Evidence Table H-5: Local Wound Applications (Dressings, Topical Applications, and Biological Therapies)

Evidence Table H-5a. Dressings trials

| **Author, year Country Overall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
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| Alm, 198943 Sweden Fair | Long-term ward patients with pressure ulcers whose condition was evaluated with the Norton scale less than or equal to 9 and greater than or equal to 7 | Pressure ulcers evaluated at less than 7 on the Norton scale at screening | NR/NR/50/50  PU N=56 | Age (Mean): 83 years Female: 75%  Race: NR | Local Wound Application: Dressing | Mean Norton Score: 12 vs. 13   Location:  Heel: 33.9% vs. 33.3% Sacrum: 27.4% vs. 37.5%  Malleolus: 11.3% vs. 12.5% Gluteal region: 8.1%^ vs. 12.5% Hip: 12.9% vs. 4.2% Other: 6.4% vs. 4.2% |
| Bale, 199744  UK  Fair | Patients 18 and older who were able to give consent. Stage II or III PU | Those with no history of poor compliance or previous involvement in the study. | NR/NR/51/50 | Age (Mean): 74 years  Female: 55%  Race: NR | Local Wound Application: Dressing | Stage:  II: 79% (N=23) vs. 71% (N=22)  III: 21% (N=6) vs. 29% (N=9) |
| Bale, 1998(b)45  UK  Poor | Leg ulcers except venous leg ulcers that were able to tolerate high compression therapy, and stage II or III PU or other granulating wounds with moderate to high levels of exudates | Pregnant and lactating women, patients with stage I or IV PU, wounds that were too large to be covered by one dressing, Wounds expected to heal within one week, wounds with sloughy or necrotic tissue or grossly infected wounds | NR/100/100/96  PU N=32 | Age (Mean): 76 years Female: 77%  Race: NR | Local Wound Application: Dressing | Stage II: 65% (N=11) vs. (40%) N=6  Stage III: 35%(N=6) vs. 60%(N=9)  Note: Mean area at baseline available for aggregate data only which includes venous leg ulcers and PU |
| Bale, 1998(a)46  UK Poor | Patients with necrotic PU who could give written informed consent | Wound greater than 8cm in diameter; immunosuppression related disease; pregnant or nursing; in any other clinical trial less than one month prior; had already participated in this study | NR/53/50/42 | Age (Mean): 77 years  Female: 61%  Race: NR | Local Wound Application: Dressing | Stage II: N=2 vs N=0  Stage III: N=20 vs. N=21  Stage IV: N=2 vs. N=1  Location:  Sacrum: N=5 vs. N=4  Ischium: N=2 vs. N=0  Heel: N=14 vs. N=19  Foot: N=2 vs N=0  Gaiter Area: N=1 vs. N=0  Elbow: N=1 vs N=0  Lateral malleolus: N=0 vs. N=1  Buttock: N=1 vs. N=0 |

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| **Evidence Table  H-5a: Dressings Trials, continued** | | | | | | |
| **Author, year Country Overall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
| Banks, 1994(a)47 UK Poor | Written, informed consent; older than 16 years old, both sexes, with shallow, moist PU, stage II and III; PU that could be covered by a single 10 x 10 cm dressing; subjects who could be managed to prevent further lesions developing | Lesions involving tissues other than skin and subcutaneous fat; stage I, IV and V PU; dry or necrotic lesions; taking systemic corticosteroids; PU that had been dressed with either of the study dressings in the preceding two weeks; sensitivity reaction to either dressing; infected PU; incapable of giving opinion of the dressing; incontinent of urine or feces with PU on the sacrum or a site likely to be soiled repeatedly | NR/NR/40/40 | Age (Mean): 72 years Female: 47% Race: NR | Local Wound Application: Dressing | Stages II and III: 100% vs. 100%  Location:  Buttock 50% vs. 45%  Sacrum 20% vs. 5%  Other 30% vs. 50% |
| Banks, 1994(b)48 UK (Wales) Poor | Written, informed consent; over 16 years old; shallow, moist pressure sores stage II or III; could be managed to prevent further lesions developing | Lesions involving tissues other than skin or subcutaneous fat; stage I, IV or V PU; dry or necrotic lesions (could be included after debriding); taking systemic corticosteroids; PU that had been dressed with either of the study dressings in preceding two weeks; previous sensitivity to either dressing; infected PU; incapable of giving opinion of dressing; incontinent of urine or feces with PU on sacrum or any other site likely to be soiled | NR/NR/29/29 | Age (Mean): 75 years Female: 64%  Race: NR | Local Wound Application: Dressing | Location: Buttock: 62% vs. 56% Sacrum: 31% vs. 38% Other: 7% vs. 6% |
| Belmin, 200249  France  Fair | Patients with ulcers located on the sacrum, elsewhere on the pelvic girdle, or on the heel; surface area of less than 50 cm2, as measured by planimetry; granulation tissue area not covering more than 50% of ulcer surface, as visually estimated by the investigator; and no clinical evidence of active infection | Serum albumin concentration below 25 g/L; being treated with radiotherapy, cytotoxic drugs, or corticosteroids; surgical or palliative care needed | NR/NR/110/ 110 | Age (Mean): 83 years  Female: 71%  Race: NR | Local Wound Application: Dressing | Stage III: 71.4%(N=40) vs. 82.7%(N=43)  Stage IV: 28.6%(N=16) vs. 17.3%(N=9) |

| Evidence Table  H-5a: Dressings Trials, continued |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
| Bito, 201250  Japan  Good | 50 years or older, 1+ NPAUP stage II or III pressure ulcer on torso or trochanter, body temp of 35.5 C-37.5C, 600kcal+ daily intake, no critical nutritional impairment, renal failure, cirrhosis, immunosuppresion, uncontrollable diabetes, or cancer. Written consent from patient or family member | Patients with <3 months life expectancy | 67/66/66/64 | Age: 81 years  Female: 51%  Race: NR | Local Wound Application: Dressing | Wrap therapy:  Stage II- 11%  Stage III- 89%  Conventional treatment:  Stage II: 28%  Stage III: 72%  Location: Sacrum, trochanter, gluteus, coccyx |
| Brod, 199051 US  Poor | Estimated life expectancy >/= 6 months and normal marrow, hepatic, and renal function; elderly with stage II or III PU | NR | NR/NR/43/43 | Age (Mean): 84 years  Female: NR  Race: NR | Local Wound Application: Dressing | All Stage II or III |
| Brown-Etris, 200852 US Fair | One or more stage II or shallow stage III, minimally to moderately draining PU or any anatomical location that could have been treated with a hydrocolloid dressing | Skin disease or abnormal conditions on or near t application site. Insulin-dependent diabetes that had inadequately controlled blood sugar; Receiving steroid, immunosuppressive therapy, or radiation to the area where the PU was located. Participating in another clinical research study  Wounds with more than 50% necrotic tissue should have undergone debridement before application of a dressing. Greater than 1cm undermining or tunneling, required use of a filling or packing material, required the dressing to be cut to a smaller size or to a specialty shape, exhibited clinical infection as, or required treatment with a concomitant medication or product | NR/NR/72/72 | Age (Mean): 75 years  Female: 56%  Race: NR | Local Wound Application: Dressing | Stage II: 65.7% vs. 59.5%  Stage III: 34.3% vs. 40.5%  Location: sacrum, buttock, ischium, heel, other |
| Chang, 199853 Malaysia  Poor | Stage II or III PU; at least 18 years old; written informed consent | Immunocompromised; infected PU; known sensitivity to study dressings | NR/NR/34/34 | Age (Mean): 58 years Female: NR Race: NR | Local Wound Application: Dressing | Stage II N=11 vs. 7 Stage III N=6 vs. 7  Note: 3 cases are missing from the gauze group, N is reported at 17, however only 14 PU are reported  Location (both groups):  Sacral: N=30  Iliac: N=3 Greater Trochanter: N=1 |
| Chuangsuwanich, 201154  Thailand  Fair | Out and in patients with PU | NR | NR/NR/40/40 | Age (Mean): 65 years Female: 54%  Race: NR | Local Wound Application: Dressing | NUPAP III-IV  Localization: Sacrum, greater trochanteric, ischium |
| Colin, 199655 Multinational Poor | NR | NR | NR/NR/135/135 | Age (Mean): 79 years  Female: 54%  Race: NR | Local Wound Application: Dressing | Stage I: 0% vs. 1.4% Stage II: 23.8% vs. 14.7% Stage III: 56.7% vs. 66.1% Stage IV: 19.4% vs. 17.6% |
| Colwell, 199356 US Poor | Non-infected stage II or III PU | Uncontrolled diabetes mellitus or radiation therapy; signs and symptoms of infection; stage I or IV PU; PU unstageable.  Did not remain in study for a minimum of 8 days or receiving any other kind of treatment that could confound the results of the treatment. | NR/NR/94/70  PU N=97 | Age (Mean): 68 years  Female: 47%  Race: NR | Local Wound Application: Dressing | Stage II: 69% vs. 44% Stage III: 31% vs. 56%  Location: Sacrum/coccyx: 60% vs. 55% Other: 40% vs. 45% |
| Darkovich, 199057 US Poor | Stage I and II PU, 2-30 cm2 on sacrum, trochanters, lower extremities, buttocks, scapula, and heel; blood sugar levels less than 180mg/dl; improved nutritional status | Known infection, sinus tracts, or fistulae in the wound; radiation therapy | NR/NR/90/90  PU N=129 | Age (Mean): 75 years Female: 61%  Race: NR | Local Wound Application: Dressing | Stage I: 43.5% vs. 46.2% Stage II: 56.4% vs. 53.7%  (Enis and Sarmienti pressure ulcer grades) |
| Day, 199558 US, UK, Canada Fair | Legal consenting age; stage II or III PU in the sacral area which required treatment | Infection; treatment with systemic steroid medication; a condition known to impair healing; receiving concomitant topical or local treatment of their PU which could not be interrupted; chronic skin disorders, hypersensitivity to skin adhesives; participation in a similar study within one month of treatment | NR/NR/103/96  PU N=96 | Age (Mean): 75 years Female: 49%  Race:  Caucasian 94%; Black, Hispanic, American Indian, Asian 6% | Local Wound Application: Dressing | Stage II: 81% vs. 84% Stage III: 19% vs. 16%  Location: Sacrum |
| Gorse, 198759 US Poor | Stage II and III PU. Stage IV PU that only extended into muscle | Osteomyelitis or extension of PU into fascia, bone, and or joints; Venous stasis and ischemic ulcers of the extremities; Rapidly fatal underlying disease; Planned hospital discharge within 7 days of treatment initiation | NR/NR/52/52  PU N=128 | Age (Mean): 70 years  Female: 0% Race: NR | Local Wound Application: Dressing | Stage II: 86.8% vs. 78.8% Stage III: NR StageIV:NR  Location:  Femoral trochanteric: 19.7% vs. 26.9% Sacral/Coccygeal: 47.45% vs. 38.5% Ischiatic: 15.8% vs. 19.2%  Other: 17.1% vs. 15.4%  Article used Shea scale for stages |
| Honde, 199460 Japan Fair | Hospitalized patients; aged >65 years; stage II to IV pressure (Shea) at any site and <10 cm in diameter | Infection, necrotic PU with black crust; PU on irradiated skin; PU requiring surgery; deep PU in bone with risk of osteitis, patients on air-fluidized beds | NR/NR/168/ 167 | Age (Mean): 82 years  Female: 72% Race: NR | Local Wound Application: Dressing | Stage II: 63.7% vs. 54.0%  Stage III: 30.0% vs. 40.2%  Stage IV: 6.2% vs. 5.7%.  Location (both): foot 54.1%, sacrum 36.3%, trochanter 29.7%, shoulder 0.59%, elbow 0.59%, knee 2.3% thigh 0.59%, back 1.78% |
| Kaya, 200561 Turkey  Poor | Hospitalized patients with spinal cord injury and with PU | NR | NR/NR/27/27 | Age (Mean): 19 years Female: 11%  Race: NR | Local Wound Application: Dressing | Stage I: 24% vs. 25%  Stage II: 68% vs. 70.8%  Stage III 8% vs. 4.2% |
| Kerihuel, 201062 France Good | PUs 5 - 100 cm2 in area. PUs of < 3 month's duration. PUs stage II or IV. PUs with abundant necrotic tissue and slough | Inability to give written consent, severe illness; PUs totally covered with necrotic tissue or requiring surgical debridement; infected ulcers requiring systemic antibiotics; allergy to study dressing; previous use of Actisorb | NR/NR/60/59 | Age (Mean): 81 years  Female: 76%  Race: NR | Local Wound Application: Dressing | Location: Heel 75.9% vs. 66.7%  Sacrum 3.8% vs. 20%  Other 10.3% vs. 13.3% |
| Kim, 199663 Korea  Poor | Admitted to the Department of Rehabilitation Medicine presenting stage I or II decubitus ulcers | Stage III or IV PU, systemic infections, endocrinologic disorders, difficulty keeping pressure relieving positions, or with aggravated conditions due to other factors | NR/NR/44/44 | Age (Mean): 49  Female: 13%  Race: NR | Local Wound Application: Dressing | Stage I: 23% vs. 33.3%  Stage II: 76.9% vs. 66.6%  Location:  Sacral ulcer: 26.9% vs. 22.2% Other pelvic girdle ulcer: 26.9% vs. 38.8% Other regions: 46.1% vs. 38.8 |
| Kloth, 200264 US  Fair | NR | Poorly controlled diabetes; terminally ill; undermining greater than 1cm; >50% of wound bed covered with necrotic tissue after debridement; allergy to adhesives | NR/53/43/40  PU N=56 | Age (Mean): 78 years  Female: 39%  Race: NR | Local Wound Application: Dressing | NR |
| Kraft, 199365 US Poor | Stage II and III ulcers; Specific eligibility criteria not reported | Stage I and IV PUs. Infected PUs. Patients on special beds. Uncontrolled diabetes. Serum albumin < 2g. Hemoglobin < 12 g. Class IV congestive heart failure. Chronic renal insufficiency. Severe peripheral vascular disease. Severe COPD | NR/NR/38/38 | Age (Mean): 56 years  Female: NR Race: 37%  African-American; 63%  Caucasian | Local Wound Application: Dressing | Stage II: 57.8%  Stage III: 42.1% |
| Kurzuk-Howard, 198566 US  Poor | All patients who were admitted with decubitus ulcers | NR | NR/NR/43/43 | Age (Mean): 77 years Female: 70%  Race: NR | Local Wound Application: Dressing | Stage I: 16.2% Stage II: 41.8% Stage III: 32.5% Stage IV: 9.3% |
| Matzen, 199967 Denmark Poor | Patients with stage III or IV non-infected PUs located in the sacral or trochanteric areas | Patients with diseases or taking drugs known to impair healing. | NR/NR/32/32 | Age (Mean): 83 years  Female: 84%  Race: NR | Local Wound Application: Dressing | All patients had stage III and IV wounds |
| Meaume, 200568 France  Fair | Hospitalized adult patients who could be seen for 14 days and who had one of the following: leg ulcer >2cm in one dimension but no larger than 20cm; APBI >0.7 within the previous six months; stage III-IV PU on the ischium, sacrum, trochanter or heel.  No signs of infection and at least two of the following criteria: continuous pain; erythema; edema; heat; moderate to high levels of serous exudate;> 50% of the wound has yellow slough, discolored, or friable granulation tissue, pocketing or undermining at the base of the wound, or foul odor | Received systemic antibiotics during the previous five days; a very poor life expectancy or with a clinical condition that might interfere with wound healing within the past 30 days; patients who had received a topical chemical debriding agent within the previous 7 days | NR/NR/101/99 | Age (Mean): 77 years  Female: 64%  Race: NR | Local Wound Application: Dressing | NR |
| Meaume, 200369 France Fair | 65 years or older; stage II PU; a Modified Norton scale of 11 or above; a red/yellow wound according to the Red-Yellow Brick System | Underlying disease that might interfere with the treatment of the PU; food and/or intake score of 2 or below on the Modified Norton Scale; allergic/hypersensitivity problem with any material in the two dressings; wound larger than 11 cm x 11 cm; or a wound with black necrotic tissue or clinical signs of local infection at baseline | NR/NR/38/38 | Age NR Female: NR Race: 100% Caucasian | Local Wound Application: Dressing | Stage II ulcer  Mostly located on heels and the sacral area |
| Motta, 199970 US  Poor | Stage II or III PU; No underlying medical condition such as long term steroid use or uncontrolled diabetes Understood and executed informed consent agreement | NR | NR/NR/10/10 | Age (Mean):60 years  Female: 50%  Race: NR | Local Wound Application: Dressing | Stage II: 30%  Stage III: 70%  Location:  Foot/Ankle: 20%; coccyx: 40%; buttock: 10%; sacrum: 10%; elbow: 20% |
| Mulder, 199371 US Poor | Stage II or III PU no smaller than 10 cm x 10 cm. At least 18 years of age, signed an informed consent, and a life expectancy of at least 2 months | Stage IV wounds or those with tendon, bone capsule, of fascia exposure; pregnant women, receiving chemotherapy, documented wound infection extensive undermining (>1.0 cm)of the ulcer, testing positive for HIV, or receiving more than 10 mg of corticosteroids per day | NR/NR/67/53 | Age (Mean):59 years Female: 15%  Race:  Caucasian - 52.4%  Black - 21%  Hispanic - 3% | Local Wound Application: Dressing | Stage II: 8 vs. 9 vs. 5 Stage III: 14 vs. 13 vs. 18 |
| Neill, 198972 US  Poor | 18 years or older, written consent obtained, stage II or III PU | Patient:  Inability to give written consent. Insulin dependent diabetes; Skin problems. Radiation treatment of PU area ;Medical condition that would interfere with study  PU: Stage I or IV, 1.5 cm in depth, undermining, or 5.6 cm x 10 cm in area, skin disease, infected Peripheral vascular ulcers, contusions, abrasions, or open skin in immediate PU area | NR/NR/65/65  PU N=87 Subject N=65 | Age (Mean):NR Female: NR Race: NR | Local Wound Application: Dressing | Stage II: 59.5% vs. 75.5%  Stage III: 40.4% vs. 24.4% |
| Oleske, 198673 US  Poor | Patient:  21 years or older; Diagnosed with a PU; Afebrile (less than 100f orally or less than 101f rectally) Expected to be hospitalized for at least two weeks. Able to communicate in English or must have next of kin who is capable of communicating in English  PU: Involves a skin break caused by pressure; Skin break is a minimum, but does not extend into muscle (stage I or II only); Not in an area that is currently being irradiated; No evidence of infection. | NR | 59/22/16/15 | Age (Mean):69 years Female: NR Race: NR | Local Wound Application: Dressing | Stage: I: 22.2% vs. 50% II: 77.7% vs. 50%  Location:  Gluteal or coccyx |
| Payne, 200974 US  Poor | At least 18 years of age; either gender; not pregnant or using contraception; Stage II PU with slight to moderate levels of exudate. If more than one eligible wound, the largest wound was selected | Known history of poor compliance; presence of infection in the; Stage I, Stage III, or Stage IV PU; and previous participation in the evaluation | NR/NR/36/36 | Age (Mean):73 years Female: 39% Race: NR | Local Wound Application: Dressing | Stage II: 100%    Location: Hip/buttocks: 35% vs. 43.8% Sacrum: 40% vs. 43.8% Upper leg: 5% vs. 0% Ankle/foot: 20% vs. 6.3% Lower leg: 0% vs. 6.3% |
| Price, 200075 UK Good | Adults with stage III and IV non infected PU | Existing dermatitis, a history of sensitivity to adhesive products, taking oral corticosteroids | NR/NR/58/50  PU N=21 | Age (Mean):71 years  Female: 64%  Race: NR | Local Wound Application: Dressing | Stage III: 80% vs. 92% Stage IV:20% vs. 8% |
| Sebern, 198676 Sebern, 198977 US Poor | Stage II or III PU Receiving VNA (Visiting Nursing Association) service | Stage I or IV PU; ulcer containing eschar; terminal patient; white count below 4,000 | NR/NR/100/48  PU N=77 | Age (Mean):74 years  Female: NR  Race: NR | Local Wound Application: Dressing | Stage II:59.4% vs. 30% Stage III: 40.5% vs. 70%  (Article used Shea ulcer stages: II, III) |
| Seeley, 199978 US Fair | Either sex,>18 years; one or more stage II or III (AHCPR system) PU | PU smaller than 1cm2 or larger than 50cm2; Clinically infected ulcer; Uncontrolled diabetes. Known history of poor compliance with medical treatment | NR/NR/40/39  PU N=40 | Age (Mean):76 years Female: 54% Race: NR | Local Wound Application: Dressing | Stage II:15%(N=3) vs. N=2 (11%) Stage III: 85%(N=17) vs. 89%(N=17)  Location:  Sacrum or Coccyx: N=4 vs. N=5 Heel: N=7 vs. N=3 Foot: N=3 vs. N=4 Trochanter: N=1 vs. N=1 Ischium: N=1 vs. N=1 Thigh: N=2 vs. N=1 Buttocks: N=1 vs. N=2 Other: N=1 vs. N=2 |
| Small, 200279 South Africa Fair | Patients in the Bloemfontein community 18 years or older with a clinically uninfected stage 2,3, or 4 PU (Stirling scale); Patients with their guardians, who gave informed consent and were willing and able to comply | NR | 60/58/58/58 | Age (Mean):77 years  Female: 61%  Race: NR | Local Wound Application: Dressing | Location:  Sacrum: N=11 vs. N=15 Trochanter: N=6 vs. N=6 Malleolus: N=3 vs. N=0 Iliac crest: N=2 vs. N=2 Ischium: N=2 vs. N=1 Heel: N=2 vs. N=3 Wrist: N=1 vs. N=0 Lat. Side of foot: N=1 vs. N=0 Elbow: N=0 vs. N=2 Scapula: N=0 vs. N=1 |
| Thomas, 199780 UK  Poor | Stage II or III PU; Any wound less than 10mm deep and maximum diameter of 8cm | <16 years of age; History of poor compliance with treatment; Insulin dependent diabetes; Unlikely to survive study period; Previous adverse reaction to test materials; Infected wounds | NR/NR/NR/99  (total N=199 including those with venous leg ulcers, which were separated in analysis) | Age (Mean):79 years  Female: 69%  Race: NR | Local Wound Application: Dressing | Stage II: N=30 vs. N=27 Stage III: N=19 vs. N=23  Location: Heel: N=25 vs. N=23 Buttock: N=2 vs. N=6 Sacrum: N=6 vs. N=10 Hip: N=4 vs. N=2 Other: N=12 vs. N=9 |
| Thomas, 199881 US Poor | >18 years old Stage II, III, IV PU area >/= to 1.0cm2 | Ulcers resulting from venous or arterial insufficiency or other nonpressure etiology Wounds with sinus tracts and or undermining greater than 1cm; Infected wounds; Concomitant use of other topical medications; Severe generalized medical conditions and estimated survival of less than 6 mo;HIV positive, currently abusing drugs, pregnant, breast feeding, non on acceptable means of contraception, cancer diagnosis or chemotherapy | NR/NR/41/30  PU N=30 | Age (Mean): 77 years Female: 54% Race: 53% Caucasian | Local Wound Application: Dressing | Stage:  Stage II: N=8 (50%) vs. N=6 (43%) Stage III: 6 (38%) vs. 7 (50%) Stage IV: 2 (13%) vs. 1 (7%) |
| Thomas, 200582 US Good | Male or female subjects, > 18 years old with a diagnosis of a non-infected stage 3 or stage 4 PU with an area greater than or equal to 1.0 cm2 | History of sensitivity to adhesive products; wound with a sinus tract and/or extensive undermining (greater than 1 cm); nonpressure ulcer; infected ulcer; concomitant use of other topical medication to study ulcer; HIV positive; pregnant, breast-feeding or not on contraception in premenopausal women, current diagnosis of cancer, severe generalized medical condition with estimated survival of <6 months, concomitant systemic steroid therapy at a dose equivalent to greater than 10 mg prednisone daily, or current alcohol or drug abuse | NR/NR/41/41 | Age (Mean): 75 years Female: 32% Race: 51% Caucasian | Local Wound Application: Dressing | Stage III: N=11 vs. N=11 Stage IV: N=10 vs. N=9 |
| Whitney, 200183 US Fair | Male or female; 18 years or older; Stage III or IV PU (NPAUP); English speaking | Documented wound infection; Dermatitis; Recurrent ulcer; Sensitivity to adhesives; Corticosteroid medication; End-stage disease with <3 mo life expectancy | NR/NR/40/29 PU N=30 | Age (Mean): 58 years Female: 38% Race: 79% Caucasian | Local Wound Application: Dressing | Ulcer Stage: III: N=7 vs. 11 IV: N=8 vs. 3  Ulcer locations:  Ischium: 5 vs. 3  Sacrum: 3 vs. 3  Coccyx: 2 vs. 1  Heel: 1 vs. 4  Malleolus: 2 vs. 2  Plantar: 0 vs. 1  Trochanter: 1 vs. 0  Thoracic: 1 vs. 0 |
| Winter, 199084 UK Poor | Chronic leg ulcers or PU | Terminally ill; Wounds <1cm2 | NR/NR/114/51 | Age (Mean): 74 years Female: 67% Race: NR | Local Wound Application: Dressing | NR |
| Xakellis, 199285 US Fair | PU with a break in the skin | Stage I and IV PU; Anticipated discharge within 1 week; PU caused by other causes | NR/NR/39/39 PU N=39 | Age (Mean): 80 years Female: 92%  Race: NR | Local Wound Application: Dressing | Stage II: N=18 vs. 19 Stage III: N=0 vs. 2   Location: Sacrum: N=6 vs. 8 Pelvic girdle: N=8 vs. 6 Other: N=4 vs. 7  (Article used Shea Ulcer rating: II and III) |
| Yapucu Gunes, 200786 Turkey  Fair | Stage II or III PU; 18 years or older | Diabetes mellitus; Terminal illness | NR/36/27/26 | Age (Mean):66 years  Female: 39%  Race: NR | Local Wound Application: Dressing | Mean stage of PU, 2.96 vs. 2.96 |
| Yastrub 200487 US  Poor | > 65 years old, location of the PU, limitations in ADLs, and the Agency for Health Care Policy and Research (AHCPR, 1994) definition of a stage II PU | NR | NR/NR/50/44 | Age (Mean):NR Female: NR  Race: NR | Local Wound Application: Dressing | NR |

| **Evidence Table H-5a: Dressings Trials, continued** |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Treatment A** | **Treatment B** | **Treatment C** | **Duration of Treatment/Followup** | **Study Setting** | **Funding Source** |
| Alm, 198943 Sweden Fair | Hydrocolloid Dressing (Comfeel Ulcus dressing system: Comfeel Ulcus sheet, Comfeel paste, Comfeel powder)  Changed when necessary  N=31 | Wet Saline Gauze  Changed 2x daily  N=25 | NA | 6 Weeks | Hospitals | NR |
| Bale, 199744  UK  Fair | Polyurethane foam dressing  N=29 | Hydrocolloid Dressing  N=31 | NA | 30 days | NR | Smith and Nephew |
| Bale, 1998(b)45  UK  Poor | Hydrocellular dressing (Allevyn): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N = 17 | Hydrocolloid dressing (Granuflex): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N =15 | NA | 8 weeks | Community | Smith and Nephew Ltd |
| Bale, 1998(a)46 UK Poor | Hydrocellular dressing (Allevyn): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N = 17 | Hydrocolloid dressing (Granuflex): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N =15 | NA | 8 weeks | Community | Smith and Nephew Ltd |
| Banks, 1994(a)50 UK Poor | Polyurethane (Spyrosorb): dressings were changed when area discolored by exudates was less than 1cm from the edge of the dressing. Removal of the dressing solely for inspection of the wound was discouraged. Cleansing with warmed sterile saline was undertaken only if necessary and no topical applications were allowed, no limit was placed on the time a dressing could remain in situ.\  N=20 | Hydrocolloid (Granuflex): dressings were changed when area discolored by exudates was less than 1cm from the edge of the dressing. Removal of the dressing solely for inspection of the wound was discouraged. Cleansing with warmed sterile saline was undertaken only if necessary and no topical applications were allowed, no limit was placed on the time a dressing could remain in situ.  N=20 | NA | 6 weeks | Community | C.V. Laboratories Ltd and Calgon Vestal Laboratories |
| Banks, 1994(b)48 UK  Fair | Semi-permeable polyurethane: dressings were changed when the area discolored by exudates was less than 1cm from the edge of the dressing and before exudates had leaked. Dressings were left in situ for a maximum of seven days. Removal of dressing for inspection of the wound was avoided and wounds were cleansed only if necessary with warmed sterile normal saline; no other topical applications were permitted.  N=13 | Hydrocolloid: dressings were changed when the area discolored by exudates was less than 1cm from the edge of the dressing and before exudates had leaked. Dressings were left in situ for a maximum of seven days. Removal of dressing for inspection of the wound was avoided and wounds were cleansed only if necessary with warmed sterile normal saline; no other topical applications were permitted.  N=16 | NA | 6 weeks | Hospital | C.V. Laboratories Ltd and Calgon Vestal Laboratories |
| Belmin, 200249 France  Fair | Alginate for 4 weeks and hydrocolloid for 4 weeks. Calcium alginate dressings were removed every other day or more often if they were saturated, especially when exudates appeared through the secondary dressing. Hydrocolloid dressings were removed every third day or more often if the area discolored by exudates was less than 1cm from the edge of the dressing or if a leakage was apparent.  N=57 | Hydrocolloid dressings alone for 8 weeks. Dressings were removed every third day or more often if the area discolored by exudates was less than 1cm from the edge of the dressing or if a leakage was apparent.  N=53 | NA | 8 weeks | Hospital | Laboratories Urgo |
| Bito, 201250  Japan  Good | Wrap therapy using food wraps and perforated polyethylene changed everyday N=35 | Standard care according to Evidence-Based Localized Pressure Ulcer Treatment Guidelines”  N=29 | NA | 3 months | 15 hospitals | Division of Health for the Elderly at Japanese Ministry of Health, Labour and Welfare |
| Brod, 199051 US  Poor | Poly-hema paste changed twice weekly N=27 | Hydrocolloid dressing changed twice weekly N=16 | NA | 16 weeks | Long-term care | Acme/Chaston Division, National Patent Development Corp. |
| Brown-Etris, 200852 US Fair | Transparent absorbent acrylic dressing (TAAD)  N=35 | Hydrocolloid dressing (HD)  N=37 | NA | 56 days | Community | 3M Company |
| Chang, 199853 Malaysia  Poor | Gauze dressings soaked in normal sterile saline changed daily or when secondary dressing was soaked through   N=17 | DuoDERM CGF Hydrocolloid dressing changed every seven days or when leakage occurred  N=17 | NA | 8 weeks | University Hospital, Kuala Lumpur | ConvaTec (Bristol-Myers Squibb) |
| Chuangsuwanich, 201154  Thailand  Fair | Silver mesh dressing with cotton gauze as outer dressing, changed every three days | Silver sulfadiazine with cotton gauze as outer dressing, changed twice daily | NA | 8 weeks | Siriraj Hospital | NR |
| Colin, 199655 Multinational Poor | Hydrogel (IntraSite) N=67 | Dextranomer paste (Debrisan), N=68 | NA | 3 weeks | "Multicenter investigation" | NR |
| Colwell, 199356 US Poor | Hydrocolloid (DuoDerm), changed every 4 days or as needed N=48 | Saline gauze, changed every 6 hours or as needed. N=49 | NA | 14 months | Long-term care | ConvaTec |
| Darkovich, 199057 US Poor | Hydrogel (BioFilm), changed every three or four days N=41 | Hydrocolloid, changed every three or four days N=49 | NA | 8.6 weeks (60 days) | Acute and long-term care | NR |
| Day, 199558 US, UK, Canada Fair | Hydrocolloid triangle N=52 | Hydrocolloid oval N=51 | NA | 10 treatment days (mean) | Hospital (acute care) | NR |
| Gorse, 198759 US Poor | Hydrocolloid (DuoDerm), changed every four days or more frequently N=76 | Saline gauze + chramine-T (Dakin's solution), changed every 8 hours  N=52 | NA | 5-40 days | Hospital | NR |
| Honde, 199460 France Fair | Amino acid copolymer (Inerpan)  N=80 | Hydrocolloid dressing (Comfeel)  N=88 | NA | 8 weeks | Hospital | Synthélabo Recherche |
| Kaya, 200561 Turkey Poor | Hydrogel-type dressing (Elasto-gel), changed every four days, or more frequently if the membrane became contaminated or non-occlusive.  N=15 patients, 25 PU | Povidone-iodine-soaked gauze, changed daily to prevent contamination  N=12 patients, 24 PU | NA | NR | Hospital | NR |
| Kerihuel, 201062 France Good | Actisorb, changed two to three times per week or more frequently in cases of abundant exudation  N=29 | Hydrocolloid dressing (DuoDerm), changed two to three times per week or more frequently in cases of abundant exudation  N=30 | NA | 4 weeks in study period. | Hospital | Systagenix Wound Management |
| Kim, 199663 Korea  Poor | Hydrocolloid occlusive dressing: dressing change every 4 to 5 days or more if leakage occurred  N=26 | Wet-to-dry gauze dressing: povidone soaked wet gauze and then covered with a layer of dry gauze changed three times per day  N=18 | NA | NR | Hospital | NR |
| Kloth, 200264 US  Fair | Normothermic Noncontact Wound Therapy: 3 separate 1-hour periods per day, N=22 | Standard care: removing moisture-retentive dressing daily, irrigating the wound with normal saline, and applying a fresh dressing, N=21 | NA | 12 weeks | Hospital and Long-term care | Augustine Medical Inc |
| Kraft, 199365 US Poor | Epi-Lock: can be left on for up to 7 days or until there is leakage of exudates  N=24 | Saline Dressings: changed once every 8 hours  N=14 | NA | 24 weeks | Hospital | Calgon Vestal Laboratories |
| Kurzuk-Howard, 198566 US  Poor | Moist Wound Healing (Op Site treatment): applied to dry, clean wound area and removed after healing or it may slough off naturally. | Dry Wound Healing (Alternative treatment); depending on ulcer stage this can vary from egg crate mattresses and turning the patient every two hours to cleaning and dressing the ulcer followed by a heat lamp for 15-20 minutes. | NA | 20 days | Hospital | Partially funded by Acme United Corporation, Bridgeport, Connecticut |
| Matzen, 199967 Denmark Poor | Hydrogel: wounds were changed and dressing changed daily  N=17 | Saline gauze compress: wounds were changed and dressing changed daily  N=15 | NA | 12 weeks | Hospital | NR |
| Meaume, 200568 France  Fair | Silvercel- A sterile non-woven pad composed of a high-G alginate, carboxymethylcellulose and silver-coated fibres. For the first 2 weeks dressings were changed at least 5 times/week, afterwards dressings were changed every 2-3 days as needed.   N=13 | Algosteril- A sterile non-woven pad composed of 100% calcium alginate. For the first 2 weeks dressings were changed at least 5 times/week, afterwards dressings were changed every 2-3 days as needed.  N= 15 | NA | 4 weeks | Hospital | Johnson and Johnson Wound Management |
| Meaume, 200369 Finland Fair | Silicone, polyurethane foam, and polyacrylate fibers; dressings changed at least once a week or more frequently as needed. If the PU was highly exudating in the initial period, the dressing was changed more frequently to avoid leakage.  N=18 | Hydropolymer containing polyurethane foam, a nonwoven layer, and polyurethane backing: dressings changed at least once a week or more frequently as needed. If the PU was highly exudating in the initial period, the dressing was changed more frequently to avoid leakage.  N=20 | NA | 8 weeks | Nursing home/LONG-TERM CARE | NR |
| Motta, 199970 US  Poor | Polymer hydrogel dressing (AcryDerm Sheet Wound Dressing) changed as needed, at least once a week.   N=5 | Hydrocolloid dressing (DuoDERM), changed as needed, at least once a week   N=5 | NA | 8 weeks | Home healthcare | AcryMed, Portland, OR |
| Mulder, 199371 US Poor | Clearsite: changed twice a week by the patient or caregiver  N=22 | DuoDERM: changed twice a week by the patient or caregiver  N=22 | Standard wet-to-moist saline gauze dressing: changed three times a day by the patient or caregiver  N=23 | 8 weeks | Hospital | NR |
| Neill, 198972 US  Poor | Hydrocolloid (Tegasorb): changed every 3 – 7 days  N=42 | Saline gauze (wet-to-dry): changed every 8 hours  N=42 | NA | 15 months | Tertiary care facility and nursing home | 3M Company, Medical-Surgical Division |
| Oleske, 198673 US  Poor | Saline: Normal saline dressings custom cut to the size of the ulcer and covered with a plastic pad. Changed every 4 hours  N=8 | Polyurethane dressing that was self adhesive. Changed only if it dislodged from the ulcer site, usually remained in place for 2 days  N=7 | NA | 10 days | Hospital | Department of Medical Neurnign, Rush-Presbyterian-St. Luke's Medical Center and the Chicago Community Trust |
| Payne, 200974 US  Poor | Self adhesive polyurethane foam: dressing change frequency determined at the discretion of the clinical investigator  N=20 | Saline-soaked gauze dressings: dressing change frequency determined at the discretion of the clinical investigator   N=16 | NA | 4 weeks | Hospital inpatient wards, outpatient clinics, long-term residential center, and a community based wound clinic | NR |
| Price, 200075 UK Good | Radiant heat dressing: warming element inserted into dressing pocket for 1 hour, twice daily (morning and evening) N=25 | Standard care (alginate absorbent dressings): cleaned as clinically indicated  N=25 | NA | 6 weeks | Multiple: Hospital, long-term care, community | NR |
| Sebern, 198676 Sebern, 198977  US Poor | Transparent Moisture vapor permeable dressing (MVP): changed daily to three times a week, N=37 | Saline gauze: changed every 24 hours, wounds were irrigated at each change with half strength hydrogen peroxide and rinsed with physiologic saline, N=40 | NA | 8 weeks | Community | NR |
| Seeley, 199978 US Fair | Hydrocellular dressing N=20 | Hydrocolloid dressing N=19 | NA | 8 weeks | Long term care facilities and Outpatient wound clinic | NR |
| Small, 200279 South Africa Good | Advanced wound care: Hydrogel dressing Foam dressing Transparent film dressing, N=28 | Standard wound care: Cotton, alginates, gauze, hydrocolloids, N=30 | NA | 6 weeks | Community | NR |
| Thomas, 199780 UK  Poor | Hydrocolloid dressing N= 49 | Hydropolymer dressing N = 50 | NA | 6 weeks | community | NR |
| Thomas, 199881 US Poor | Topical hydrogel dressing  N=16 | Saline gauze  n=14 | NA | 10 weeks | Skilled nursing facilities and Community | Carrington Laboratories |
| Thomas, 200582 US Good | Radiant heat dressing, N=21 | Hydrocolloid, N=20 | NA | 12 weeks | Outpatient clinics, Long-term care, and rehabilitation center | NR |
| Whitney, 200183 US Fair | Noncontact normothermic wound therapy (heated dressing)  N=15 | Standard care (moisture retentive dressings including alginates with saline gauze, foam, hydrocolloids, or hydrogels)  N=14 | NA | 8 Weeks | Multiple: Acute care, community, and long-term care | Augustine Medical Inc  and Small Business Innovation Grant No. NIH |
| Winter, 199084 UK Poor | Hydrocolloid  N=58 | Paraffin Gauze  N=56 | NA | 12 Weeks | Hospital and community | Coloplast Ltd |
| Xakellis, 199285 US Fair | Hydrocolloid N=18 | Saline gauze N=21 | NA | 6 Months | Long-term care | Family Health Foundation of America and ConvaTec |
| Yapucu Gunes, 200786 Turkey  Fair | Honey dressing, N=15 | Exthoxy-diaminoacridine + nitrofurazone dressing, N=11 | NA | 5 weeks | Hospital | NR |
| Yastrub, 200487 US  Poor | Polymer membrane dressing, N=21 | Dry clean dressing (gauze and antibiotic ointment), N=23 | NA | 4 weeks | LONG-TERM CARE | Partially funded by NPUAP |

| **Evidence Table  H-5a: Dressings Trials, continued** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year Country Overall Quality Rating** | **Outcomes: Complete Wound Healing** | **Outcomes: Wound Surface Area** | **Outcomes: Healing Time** | **Outcomes: Infection Rate** | **Outcomes: Osteomyelitis Rate** | **Outcomes: Recurrence Rate** | **Outcomes: Pain** | **Other Outcomes: Specify** |
| Alm, 198943 Sweden Fair | Treatment A: 50-60% had healed  Treatment B:  Saline Gauze: 10-20% had healed | Treatment A:  At 6 weeks median value: 0%  Treatment B:  At 6 weeks median value: 31%  (p=0.016) | " Healing was faster in ulcers dressed with the hydrocolloid dressing” | NR | NR | NR | Treatment A:  Authors report that neither the patients nor the staff believed that the dressing change was ever painful.  Treatment B:  NR | NR |
| Bale, 199744  UK  Fair | Treatment A:  N=7  Treatment B:  N=5 | NR | NR | NR | NR | NR | NR | NR |
| Bale, 1998(b)45  UK  Fair | Treatment A: N=10 (59%)  Treatment B:  N=4 (27%) | NR | NR | NR | NR | NR | NR | NR |
| Bale, 1998(a)46 UK Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Banks, 1994(a)50 UK Poor | Treatment A:  60% complete wound healing  Treatment B:  50% complete wound healing | Treatment A:  30% showed improvement.  Treatment B:  0% showed improvement | NR | NR | NR | NR | Treatment A: NR  Treatment B: Authors report Two patients were withdrawn at their own request because discomfort they experienced with the dressing. | NR |
| Banks, 1994(b)48 UK  Fair | Treatment A:  77% complete wound healing  Treatment B:  62.5% complete wound healing | Treatment A:  No data  Treatment B:  6.1% greatly improved | Treatment A:  13.36 days  Treatment B:  12.69 days | NR | NR | NR | NR |  |
| Belmin, 200249  France  Fair | Treatment A:  5.1% complete wound healing  Treatment B:  15.1% complete wound healing  (p=0.162) | Wound surface area mean:  Treatment A: 5.0cm2, 66% improvement  Treatment B: 7.4cm2, 42% improvement  (p<0.0001) | NR | NR | NR | NR | NR | NR |
| Bito, 201250  Japan  Good | Treatment A:  52%  Treatment B:  46% | NR | Treatment A:  60 days  Treatment B:  58 days | NR | NR | NR | NR | NR |
| Brod, 199051 US  Poor | Treatment A: 52%  Treatment B:  62%  (p=0.54) | NR | Treatment A: 0.18cm2/week  Median time to complete healing: 32 days  Treatment B:  Hydrocolloid: 0.10cm2/week  (p=0.005)  Median time to complete healing: 42 days  (p=0.56) | NR | NR | NR | NR | NR |
| Brown-Etris, 200852 US Fair | Treatment A: 21, 60%  Treatment B: 22, 59.5%,  (p=0.963) | Treatment A: 1.1 cm2  Treatment B: HD: 1.6 cm2  (p=0.598) | Treatment A:  Linear healing rate, mean: 0.10cm2  Treatment B:  Linear healing rate, mean: 0.12cm2  (p=0.6520) | NR | NR | NR | NR | NR |
| Chang, 199853 Malaysia  Poor | NR | Treatment A:  mean reduction of 34% from baseline surface area  Treatment B:  mean 9% increase to baseline surface area  p=0.2318 | NR | Treatment A: NR  Treatment B: One subject developed infection | NR | NR | Overall comfort Treatment A: 0% uncomfortable  Treatment B:  50% uncomfortable  (p<0.01) | Exudate handling good/excellent: Treatment A: 69%  Treatment B: 44% (p<0.019) |
| Chuangsuwanich, 201154  Thailand  Fair | NR | Treatment A:  Mean surface area at 8th week 7.96 cm2  Treatment B: Mean surface area at 8th week 18.22 cm2  (p=0.093) | Treatment A:  Mean healing rate, 36.95%  Treatment B:  Mean healing rate, 25.06%  (p=0.507) | Treatment A: 3 patients had microbiologic growth rated as “numerous”  Treatment B:  9 patients had microbiologic growth rated “numerous” | NR | NR | NR | NR |
| Colin, 199655 Multinational Poor | NR | Treatment A: – 35%  Treatment B:  7%  (p=0.03) | NR | NR | NR | NR | NR | NR |
| Colwell, 199356 US Poor | Treatment A: 22%  Treatment B: 2% | Treatment A: 0.73 cm reduction  Treatment B: 0.67 cm increase | NR | NR | NR | NR | NR | NR |
| Darkovich, 199057 US Poor | Treatment A: 43%  Treatment B: 24% | Treatment A: 68% (7.5cm2) wound area difference from baseline  Treatment B:  40% (3.7cm2) difference from baseline | Treatment A: 8.1% wound area/day  Treatment B:  3.1% wound area/day | NR | NR | NR | NR | NR |
| Day, 199558 US, UK, Canada Fair | Treatment A: 36%  Treatment B: 22%  (p=0.17) | Treatment A:  Mean width reduction: 32% Mean length reduction: 28%  Treatment B: Mean width reduction: 17% (p=0.034) Mean length reduction: 24% (NS) | Treatment A:  Hydrocolloid triangle: 13.5 days  Treatment B:  Hydrocolloid oval: 11.0 days | NR | NR | NR | Treatment A: (baseline vs. final): 47% vs. 18%  Treatment B:  29% vs. 32%  Pain higher at final assessment in treatment B group (p=0.04) | NR |
| Gorse, 198759 US Poor | Treatment A:  87% healed  Treatment B:  69% healed | Treatment A:  15.7% healing  Treatment B;  19.2% healing | Treatment A:  0.72cm2/day  Mean healing days: 10  Treatment B:  0.55cm2/day  Mean healing days: 8.7 | NR | NR | NR | NR | NR |
| Honde, 199460 France Fair | Treatment A:  38.7% achieved healing (chi-square test; (p=0.089)  Treatment B:  26.1% achieved healing (p=0.089) | Treatment B: The authors report that progress toward healing tended to be higher (p=0.090). | Treatment A:  32 days  Treatment B:  38 days  (p=0.44) | NR | NR | NR | NR | Authors report that Shea grade distributions in each group were compared, and on day 14, there were more patients healed or nearing healing (Grade I) in treatment A (25.8%) than treatment B (8.3%), (p=0.029) |
| Kaya, 200561 Turkey Poor | Treatment A:  84% of wounds became epithelialized  Treatment B:  54.2% of wounds became epithelialized  (p=0.04) | NR | Treatment A:  0.12cm2/days  Healing time was 48 days  Treatment B:  0.08cm2/days  Healing time was 45.23 days  (p=0.06) | NR | NR | NR | NR | NR |
| Kerihuel, 201062 France Good | NR | Treatment A:  26.9% wound reduction  Treatment B:  18.5% wound reduction | NR | NR | NR | NR | NR | NR |
| Kim, 199663 Korea  Poor | Treatment A:  80% complete wound healing  Treatment B:  77.8% complete wound healing | NR | Treatment A: 9.1mm2/day  Treatment B:  7.9mm2/day | NR | NR | NR | NR | NR |
| Kloth, 200264 US  Fair | Treatment A:  48% wound closure  Treatment B:  36% wound closure | Treatment A:  69% decrease in mean surface area  Treatment B:  50% decrease in mean surface area | Treatment A:  0.52cm2 per week  Treatment B:  0.23cm2 per week (p=0.02) | NR | NR | NR | NR | NR |
| Kraft, 199365 US Poor | Treatment A:  42% healed  Treatment B:  21% healed | NR | NR | NR | NR | NR | NR | NR |
| Kurzuk-Howard, 198566 US  Poor | 32.5% total healing (Treatment A and B combined) | No significant difference between treatment A and treatment B was found in the average rate of improvement in the size (p<0.66) | The rate of improvement over time was greater for the treatment A than for the treatment B. | Treatment A: 1 patient experienced an infection  Treatment B: NR | NR | NR | Many patients reported being more comfortable after an application of Treatment A to the ulcers.  Treatment B: NR | No significant difference was found for the average overall rate of improvement in size, depth, and redness for the two treatment groups (p<0.61) |
| Matzen, 199967 Denmark Poor | Treatment A:  29% complete wound healing  Treatment B:  0% complete wound healing | NR | NR | Treatment A: NR  Treatment B: 40% developed necrotic tissue with infection | NR | NR | Treatment A: Median of 2 patients reported pain  Treatment B: Median of 2 patients reported pain | NR |
| Meaume, 200568 France  Fair | NR | Treatment A:  Absolute decrease: 7.2cm2  wound reduction: 31.6%  Treatment B:  Absolute decrease: 0.8cm2  wound reduction: 13.9% | Treatment A:  0.26cm2/day  Treatment B:  0.03cm2/day | NR | NR | NR | Treatment A: NR  Treatment B: Pain during dressing and erythema, pain reported | NR |
| Meaume, 200369 Finland Fair | Treatment A:  44.4% healed  Treatment B:  50% healed | Treatment A:  38.8% showed improvement  Treatment B:  NR | NR | NR | NR | Treatment A: 0% developed new ulcers  Treatment B: 10% developed new ulcers | NR | NR |
| Motta, 199970 US  Poor | Treatment A:  40% healed  Treatment B:  40% healed | Treatment A:  79.2% wound improvement  Treatment B:  88.6% wound improvement | Treatment A:  0.15cm/day  Treatment B:  0.35cm/day | NR | NR | NR | NR | NR |
| Mulder, 199371 US Poor | NR | NR | Treatment A vs. Treatment B vs. Treatment C:  Mean reduction/week  8% vs. 3.3% vs. 5.1% (p=0.89) | Treatment A: 1 case of inflammation  Treatment B:  NR | NR | NR | NR | NR |
| Neill, 198972 US  Poor | Treatment A:  31% healed  Treatment B:  22% healed | 50% or more reduction in size:  Treatment A:  50%  Treatment B: 46% | NR | Treatment A: No infection occurred  Treatment B: NR | NR | NR | NR | NR |
| Oleske, 198673 US  Poor | Treatment A:  1 ulcer healed  Treatment B:  0 healed | Treatment A:  Mean 7.7 cm2 SD (pre and post change not significant)  Treatment B: Mean 2.0 cm2 (pre and post change significant at p=0.01) | NR | Treatment A: One patient developed an infection in the treated ulcer and died the next day from pulmonary embolism and sepsis. It is not clear what (the underlying disease, or the dressing) contributed to the infection  Treatment B:  NR | NR | NR | NR | Authors note that in one instance a patient in the treatment B with two ulcers within 1 cm of one another, the two ulcers merged into a single ulcer with greater depth. |
| Payne, 200974 US  Poor | Treatment A:  55.5% healed  Treatment B:  37.5% healed | NR | NR | Treatment A: 5.56% showed signs of infection  Treatment B: No infections reported | NR | NR | NR | NR |
| Price, 200075 UK Good | Treatment A:  12% complete wound healing  Treatment B:  8% complete wound healing | Reduction of initial wound area:  Treatment A:  75%  Treatment B:  40% | Treatment A:  66.7cm2/week  Treatment B:  63.3cm2/week | NR | NR | NR | Treatment A: No difference in pain scores from baseline to end of study  Treatment B: No difference in pain scores from baseline to end of study. | NR |
| Sebern, 198676 Sebern, 198977 US Poor | Grade II  Treatment A: 64%  Treatment B: 0%  (p<0.01) | Grade II  Median improvement:  Treatment A: 100%  Treatment B: 52% (p<0.05) | NR | Treatment A: No sepsis reported  Treatment B: No sepsis reported | NR | NR | NR | NR |
| Seeley, 199978 US Fair | Treatment A:  40% of all PU healed  Treatment B:  40% of all ulcers healed | Treatment A:  Stage II median improvement: 100%  Stage III median improvement: 67%  Treatment B: Stage II median improvement: 52% (p<0.01)  Stage III median improvement: 44% | NR | NR | NR | NR | Treatment A: Mean wound pain 0.15  Treatment B:  mean wound pain 0.47 | NR |
| Small, 200279 South Africa Good | Treatment A: 53.6%  Treatment B:  30% | NR | NR | Treatment A: 1 infection  Treatment B: 1 infection | NR | NR | NR | NR |
| Thomas, 199780 UK  Poor | Treatment A: 33%  Treatment B: 20% | Treatment A: 47%  Treatment B: 10% | NR | NR | NR | NR | NR | NR |
| Thomas, 199881 US Poor | Treatment A: 63%  Treatment B:  64% | NR | Treatment A: 5.3 weeks  Treatment B:  5.2 weeks (p=0.87) | NR | NR | NR | NR | NR |
| Thomas, 200582 US Good | Treatment A: 57%  Treatment B:  44% (p=0.46) | NR | NR | NR | NR | NR | NR | NR |
| Whitney, 200183 US Fair | Treatment A: 53%  Treatment B:  43% | NR | Mean linear rate of healing: Treatment A: 0.012cm2 per day  Treatment B:  0.004 cm2 per day  (p=0.01) | NR | NR | NR | NR | NR |
| Winter, 199084 UK Poor | Treatment A: 63% (n=12)  Treatment B: 19% (n=3) | NR | NR | NR | NR | NR | NR | NR |
| Xakellis, 199285 US Fair | Treatment A: 89%  Treatment B: 86% | NR | Treatment A: 9 days (median)  Treatment B: 11 days (median) (p=0.12) | NR | NR | NR | NR | NR |
| Yapucu Gunes, 200786 Turkey  Fair | Treatment A: 20%  Treatment B:  0% (p<0.05 ) | Decrease in ulcer size: (mean) Treatment A: 56% reduction  Treatment B: 13% (p<0.001 ) | NR | NR | NR | NR | NR | Improved PUSH tool scores: Treatment A:6.55  Treatment B:12.62  (p<0.001 ) |
| Yastrub, 200487 US  Poor | NR | improvement in wound healing:  Treatment A: 87%  Treatment B: 65.2% | NR | NR | NR | NR | NR | NR |

| **Evidence Table**  **H-5a: Dressings Trials, continued** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year Country Overall Quality Rating** | **Harms: Pain** | **Harms: Dermatologic Complications** | **Harms: Bleeding** | **Harms: Infection** | **Other Harms: Specify** | **Severe Adverse Events** | **Withdrawal Due to Adverse Events** | **Overall Adverse Events Rate** |
| Alm, 198943 Sweden Fair | Treatment A:  No pain reported on dressing removal   (Although, it later says one patient withdrew due to pain.)  Treatment B:  No pain reported on dressing removal | NR | NR | NR | NR | NR | 1 patient withdrawn from hydrocolloid due to pain from changing the dressings | Hydrocolloid dressing: N=1  Wet saline gauze: N=0 |
| Bale, 199744  UK  Fair | NR | Treatment A:  Skin rash, N=1  Treatment B:  Skin rash, N=0 | NR | NR | NR | NR | NR | NR |
| Bale, 1998(b)45  UK  Poor | Patients who found the dressing "uncomfortable" are reported, but only in aggregate with the other types of wounds | NR | NR | NR | NR | NR | NR | NR |
| Bale, 1998(a)46 UK Poor | Patients who found the dressing "uncomfortable" are reported, but only in aggregate with the other types of wounds | NR | NR | NR | NR | NR | NR | NR |
| Banks, 1994(a)50 UK Poor | Treatment A: NR  Treatment B: Two patients were withdrawn at their own request because of the discomfort they experienced using the dressing. | NR | NR | NR | NR | NR | NR | NR |
| Banks, 1994(b)48 UK (Wales) Poor | NR | NR | NR | NR | Treatment A: Wound deterioration, n=1  Wound/dressing-related problems n=1  Treatment B:  Wound deterioration, n=3  Wound/dressing related problems, n=1 | NR | Treatment A:  3  Treatment B:  4 | 20.6% |
| Belmin, 200249 France  Fair | Treatment A: 31.3% reported pain during the removal of the dressings.  Treatment B: 35.6% reported pain during the removal of the dressings.  p=.03 | Treatment A: Erythema of surrounding skin 3.5%, Maceration 1.8%  Treatment B: Erythema of surrounding skin 0%, Maceration 0% | Treatment A: N=1  Treatment B: N=0 | Treatment A: n=1  Treatment B: n=0 | Hypergranulation:  Treatment A: n=1,  Treatment B: n=5 | NR | Treatment A: n=1  Treatment B: n=3 | Treatment A: local adverse events n=6  Treatment B: local adverse events n=5 |
| Bito, 201250  Japan  Good | NR | Treatment A: 6 cases of eczema, maceration, or rash with the covered skin  Treatment B:  Cases of eczema, maceration, and rash reported N not given | NR | NR | NR | None related to treatment | NR | NR |
| Brod, 199051 US  Poor | NR | NR | NR | NR | NR | NR | Treatment A: NR  Treatment B: n=1 | 2.3% |
| Brown-Etris, 200852 US Fair | NR | NR | NR | NR | NR | NR | NR | NR |
| Chang, 199853 Malaysia  Poor | Treatment A: Pain during dressing removal moderate/severe 0%  Treatment B: Pain during dressing removal moderate/severe, 44% p<0.01 | Treatment A: Adherence to surrounding skin, non-adherent 44%    Treatment B:  Adherence to surrounding skin non adherent, 94% p<0.01 | NR | Treatment A: No infection reported  Treatment B: 1 infection reported | Adherence to wound bed:  Treatment A: 100%  Treatment B: 44% (p<0.01) | NR | Treatment A: NR  Treatment B: 1 subject in gauze group developed wound infection and withdrew | NR |
| Chuangsuwanich, 201154  Thailand  Fair | NR | NR | NR | NR | NR | NR | NR | NR |
| Colin, 199655 Multinational Poor | Treatment A: No pain reported  Treatment B: One patient reported pain when dressing was removed | NR | NR | NR | Treatment A: Only dressing related adverse event was pain upon application of dressing, n=1  Treatment B: NR | NR | NR | NR |
| Colwell, 199356 US Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Darkovich, 1990 57 US Poor | NR | NR | NR | NR | Wound deterioration:  Treatment A: 1.5%  Treatment B: 10% | NR | NR | NR |
| Day, 199558 US, UK, Canada Fair | Treatment A: Mean pain score at dressing change 3.8 (range 1-10)  Treatment B: Mean pain score at dressing changes 4.3 (range 2-9) | Hydrocolloid triangle Wound Deterioration  Treatment A: 4%  Treatment B: 31% | Treatment A: NR  Treatment B: Minor bleeding reported | NR | Erythema, severe pain, increase in necrotic tissue, wound size, and depth: Treatment A: 4%  Treatment B: 31% | Treatment A: NR  Treatment B: Deteriorating wound appearance, inflammation of surrounding skin, severe pain upon dressing removal/redness of the surrounding skin, minor bleeding at the wound site | Treatment A: NR  Treatment B: n=7 patients | 10% |
| Gorse, 198759 US Poor | NR | NR | NR | Treatment A: Rate of wound increase: 2.89cm2/day  Treatment B: Rate of wound increase: 0.75cm2/day | NR | NR | NR | NR |
| Honde, 199460 France Fair | NR | Ten withdrew from the study for emergent reasons (4 Treatment A and 6  Treatment B) because of local complication (mainly necrosis) | NR | NR | NR | Local complications (mainly necrosis) | 10 | 5.9% |
| Kaya, 200561 Turkey Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Kerihuel, 201062 France Good | Harms:  A: 7% (infection, pruritus)  B: 16% (maceration/exudation, infection, wound aggravation, overgranulation, eczema) | None | None | Treatment A: 1 patient  Treatment B: 2 patients | NR | Maceration/high exudation; wound infection; wound aggravation; overgranulation; eczema; pruritus | 1 from hydrocolloid group | 16.9% |
| Kim, 199663 Korea  Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Kloth, 200264 US  Fair | NR | NR | NR | NR | NR | NR | NR | NR |
| Kraft, 199365 US Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Kurzuk-Howard, 198566 US  Poor | NR | NR | NR | Treatment A: 1 patient  Treatment B: NR | NR | NR | NR | NR |
| Matzen, 199967 Denmark Poor | NR | NR | NR | NR | NR | NR | 9 | 28.1% |
| Meaume, 200568 France  Fair | NR | NR | NR | NR | Poor local acceptability and/or tolerability was noted in 1 PU case in the treatment A group | Dry wound; pain; peri-wound eczema | 19 withdrawals: 10 vs. 9 | 19.2% |
| Meaume, 200369 Finland Fair | NR | In most patients, the sign/symptom reported as damage to the surrounding skin was redness. Two patients in Treatment B developed blisters on the surrounding skin. This was not observed in Treatment A. | NR | NR | NR | None | None | NR |
| Motta, 199970 US  Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Mulder, 199371 US Poor | NR | NR | NR | NR | NR | NR | NR | NR |
| Neill, 198972 US  Poor | NR | Treatment A: mild skin irritation, perilesional erythema, and eczema reported  Treatment B:  NR | NR | NR | Treatment A: NR  Treatment B: One sore enlarged by 216% | NR | Treatment A: 9  Treatment B: 1 | 18% vs. 2% |
| Oleske, 198673 US  Poor | NR | NR | NR | Treatment A: One patient developed an infection in the treated ulcer and died the next day from pulmonary embolism and sepsis. It is not clear what (the underlying disease, or the dressing) contributed to the infection  Treatment B: NR | Treatment A: One a patient with two ulcers within 1 cm of one another, the two ulcers merged into a single ulcer with greater depth. | NR | NR | NR |
| Payne, 200974 US  Poor | NR | NR | NR | Treatment A: One patient (5%) in the foam group showed clinical signs of infection in the reference wound and was withdrawn from the study.  Treatment B: No infection was reported in the saline group | NR | NR | 0 | NR |
| Price, 200075 UK Good | Treatment A: No pain reported due to dressing  Treatment B: No pain reported due to treatment | NR | NR | NR | Undermining, no difference reported in the occurrence of undermining | NR | NR | NR |
| Sebern, 198676 Sebern, 198977 US Poor | NR | Treatment A:  Wound deterioration: 14%  Stage II skin maceration: 50%  Stage III skin maceration: 40%  Treatment B:  Wound deterioration: 58% Stage II skin maceration: 25%  Stage III skin maceration: 25%  (p<0.01) | NR | Treatment A: 0  Treatment B: 0 | 11 ulcers developed necrosis and eschar after being randomly assigned treatment | NR | NR | NR |
| Seeley, 199978 US Fair | Treatment A: mean wound pain 0.15  Treatment B: mean wound pain 0.47  (wound pain rated on a scale of non, mild, moderate, or severe) | Treatment A: Blisters beneath adhesive border 5% (1)  Treatment B:  Maceration of ulcer 5% (1); Rash beneath dressing 5% (1) | NR | NR | Adverse incidents (blisters, rash or maceration) Treatment A: 5%  Treatment B: 10% | NR | Treatment A: 1 patients  Treatment B: 2 patients | 8% (n=3) |
| Small, 200279 South Africa Good | NR | NR | NR | NR | NR | NR | NR | NR |
| Thomas, 199780 UK  Poor | NR | NR | NR | NR | Minor trauma or erythema removal during dressing change, maceration, bleeding, and wound dehydration  Treatment A: n=7  Treatment B: n=10  Note: leg ulcer group and PU group data combined. | Five patients died during the study for reasons unrelated to the treatments | NR | NR |
| Thomas, 199881 US Poor | NR | NR | NR | NR | Worsening of Ulcer:  Treatment A: 6% (n=1) Treatment B: 7% (n=1) | NR | 2 | 7% (n=2) |
| Thomas, 200582 US Good | NR | NR | NR | NR | NR | NR | NR | NR |
| Whitney, 200183 US Fair | NR | Treatment A: 1 patient had maceration of wound due to treatment  Treatment B: NR | NR | NR | Treatment A: NR  Treatment B: periwound maceration related to treatment 7% (N=1 ) | NR | Treatment B: 1 patient withdrawn due to periwound maceration related to treatment | 3% (1 out of 30) |
| Winter, 199084 UK Poor | NR | Treatment A: Rash, inflammation, or allergic reaction to dressing 1  Treatment B:  Rash, inflammation, allergic reaction to dressing, 1 | NR | Treatment A: N=5  Treatment B: N=4 | Wound deterioration:  Treatment A: N=3  Treatment B: N1 | NR | 15 patients did not proceed beyond the first week of the study owing to non-compliance, allergic reaction to the dressing or invasive infection. | NR |
| Xakellis, 199285 US Fair | NR | NR | NR | NR | NR | NR | NR | NR |
| Yapucu Gunes, 200786 Turkey  Fair | NR | NR | NR | NR | NR | NR | NR | NR |
| Yastrub, 200487 US  Poor | NR | NR | NR | NR | NR | NR | NR | NR |

Abbreviations: LONG-TERM CARE, long-term care; NR, not reported; PU, pressure ulcer.