasted for 8-weeks | NA | NA | Treatment A:  End of followup: 10/35(35.7%)  End of treatment: 5/35(14.3%)  Treatment B:  End of followup: 9/28(25.7%),  End of treatment: 3/28(10.7%), | Treatment A:  Day 45: 11.15  Day 147: 2.53  Treatment B:  Day 45: 16.7 cm2,  Day 147: 2.88 cm2, | Speed of wound closure:  Mean time to complete closure:  Treatment A: 63.4  Treatment B: 89.7 | NR | NR |
| Ahmad, 2008(a)143  Ahmad, 2008(b)144 Saudi Arabia  Fair | A: HVPC for 45 minutes daily for 7 days | B: HVPC for 60 minutes daily for 7 days | C: HVPC for 120 minutes daily for 7 days | D: Comparator - VPC for 45 minutes daily for 7 days (voltage maintained at zero) | NR | Treatment A:  Wound surface areas decreased (cm2) to: 5.1  Treatment B:  Wound surface areas decreased (cm2) to: 0.6  Treatment C:  Wound surface areas decreased (cm2) : 0.64 cm2  Treatment D:  Wound surface areas decreased (cm2): 5.39 | Mean healing rate (cm2 /week): 0.40  1.30.  1.30.  0.27 | NR | NR |
| Baker, 1996145 US Fair | A: Asymmetric biphasic (A) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - below contraction Phase duration - 100 microsec frequency - 50 pulses/s | B: Symmetric biphasic (B) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - below contraction Phase duration - 300 μsec frequency - 50 pulses/s | C: Microcurrent (MC) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - 4 mA Phase duration - 10 μsec frequency - 1 pulses/s | D: Comparator (C) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - 0 Phase duration - 100 μsec frequency - 1 pulses/s | NR | Treatment A:  Change in surface area (%/week): 36.4  Treatment B:  Change in surface area (%/week): 29.7 vs.  Treatment C:  Change in surface area (%/week): 23.3  Treatment D: Change in surface area (%/week): 32.7 | NR | NR | NR |
| Burke, 1998\*146 US  Fair | A: (non-whirlpool) conservative treatment – debridement, saline irrigation, and dressing of wounds with 4x4 cotton pads soaked with saline solution. Dressings changed 2x/day | B: (whirlpool) conservative treatment plus hydrotherapy in a whirlpool with water warmed to 96 to 98 °F. The jet stream of the whirlpool was positioned so that no pressure ulcer would be directly exposed to the stream, reducing the risk of granulation tissue damage by water agitation. Each wound received 20 min of whirlpool therapy once per day. | NA | NA | Healing: Group B > A, p=0.0435 | Treatment A: Change in surface area: 27%  Treatment B: Change in surface area: 58% | NR | NR | NR |
| Comorosan, 1993147  Romania  Fair | A: Control - conventional therapy - H2O2 cleansing and local applications of talcum powder, methylene blue in solution and tetracycline at undefined intervals for 3-5 weeks | B: Placebo - conventional therapy plus placebo Diapulse treatment applied to ulcer area directly through dressings for 30 minutes/2x day at 6 hour intervals for 3-5 weeks | C: Diapulse Treatment - conventional therapy plus Diapulse treatment - standard 117 volts, 27.12 MHz, at 80-600 pulse/sec applied to ulcer area directly through dressings for 30 minutes/2x day at 6 hour intervals for 3-5 weeks | NA | Complete healing at end of treatment (3-4 weeks):  Treatment A: 0%  Treatment B: 0%  Treatment C: 85% | NR | Mean healing time (weeks):  Treatment A: NR  Treatment B: NR  Treatment C: 3.5 | NR | NR |
| Dehlin, 2003148 Denmark Fair | A: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings  monochromatic phototherapy treatment - probe containing 30 diodes emitting infrared light at 956 nm and 80 diodes emitting red light 637 nm, placed 3 cm above ulcer and administered in identical sequence for every session   week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes  weeks 3/5/7/9/11 - 3x/week for 6 minutes | B: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings  placebo light treatment - emitting no infrared or red light was administered for every session    week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes  weeks 3/5/7/9/11 - 3x/week for 6 minutes | NA | NA | Treatment A: Complete healing: 34/78(43.6%) .  Treatment B:  Complete healing:  34/78(39.5%) | Reductions in wound surface area over time in both groups were statistically significant (p=<0.0001) but there was no statistically significant difference in reduction of wound surface area (p=0.18) | Time until total healing was assessed every week for 12 weeks or until complete healing | NR | NR |
| Dehlin, 2007149 Denmark Fair | A: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings  monochromatic phototherapy treatment - probe containing 30 diodes emitting infrared light at 956 nm and 80 diodes emitting red light 637 nm, placed 3 cm above ulcer and administered in identical sequence for every session   week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes  weeks 3/5/7/9/11 - 3x/week for 6 minutes | B: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings  placebo light treatment - emitting no infrared or red light was administered for every session    week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes  weeks 3/5/7/9/11 - 3x/week for 6 minutes | NA | NA | Treatment A: Complete healing: 43/79(54.4%)  Treatment B:  Complete healing:  50/84(59.5%) | Treatment A:  Mean normalized reduction in pressure ulcer size at week 12 - 0.79   Normalized weekly reduction in pressure ulcer size over time - 15.1%  Treatment B:  Mean normalized reduction in pressure ulcer size at week 12 - 0.50,  Normalized weekly reduction in pressure ulcer size over time 10.9% | Time until total healing was assessed every week for 12 weeks or until complete healing | NR | NR |
| Durovic, 2008150 Serbia Fair | A: (E - experimental group) - standard cleaning and dressing - application of a gauze with normal saline (NaCl), then a dry gauze, next it a cotton wool and adhesive strip Polarized light therapy using a linear polarized light source (Bioptron lamp settings - wavelength: 400–2000 nm; degree of polarization: > 95%; power density: 40 mW/cm2; light energy: 2,4 J/cm2) performed for 6 min/day at a distance of 10 cm, 5 x week/4 weeks | B: (C - comparator group) - standard cleaning and dressing - application of a gauze with normal saline (NaCl), then a dry gauze, next it a cotton wool and adhesive strip | NA | NA | NR | Treatment A: Surface of the pressure ulcers (cm2) - 10.80  Treatment B: Surface of the pressure ulcers (cm2) - 22.97 | NR | NR | NR |
| Ford, 2002151 US Fair | A: VAC dressings were changed Mondays, Wednesdays, and Fridays (manufacturer recommends dressing changes every 48 hours). | B: HP dressings were changed once or twice daily, depending on the degree of wound drainage. Strict pressure reduction with the appropriate beds and positioning was instituted. The Healthpoint System (HP) offers a second innovative approach to the management of pressure ulcers. It consists of three FDA-approved gel products—Accuzyme, Iodosorb, and Panaﬁl— each targeted to optimize a particular macroscopic phase of wound healing. | NA | NA | Complete wound healing: 2/20(10%) vs. 2/15 (13%) | Treatment A:  Change in wound surface area: 36.9 x 40.0 cm  Mean reduction in ulcer volume - 57%  Treatment B:  Change in wound surface area: 18.7 x 19.0 cm  Mean reduction in ulcer volume - 25% | NR | NR | 15/35 wounds (42.9%) were suspicious for osteomyelitis and underwent bone biopsy and MRI. |
| Gentzkow, 1991152 US and Canada Fair | A: Sham treatment | B: Dermapulse stimulator - pulsed electrical current for 30 minutes/2x daily/4 weeks pulse rate: 2 pps/350 microseconds intensity: 0-150 mA | NA | NA | Complete wound healing: 23.4% vs. 49.8%, p=0.042 | NR | NR | NR | NR |
| Griffin, 1991153 US Fair | A: HVPC for 1 hour daily for 20 days | B: Placebo HVPC for 1 hour daily for 20 days, no current flowed through to patient | NA | NA | Complete wound healing was reported at 5 days, 10 days, 15 days and 20 days | Median wound surface area decrease of 80% at 20 days | Median wound surface area decrease at 5 days: 32% 10 days: 47% 15 days: 20% | NR | NR |
| Gupta, 2009154 India Fair | A: Standard pressure ulcer care with daily dressing with normal saline  PEMF: exposure to 1 Hz frequency sine waves with 30 mili-Ampere current intensity/45 minutes/day/5x week/30 sessions using “Pulsatron” equipment (couch encircled by a metallic frame. Homogenous pulsating electromagnetic field is generated by metallic frame which encircles a “couch” on which the subject lies either supine or prone for the duration of the treatment) | B: Standard pressure ulcer care with daily dressing with normal saline  Placebo/Sham: 0 Hz frequency sine waves with 0 mili-Ampere current intensity/45 minutes/day/5x week/30 sessions using “Pulsatron” equipment | NA | NA | Treatment A: (n=13 ulcers on 12 subjects)  Complete healing of pressure ulcers in less than 30 sessions:  2/12(16.7%)  Healing of the ulcers (NPUAP ulcer stage) at the end of the study  A (p=0.008)  BJWAT scores at admission and discharge  p=0.001  Treatment B: (b=11 ulcers on 6 subjects):  Complete healing of pressure ulcers in less than 30 sessions:  0/6(0%)  Healing of the ulcers (NPUAP ulcer stage) at the end of the study  p=0.014   BJWAT scores at admission and discharge p=0.003 | NR | Mean duration of the illness at the beginning of study was 6.42 months (1 to 20 months)   Mean duration of pressure ulcer was 103.75 days (10 to 420 days). | NR | NR |
| Ho, 2010155  US Fair | A: Standard wound care - pressure relief (e.g., low-air-loss mattress, turning, etc), debridement (e.g., sharp, mechanical, enzymatic), routine dressing changes, biophysical modalities (e.g., hydrotherapy), and cleansing as appropriate. | B: Standard wound care - pressure relief (e.g., low-air-loss mattress, turning, etc), debridement (e.g., sharp, mechanical, enzymatic), routine dressing changes, biophysical modalities (e.g., hydrotherapy), and cleansing as appropriate.  Negative Pressure Wound Therapy | NA | NA | NR | Treatment A: Mean wound surface area decrease - 50%  Treatment B:  Mean wound surface area decrease -  43%, | NR | NR | NR |
| Ho, 2012156  US  Fair | A: Pulsatile lavage + standard wound care protocol (dressing changes and pressure relief with the use of a low air-loss mattress and turning every 2 hours.  Low pressure lavage: battery-powered system consisting of a portable handheld pump that produces pulsed jets of fluid | B: Sham treatment + standard wound care  protocol. | NA | NA | NR | Treatment A:  Mean wound surface area decrease –  1.95 cm2(1.3 x 1.5 cm)  Treatment B:  Mean wound surface area decrease –  0.3 cm2(1.5 x 0.2 cm) | Treatment A:  Mean volume decrease over time (at 3 weeks) – 4 cm3  Treatment B:  Mean volume decrease over time (at 3 weeks) –2 cm3 | NR | NR |
| Houghton, 2010157 Canada Good | A: HVPC frequency of 100 Hz for 20 minutes, 10 Hz for 20 minutes and 20 minutes off, 8 hours a day for at least 3 months + standard wound care (SWC) | B: standard wound care (SWC) included nutrition, wound dressing and continence management which was customized for each patient as necessary | NA | NA | 42.9% achieved complete wound healing | 70% mean decrease in wound surface area p=0.048 | 42.9% achieved complete wound healing at 3 months | NR | NR |
| Iordanou, 2002158 Greece Fair | A: Standard care - turning the subjects every 2–3 hours, provision of electric pressure relieving overlay and a 30° lateral side-lying position given to avoid friction and shearing forces. Concerning the ulcers, these were of 1st, 2nd and 3rd grades without necrotic tissue; thus, the concentration was on two essential components of cleaning and dressing. Cleaning solution of choice was 0.9% sodium chloride and the dressing was chosen to match ulcer stage.  Polarized light therapy - energies delivered were typically 4 J/cm2 per min, degree of polarization of > 95% using a 20 W Bioptron electrical lamp. The treatment consisted of polarized treatment for 5 min per day/5 days per week/2 weeks | A: Standard care - turning the subjects every 2–3 hours, provision of electric pressure relieving overlay and a 30° lateral side-lying position given to avoid friction and shearing forces. Concerning the ulcers, these were of 1st, 2nd and 3rd grades without necrotic tissue; thus, the concentration was on two essential components of cleaning and dressing. Cleaning solution of choice was 0.9% sodium chloride and the dressing was chosen to match ulcer stage. | NA | NA | NR | Treatment A:  Change in Wound Size (mean): -.54  Treatment B:  Change in Wound Size (mean): -.06 cm2 | NR | NR | NR |
| Kloth, 1988159 US Fair | A: Treatment group - DynaWave® Model 12 high voltage, monophasic twin-pulsed generator\* in this study and arbitrarily set the stimulus variables at a frequency of 105 Hz, an intraphase interval of 50 μsec, and a voltage just below that capable of producing a visible muscle contraction (100-175 V). At 100 V with an intraphase interval of 100 μsec, the single-phase charge was calculated at about 1.6 μC with a total-pulse charge accumulation of 342 μC/sec. 45 minutes of ESTR applied to the ulcer site once a day, five days a week. | B: Comparator group - Comparator Group had electrodes applied in the same manner as patients in the Treatment Group, but the voltage was maintained at zero | NA | NA | Complete wound healing: 100% vs. NR | Treatment A: Change in surface area: 4.08 cm2  Treatment B:  Change in surface area:  5.20 cm2 | Treatment A: Mean healing rate: 44.8%/week  Treatment B: Mean healing rate: 11.59%/week | NR | NR |
| Lucas, 2003160 Netherlands Fair | A: Comparator - consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient’s position. | B: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient’s position.   LLLT treatments - using an LLLT device with a microprocessor-controlled, multiple monochromatic optical source probe . The handheld probe with 12 70 W monochromatic infrared GaAs-diodes (gallium arsenide) operated at a wavelength of 904 nm in a 830 Hz, pulse frequency mode with an average beam power of 8 mW and a radiant exposure of 1 J/cm2 covered an area of 30 cm2. | NA | NA | NR | Treatment A: Absolute improvement (mm2) mean: 138  Treatment B: Absolute improvement (mm2) mean: 48 | NR | NR | NR |
| Lucas, 2000(a)161 Netherlands Fair | A: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient’s position.   LLLT treatments - using an LLLT device with a microprocessor-controlled, multiple monochromatic optical source probe . The handheld probe with 12 70 W monochromatic infrared GaAs-diodes (gallium arsenide) operated at a wavelength of 904 nm in a 830 Hz, pulse frequency mode with an average beam power of 8 mW and a radiant exposure of 1 J/cm2 covered an area of 30 cm2. | B: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient’s position. | NA | NA | NR | Treatment A: Change in median wound surface area (mm2): 83%  Treatment B: Change in median wound surface area (mm2):95% | NR | NR | NR |
| Maeshige, 2010162 Japan Fair | A: ultrasound irradiation (US) administered to the pressure ulcer through the same dressing used for 2–4 weeks  - The area of dressing in which exudate seeped fully was covered with US gel, US irradiation was applied with the dressing in place  - 1 MHz was used for all ulcers at 0.5 W/cm2 at the wound surface - 3 MHz was used for ulcers close to the bone at 0.5 W/cm2 at the wound surface | B: standard treatment with dressings that promote a moist wound healing environment All pressure ulcers were covered with a hydrocolloid dressing.  -To avoid US reflection, a polyurethane film was placed over the hydrocolloid dressing; any air bubbles between the layers were removed.  - The area of dressing in which exudate seeped fully was covered with US gel, US irradiation was applied with the dressing in place  - 1 MHz was used for all ulcers at 0.5 W/cm2 at the wound surface - 3 MHz was used for ulcers close to the bone at 0.5 W/cm2 at the wound surface | NA | NA | DESIGN score:  A(n=4) vs. B (n=3)  Stage III - 3/4 vs. 1/3 Stage IV- 1/4 vs. 2/3   End of Study Complete healing: NR | Change in Wound Size (mean): 5.04 cm2 | Healing time (mean): 108.25 vs. 97 days |  |  |
| McDiarmid, 1985163 UK  Fair | A: Ultrasound: treatment minimum of 5 minutes for all pressure sores up to 3m2 (additional minute for each added 0.5 cm2) for a maximum 10 minutes/3x week  Frequency - 3 MHz peak intensity - 0.8W cm-2 | B: Mock ultrasound (placebo) | NA | NA | Healed at end of treatment: 10/21 (41%) vs. 8/19(42%) | NR | Mean: 32 vs. 36 days | NR | NR |
| Nussbaum, 1994164 UK Fair | A: Comparator - This group received standard wound care only, consisting of wound cleansing twice daily using Hygeol\* (1:20),+ Jelonet dressings to keep the wound surface moist, and avoidance of lying the wound, using coupling gel for contact, for 5 minutes per 5 cm2 of wound area. | B: Ultrasound/Ultra-violet C (US/UVC) - Ultrasound treatment was applied using an Omnisound 3000, IP which was calibrated by the manufacturer at the start of the study. The size of the treatment head was 5 cm2, and treatment was delivered at a frequency of 3 MHz and at an SATA intensity of 0.2 w/cm2 (1:4 pulse ratio).  Ultrasound was applied to intact skin surrounding the wound, using coupling gel for contact, for 5 minutes per 5 cm2 of wound area.  The US and UVC treatments were alternated 1x day/5 days/week | C: Control groupl | NA | NR | Treatment A:  Change in wound surface area: 32.4%  Treatment B: 53.5%  Treatment C: 23.7% | NR | NR | NR |
| Onigbinde, 2010165  South Africa  Poor | A: traditional saline-wet-to-moist (WM) wound dressing, and high-intensity ultraviolet B radiation - (UVB) lamp (Philips 8P3114) at 3 inches from the wound surface, using progressively increased exposure duration with each session (3/4, 1, 2, 2 1/2, 3, 4 and 5 minutes for the first 7 sessions). Wounds radiated 1x every 3 days/ 6 weeks. Skin surrounding wound was protected with 2 mm thickness of Vaseline and cotton wool | B: traditional saline-wet-to-moist (WM) wound dressing | NA | NA | NR | Change in Mean Ulcer Surface Area (cm2):  Treatment A: 59.9  Treatment B:16.4 | NR | NR | NR |
| Ozdemir, 2011166  Turkey  Poor | A: Magnetotherapy group - magnetic field treatment was applied on a daily basis for 30 minutes, with a 10 x 10 ms pulse, at intervals of 30 ms, and a frequency of 25 Hz, and 9\*5ms pulse at intervals of 212 ms and a frequency of 4,6 Hz with a magnitude of 15 mT (150G) for a duration of 15 days.  The surface areas of the pressure sores were recorded at the onset of treatment (1st day), on the 7th and the 15th days on transparency papers, templates were made and converted onto milimetric graphic papers. The squares inside the drawings were counted and the surface area was calculated in terms of square centimeters. | B: Control group | NA | NA | NR | No significant differences in size (Day 1-7)  Day 1 : p=0.871  Day 7:: p=1.67  Day 15: p<0.001 | Treatment A: Healing time (mean) 10.80 days  Treatment B: 18.85 days | NR | NR |
| Salzberg, 1995167 US Fair | A: Placebo (sham) | B: Diapulse current - 27.12 MHz at 80-600 pulses/sec, a pulse width of 65 microseconds, a duty cycle between 0.5% and 3.9%, and a per pulse power range between 293-975 peak watts | NA | NA | Treatment A:  Stage II (n=10 vs. 10) week 1: 84%  End of Study Complete healing:  9/15  Stage III (n=5 vs. 5) week 1: NR End of Study Complete healing: 3/5(60%)  Treatment B:  Stage II (n=10 vs. 10) week 1: 40% End of Study Complete healing:  6/15  Stage III (n=5 vs. 5) week 1: NR End of Study Complete healing: 0/5(0%) | Change in surface area: Stage II (n=10 vs. 10): NR  Stage III (n=5 vs. 5): 70.6% vs. 20.7% | Mean Healing Time Stage II: NR Stage III: 43 days | NR | NR |
| Schubert, 2001168 Sweden Fair | A: (Group 1) Conventional/standard ulcer therapy - not described | B: (Group 2) Conventional/standard ulcer therapy - not described  Phototherapy with pulsed monochromatic light (PML): A probe contained both 30 diodes, which could emit infrared light at 956 nm, and 80 diodes, which could emit red light at 637 nm. Treatments lasted 9 min each time using a regimen with pulse repetition frequency varied between 15.6 Hz and 8.58 kHz. Patients were followed for 10 weeks or until the ulcer was healed, whichever occurred first.  The number of treatments given per week was as follows: Week 1: 5 x week;  Week 2: 4 x week  Week 3: 2 x week  Week 4+: 1 x week | NA | NA | NR | NR | Healing rate (mm2/week): 0.200 vs. 0.298, p<0.05 (healing rate was 49% higher in treatment group (Group 2) than in comparator (Group 1) | NR | NR |
| Schwien, 2005169 US Poor | A: Negative Pressure Wound Therapy (NPWT) - specific technologies and treatment used not reported | B: Comparison group - standard care through end of treatment, specific treatments not reported | NA | NA | NR | NR | NR | NR | NR |
| Srivastava, 2010170  India  Poor | A: Negative pressure device (NPD) included sterilized piece of foam, a low power continuous suction apparatus (Romovac) and transparent polyurethane adhesive dressing (Opsite). Perforated end of drainage tube was placed on wound surface and other exiting 10cms away from wound margin connected to Romovac. Sterilized foam was trimmed to size and geometry of wound as cover. Opsite closed the wound with an airtight seal. The bellow of Romovac  charged to attain negative pressure. Recharging was done in 5–6 hrs. Wound inspected and dressing changed every 5–7 days. | B: Conventional dressing | NA | NA | Mean decrease in wound area:  At 10 days - Treatment A: 13%  Treatment B: 8%  At 3 weeks -  Treatment A: 33%  Treatment B: 15% | NR | NR | NR | NR |
| Taly, 2004171 India Good | A: Usual care - daily dressing with sterile gauze soaked in normal saline and pressure relief with either a water mattress or a split mattress.   multi-wave light therapy - 14 treatments were given, 1 every alternate day, 3 times a week, until the ulcer healed or the ulcer received 14 exposures.  Each ulcer was divided into 10cm2 squares. During every session, each square was exposed for 60 seconds. The central 820nm laser source was surrounded by 45 supraluminous diodes of different wavelengths. Energy applied to the ulcer was calculated by using the formula: energy delivered = (power/spot size)(time). Energy given was 4.5J/cm2. | B: Usual care - daily dressing with sterile gauze soaked in normal saline and pressure relief with either a water mattress or a split mattress.  sham treatment - multi-wave light therapy - 14 treatments were given, 1 every alternate day, 3 times a week, during which the multi wavelength light therapy source was held over the ulcer after switching off the beam | NA | Ulcer healing was defined as the complete closure of the wound with healthy scar tissue. Eschar was removed before application of intervention. Ulcers with eschar at the end of the study period were considered not healed.  Complete Healing (ulcers)- Treatment A: 18/35 (51%)  Treatment B: 14/29 (48%), | NR | The mean time taken for the ulcers to heal from the day of randomization was 2.45 2.06 weeks in the treatment group and 1.78 2.13 weeks in the comparator group. This difference was not statistically significant (t .987, P .330). The PSST score and the stage of the 32 ulcers that did not heal during the study | NR | NR | NR |
| ter Riet, 1995172 ter Riet, 1996173 Netherlands Good | A: Sham treatment - duration varied according to formula: treatment area estimate + effective radiating area (at the face of the transducer) x 3 minutes (minimum treatment duration was 3 minutes 45 seconds) at 1 x day/5 days /week for 6 weeks (60 treatments)  Frequency - 0 MHz Pulse duration - 0 ms Pulse repetition frequency - 0 Hz | B: Ultrasound therapy - Treatment duration varied according to formula: treatment area estimate + effective radiating area (at the face of the transducer) x 3 minutes (minimum treatment duration was 3 minutes 45 seconds) at 1 x day/5 days /week for 6 weeks (60 treatments)  Frequency - 3.28 MHz Pulse duration - 2 ms Pulse repetition frequency - 100 Hz | NA | NA | NR | Mean surface reduction (cm2) – Treatment A: 0.18  Treatment B: 0.31 | Mean healing rate (cm/week) - 0.18 vs. 0.13, p=0.18 | NR | NR |
| Wanner, 2003174  Switzerland Fair | A: In the vacuum-assisted group we used the equipment obtained from KCI Mediscus consisting of drainage tubes, polyvinyl foam, a transparent polyurethane dressing, and a vacuum suction pump. Continuous subatmospheric pressure of 125 mm Hg was applied. The dressings were changed after two to seven days, depending on the amount of fluid produced by the wound (when the canister was full). | B: Our standardized treatment of deep pressure sores is surgical debridement followed by a period of wound preparation and, Nelly closure with a flap. After debridement we started the local treatment on the first day after the operation. In the wet-to-dry/wet-to-wet (traditional) group the dressings consisted of gauze soaked with Ringer’s solution.  These dressings were changed three times a day until clean granulation tissue was observed. From then on, we kept the wound wet with Ringer solution and changed the dressings one to three times a day to keep the wound moist. | NA | NA |  | Wound size in the two groups (ml) (n = 11 in each group) Wound volume (ml) Vacuum-assisted closure Wet-to-dry/ wet-to-wet Range 3–132 5–68 Mean (SD) 50 (33) 42 (16) | Time to reach 50% health: 27 days vs. 28 days | NR | NR |
| Wood, 1993175 US Fair | A: PLIDC of 600*m*A with frequency of approx 0.8Hz / 3x week until healing | B: non-PLIDC sham, current delivery output was impeded | NA | NA | Complete wound healing - 58% vs. NR | Change in surface area:  Treatment A: NR  Treatment B: 72.9% decreased more than 80% in size | Speed of wound closure: NR vs. 58%(8 weeks) | NR | NR |

| **Evidence Table**  **H-9a: Adjunctive**  **Trial and Observational**  **Studies, continued** |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year Country Overall Quality Rating** | **Recurrence Rate** | **Other: Specify** | **Duration of Followup** | **Study setting: Hospital Nursing Home/LTC facility Community Other: Specify** | **Pain** | **Dermatologic Complications** |
| Adegoke, 2001141 Nigeria Fair | NR | NR | NR | Hospital | NR | NR |
| Adunsky, 2005142 Israel Fair | NR | NR | 147 days | Hospital | NR | Skin irritation - 2 vs. 0 patients |
| Ahmad, 2008(a)143  Ahmad, 2008(b)144 Saudi Arabia  Fair | NR | NR | 5 weeks | Investigating sites | NR | NR |
| Baker, 1996145 US Fair | NR | NR | Every 2-4 weeks until healing | Hospital | NR | NR |
| Burke, 1998\*146 US  Fair | NR | NR | Followup until complete healing | Hospital | NR | NR |
| Comorosan, 1993147  Romania  Fair | NR | NR | NR | Hospital (Social Care Unit) | NR | NR |
| Dehlin, 2003148 Denmark Fair | NR | NR | Followup until complete healing | Hospital | NR | NR |
| Dehlin, 2007149 Denmark Fair | NR | NR | Followup until complete healing | Hospital | NR | NR |
| Durovic, 2008150 Serbia Fair | NR | Total PUSH score of the pressure ulcers - 7.35 vs. 11.85, p=0.00003 | NR | Hospital | NR | NR |
| Ford, 2002151 US Fair | NR | NR | Followup ranged from 3 to 10 months. | Hospital | NR | NR |
| Gentzkow, 1991152 US and Canada Fair | NR | NR | 4 weeks after end of treatment | Hospital | NR | NR |
| Griffin, 1991153 US Fair | NR | NR | 20 days | Hospital | NR | NR |
| Gupta, 2009154 India Fair | NR | NR | The mean duration of stay in the rehabilitation unit was 98.66 days (24-193 days).   The number of treatment sessions in patients ranged from 22-30, mean of 29.06. | Hospital | NR | NR |
| Ho, 2010155 US Fair | NR | NR | NR | Hospital | NR | NR |
| Ho, 2012156  US  Fair | NR | NR | 1 x week for 3 weeks during treatment | Hospital | NR | NR |
| Houghton, 2010157 Canada Good | NR | NR | 6 months | Community | NR | NR |
| Iordanou, 2002158 Greece Fair | NR | NR | At the end of each week, experimental and comparator ulcers were reassessed and a detailed report was completed, no additional followup after end of treatment reported | Hospital | NR | NR |
| Kloth, 1988159 US Fair | NR | NR | NR | Hospital | NR | NR |
| Lucas, 2003160 Netherlands Fair | NR | NR | NR | Hospital | NR | NR |
| Lucas, 2000(a)161 Netherlands Fair | NR | NR | NR | Hospital | NR | NR |
| Maeshige, 2010162 Japan Fair | NR | NR | NR | Hospital | NR | NR |
| McDiarmid, 1985163 UK  Fair | NR | NR | NR | Hospital | NR | NR |
| Nussbaum, 1994164 UK Fair | NR | NR | NR | Hospital | NR | NR |
| Onigbinde, 2010165  South Africa  Poor | NR | Change in Mean Ulcer Volume (ml):  Treatment A: 26.2  Treatment B: 2.1 | NR | Hospital | NR | NR |
| Ozdemir, 2011166  Turkey  Poor | NR | NR | NR | Hospital | NR | NR |
| Salzberg, 1995167 US Fair | NR | NR | NR | Hospital | NR | NR |
| Schubert, 2001168 Sweden Fair | NR | NR | NR | Hospital | NR | NR |
| Schwien, 2005169 US Poor | NR | Rates of hospitalization: 35% vs. 48%, p<0.05. Rates of hospitalization due to wound problems: 5% vs. 14%, p<0.01. Rates of emergent care for wound problems: 0% vs. 8%, p=0.01. | NR | Home health agencies | NR | NR |
| Srivastava, 2010170  India  Poor | NR | Mean decrease in wound depth:  At 10 days - 32% vs. 10%  At 3 weeks - 98% vs. 36% | NR | Hospital | NR | NR |
| Taly, 2004171 India Good | NR | 2 weeks after completion of treatment protocol | Hospital | NR | NR | NR |
| ter Riet, 1995172 ter Riet, 1996173 Netherlands Good | NR | NR | 6 weeks after end of treatment | Hospital | Pain - 1/43 vs. 1/45 patients complained of the US therapy being painful at times | NR |
| Wanner, 2003174 Switzerland Fair | NR | NR | The endpoint was defined as when the wound volume had decreased by 50%, because all ulcers were then closed with a flap | Hospital | NR | NR |
| Wood, 1993175 US Fair | NR | NR | 8 weeks | Hospital | NR | NR |

Abbreviations: LTC, long-term care; NR, not reported.