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

Evidence Table H-5a. Dressings trials

| **Author, yearCountryOverall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **AgeSexRace** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
| --- | --- | --- | --- | --- | --- | --- |
| Alm, 198943SwedenFair | 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/50/50PU N=56 | Age (Mean): 83 yearsFemale: 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, 199744UKFair | 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 yearsFemale: 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)45UK 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/100/100/96PU N=32 | Age (Mean): 76 yearsFemale: 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 UKPoor | 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 yearsFemale: 61%Race: NR | Local Wound Application: Dressing | Stage II: N=2 vs N=0Stage III: N=20 vs. N=21Stage IV: N=2 vs. N=1Location: Sacrum: N=5 vs. N=4Ischium: N=2 vs. N=0Heel: N=14 vs. N=19Foot: N=2 vs N=0Gaiter Area: N=1 vs. N=0Elbow: N=1 vs N=0Lateral malleolus: N=0 vs. N=1Buttock: N=1 vs. N=0 |

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| **Evidence Table H-5a: Dressings Trials, continued** |
| **Author, yearCountryOverall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **AgeSexRace** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
| Banks, 1994(a)47UKPoor | 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 yearsFemale: 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)48UK (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 yearsFemale: 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 yearsFemale: 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, yearCountryOverall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **AgeSexRace** | **Intervention Type** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
| Bito, 201250JapanGood | 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 yearsFemale: 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, 199051USPoor | 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 yearsFemale: NR Race: NR | Local Wound Application: Dressing | All Stage II or III |
| Brown-Etris, 200852USFair | 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 studyWounds 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 yearsFemale: 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, 199853MalaysiaPoor | 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 yearsFemale: NRRace: NR | Local Wound Application: Dressing | Stage II N=11 vs. 7Stage III N=6 vs. 7Note: 3 cases are missing from the gauze group, N is reported at 17, however only 14 PU are reportedLocation (both groups): Sacral: N=30 Iliac: N=3Greater Trochanter: N=1 |
| Chuangsuwanich, 201154ThailandFair | Out and in patients with PU | NR | NR/NR/40/40 | Age (Mean): 65 yearsFemale: 54% Race: NR | Local Wound Application: Dressing | NUPAP III-IVLocalization: Sacrum, greater trochanteric, ischium |
| Colin, 199655MultinationalPoor | NR | NR | NR/NR/135/135 | Age (Mean): 79 yearsFemale: 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, 199356USPoor | 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/94/70PU N=97 | Age (Mean): 68 yearsFemale: 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, 199057USPoor  | 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/90/90PU N=129 | Age (Mean): 75 yearsFemale: 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, 199558US, UK, CanadaFair  | 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/103/96PU N=96 | Age (Mean): 75 yearsFemale: 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, 198759USPoor  | 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/52/52PU N=128 | Age (Mean): 70 yearsFemale: 0%Race: NR | Local Wound Application: Dressing | Stage II: 86.8% vs. 78.8%Stage III: NRStageIV:NRLocation: 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, 199460JapanFair | 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 yearsFemale: 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, 200561TurkeyPoor | Hospitalized patients with spinal cord injury and with PU | NR | NR/NR/27/27 | Age (Mean): 19 yearsFemale: 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, 201062FranceGood | 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 yearsFemale: 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, 199663KoreaPoor | 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): 49Female: 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, 200264USFair | NR | Poorly controlled diabetes; terminally ill; undermining greater than 1cm; >50% of wound bed covered with necrotic tissue after debridement; allergy to adhesives | NR/53/43/40PU N=56 | Age (Mean): 78 yearsFemale: 39%Race: NR | Local Wound Application: Dressing | NR |
| Kraft, 199365USPoor | 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 yearsFemale: NRRace: 37%African-American; 63% Caucasian | Local Wound Application: Dressing | Stage II: 57.8%Stage III: 42.1%  |
| Kurzuk-Howard, 198566USPoor | All patients who were admitted with decubitus ulcers  | NR | NR/NR/43/43 | Age (Mean): 77 yearsFemale: 70% Race: NR | Local Wound Application: Dressing | Stage I: 16.2%Stage II: 41.8%Stage III: 32.5%Stage IV: 9.3% |
| Matzen, 199967DenmarkPoor | 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 yearsFemale: 84% Race: NR | Local Wound Application: Dressing | All patients had stage III and IV wounds |
| Meaume, 200568FranceFair | 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 yearsFemale: 64% Race: NR | Local Wound Application: Dressing | NR |
| Meaume, 200369FranceFair |  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 NRFemale: NRRace: 100% Caucasian | Local Wound Application: Dressing | Stage II ulcerMostly located on heels and the sacral area |
| Motta, 199970USPoor | Stage II or III PU; No underlying medical condition such as long term steroid use or uncontrolled diabetesUnderstood and executed informed consent agreement | NR | NR/NR/10/10 | Age (Mean):60 yearsFemale: 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, 199371USPoor | 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 yearsFemale: 15%Race:Caucasian - 52.4%Black - 21% Hispanic - 3%  | Local Wound Application: Dressing | Stage II: 8 vs. 9 vs. 5Stage III: 14 vs. 13 vs. 18 |
| Neill, 198972USPoor | 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 studyPU: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=87Subject N=65 | Age (Mean):NR Female: NRRace: NR |  Local Wound Application: Dressing | Stage II: 59.5% vs. 75.5%Stage III: 40.4% vs. 24.4% |
| Oleske, 198673USPoor | 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 EnglishPU: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 yearsFemale: NRRace: NR | Local Wound Application: Dressing | Stage:I: 22.2% vs. 50%II: 77.7% vs. 50%Location: Gluteal or coccyx |
| Payne, 200974USPoor | 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, 200075UKGood | Adults with stage III and IV non infected PU | Existing dermatitis, a history of sensitivity to adhesive products, taking oral corticosteroids | NR/NR/58/50PU N=21 | Age (Mean):71 yearsFemale: 64%Race: NR | Local Wound Application: Dressing | Stage III: 80% vs. 92%Stage IV:20% vs. 8% |
| Sebern, 198676Sebern, 198977USPoor | Stage II or III PUReceiving VNA (Visiting Nursing Association) service | Stage I or IV PU; ulcer containing eschar; terminal patient; white count below 4,000 | NR/NR/100/48PU N=77 | Age (Mean):74 yearsFemale: NRRace: 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, 199978USFair | 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/40/39PU N=40 | Age (Mean):76 yearsFemale: 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=5Heel: N=7 vs. N=3Foot: N=3 vs. N=4Trochanter: N=1 vs. N=1Ischium: N=1 vs. N=1Thigh: N=2 vs. N=1Buttocks: N=1 vs. N=2Other: N=1 vs. N=2 |
| Small, 200279South AfricaFair | 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 yearsFemale: 61%Race: NR | Local Wound Application: Dressing | Location: Sacrum: N=11 vs. N=15Trochanter: N=6 vs. N=6Malleolus: N=3 vs. N=0Iliac crest: N=2 vs. N=2Ischium: N=2 vs. N=1Heel: N=2 vs. N=3Wrist: N=1 vs. N=0Lat. Side of foot: N=1 vs. N=0Elbow: N=0 vs. N=2Scapula: N=0 vs. N=1 |
| Thomas, 199780UKPoor | 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 yearsFemale: 69% Race: NR |  Local Wound Application: Dressing | Stage II: N=30 vs. N=27Stage III: N=19 vs. N=23Location:Heel: N=25 vs. N=23Buttock: N=2 vs. N=6Sacrum: N=6 vs. N=10Hip: N=4 vs. N=2Other: N=12 vs. N=9 |
| Thomas, 199881USPoor | >18 years oldStage II, III, IV PU area >/= to 1.0cm2 | Ulcers resulting from venous or arterial insufficiency or other nonpressure etiologyWounds 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/41/30PU N=30 | Age (Mean): 77 yearsFemale: 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, 200582USGood | 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 yearsFemale: 32%Race: 51% Caucasian  | Local Wound Application: Dressing | Stage III: N=11 vs. N=11Stage IV: N=10 vs. N=9 |
| Whitney, 200183USFair | 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/40/29PU N=30 | Age (Mean): 58 yearsFemale: 38%Race: 79% Caucasian | Local Wound Application: Dressing | Ulcer Stage:III: N=7 vs. 11IV: N=8 vs. 3 Ulcer locations: Ischium: 5 vs. 3Sacrum: 3 vs. 3Coccyx: 2 vs. 1Heel: 1 vs. 4Malleolus: 2 vs. 2Plantar: 0 vs. 1Trochanter: 1 vs. 0Thoracic: 1 vs. 0 |
| Winter, 199084UKPoor | Chronic leg ulcers or PU | Terminally ill; Wounds <1cm2 | NR/NR/114/51 | Age (Mean): 74 yearsFemale: 67%Race: NR | Local Wound Application: Dressing | NR |
| Xakellis, 199285USFair  |  PU with a break in the skin | Stage I and IV PU; Anticipated discharge within 1 week; PU caused by other causes  | NR/NR/39/39PU N=39 | Age (Mean): 80 yearsFemale: 92%Race: NR | Local Wound Application: Dressing | Stage II: N=18 vs. 19Stage III: N=0 vs. 2 Location:Sacrum: N=6 vs. 8Pelvic girdle: N=8 vs. 6Other: N=4 vs. 7(Article used Shea Ulcer rating: II and III) |
| Yapucu Gunes, 200786TurkeyFair | Stage II or III PU; 18 years or older | Diabetes mellitus; Terminal illness | NR/36/27/26 | Age (Mean):66 yearsFemale: 39% Race: NR | Local Wound Application: Dressing | Mean stage of PU, 2.96 vs. 2.96 |
| Yastrub 200487USPoor | > 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):NRFemale: NRRace: NR | Local Wound Application: Dressing | NR |

| **Evidence Table H-5a: Dressings Trials, continued** |  |  |  |  |  |  |
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| **Author, yearCountryOverall Quality Rating** | **Treatment A**  | **Treatment B** | **Treatment C** | **Duration of Treatment/Followup** | **Study Setting** | **Funding Source** |
| Alm, 198943SwedenFair | Hydrocolloid Dressing (Comfeel Ulcus dressing system: Comfeel Ulcus sheet, Comfeel paste, Comfeel powder)Changed when necessaryN=31 | Wet Saline GauzeChanged 2x dailyN=25 | NA | 6 Weeks | Hospitals | NR |
| Bale, 199744UKFair | Polyurethane foam dressing N=29 | Hydrocolloid DressingN=31 | NA | 30 days | NR | Smith and Nephew  |
| Bale, 1998(b)45UK 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 investigationN = 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 investigationN =15 | NA | 8 weeks | Community | Smith and Nephew Ltd |
| Bale, 1998(a)46UKPoor | 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 investigationN = 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 investigationN =15 | NA | 8 weeks | Community | Smith and Nephew Ltd |
| Banks, 1994(a)50UKPoor | 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)48UK 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, 200249France 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, 201250JapanGood | 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, 199051USPoor | Poly-hema paste changed twice weeklyN=27 | Hydrocolloid dressing changed twice weeklyN=16 | NA | 16 weeks | Long-term care | Acme/Chaston Division, National Patent Development Corp. |
| Brown-Etris, 200852USFair | Transparent absorbent acrylic dressing (TAAD)N=35 | Hydrocolloid dressing (HD)N=37 | NA | 56 days  | Community | 3M Company |
| Chang, 199853MalaysiaPoor | 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 occurredN=17 | NA | 8 weeks | University Hospital, Kuala Lumpur | ConvaTec (Bristol-Myers Squibb) |
| Chuangsuwanich, 201154ThailandFair | 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, 199655MultinationalPoor | Hydrogel (IntraSite)N=67 | Dextranomer paste (Debrisan), N=68 | NA | 3 weeks | "Multicenter investigation" | NR |
| Colwell, 199356USPoor | Hydrocolloid (DuoDerm), changed every 4 days or as neededN=48 | Saline gauze, changed every 6 hours or as needed.N=49 | NA | 14 months | Long-term care | ConvaTec |
| Darkovich, 199057USPoor | Hydrogel (BioFilm), changed every three or four daysN=41 | Hydrocolloid, changed every three or four daysN=49 | NA | 8.6 weeks (60 days) | Acute and long-term care | NR |
| Day, 199558US, UK, CanadaFair  | Hydrocolloid triangleN=52 | Hydrocolloid ovalN=51 | NA | 10 treatment days (mean) | Hospital (acute care) | NR |
| Gorse, 198759USPoor | Hydrocolloid (DuoDerm), changed every four days or more frequentlyN=76 | Saline gauze + chramine-T (Dakin's solution), changed every 8 hoursN=52 | NA | 5-40 days | Hospital | NR |
| Honde, 199460FranceFair | Amino acid copolymer (Inerpan)N=80 | Hydrocolloid dressing (Comfeel)N=88 | NA | 8 weeks | Hospital | Synthélabo Recherche |
| Kaya, 200561TurkeyPoor | 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 contaminationN=12 patients, 24 PU | NA | NR | Hospital | NR |
| Kerihuel, 201062FranceGood | Actisorb, changed two to three times per week or more frequently in cases of abundant exudationN=29 | Hydrocolloid dressing (DuoDerm), changed two to three times per week or more frequently in cases of abundant exudationN=30 | NA | 4 weeks in study period. | Hospital | Systagenix Wound Management |
| Kim, 199663KoreaPoor | Hydrocolloid occlusive dressing: dressing change every 4 to 5 days or more if leakage occurredN=26 | Wet-to-dry gauze dressing: povidone soaked wet gauze and then covered with a layer of dry gauze changed three times per dayN=18 | NA | NR | Hospital | NR |
| Kloth, 200264USFair | 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, 199365USPoor | Epi-Lock: can be left on for up to 7 days or until there is leakage of exudatesN=24 | Saline Dressings: changed once every 8 hoursN=14 | NA | 24 weeks | Hospital | Calgon Vestal Laboratories |
| Kurzuk-Howard, 198566USPoor | 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, 199967DenmarkPoor | Hydrogel: wounds were changed and dressing changed dailyN=17 | Saline gauze compress: wounds were changed and dressing changed dailyN=15 | NA | 12 weeks  | Hospital | NR |
| Meaume, 200568FranceFair | 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, 200369FinlandFair | 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, 199970USPoor | 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, 199371USPoor | Clearsite: changed twice a week by the patient or caregiverN=22 | DuoDERM: changed twice a week by the patient or caregiverN=22 | Standard wet-to-moist saline gauze dressing: changed three times a day by the patient or caregiverN=23 | 8 weeks | Hospital | NR |
| Neill, 198972USPoor | Hydrocolloid (Tegasorb): changed every 3 – 7 daysN=42 | Saline gauze (wet-to-dry): changed every 8 hoursN=42 | NA | 15 months | Tertiary care facility and nursing home | 3M Company, Medical-Surgical Division |
| Oleske, 198673USPoor | Saline: Normal saline dressings custom cut to the size of the ulcer and covered with a plastic pad. Changed every 4 hoursN=8 | Polyurethane dressing that was self adhesive. Changed only if it dislodged from the ulcer site, usually remained in place for 2 daysN=7 | NA | 10 days | Hospital | Department of Medical Neurnign, Rush-Presbyterian-St. Luke's Medical Center and the Chicago Community Trust |
| Payne, 200974USPoor | Self adhesive polyurethane foam: dressing change frequency determined at the discretion of the clinical investigatorN=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, 200075UKGood | 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 indicatedN=25 | NA | 6 weeks | Multiple: Hospital, long-term care, community | NR |
| Sebern, 198676Sebern, 198977USPoor | 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, 199978USFair | Hydrocellular dressing N=20 | Hydrocolloid dressing N=19 | NA | 8 weeks | Long term care facilities and Outpatient wound clinic | NR |
| Small, 200279South AfricaGood |  Advanced wound care: Hydrogel dressingFoam dressingTransparent film dressing, N=28 |  Standard wound care: Cotton, alginates, gauze, hydrocolloids, N=30 | NA | 6 weeks | Community  | NR |
| Thomas, 199780UKPoor | Hydrocolloid dressingN= 49 | Hydropolymer dressing N = 50 | NA | 6 weeks | community | NR |
| Thomas, 199881USPoor | Topical hydrogel dressingN=16 | Saline gauze n=14 | NA | 10 weeks | Skilled nursing facilities and Community | Carrington Laboratories |
| Thomas, 200582USGood | Radiant heat dressing, N=21 | Hydrocolloid, N=20 | NA | 12 weeks | Outpatient clinics, Long-term care, and rehabilitation center | NR |
| Whitney, 200183USFair | 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 Incand Small Business Innovation Grant No. NIH |
| Winter, 199084UKPoor | HydrocolloidN=58 | Paraffin GauzeN=56 | NA | 12 Weeks | Hospital and community  | Coloplast Ltd |
| Xakellis, 199285USFair  | Hydrocolloid N=18 | Saline gauze N=21 | NA | 6 Months | Long-term care | Family Health Foundation of America and ConvaTec |
| Yapucu Gunes, 200786TurkeyFair | Honey dressing, N=15 | Exthoxy-diaminoacridine + nitrofurazone dressing, N=11 | NA | 5 weeks  | Hospital | NR |
| Yastrub, 200487USPoor | 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, yearCountryOverall 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, 198943SwedenFair | Treatment A: 50-60% had healedTreatment 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, 199744UKFair | Treatment A:N=7Treatment B: N=5 | NR | NR | NR | NR | NR | NR | NR |
| Bale, 1998(b)45UK Fair | Treatment A: N=10 (59%)Treatment B:N=4 (27%) | NR | NR  | NR | NR | NR | NR | NR |
| Bale, 1998(a)46UKPoor | NR | NR | NR  | NR | NR | NR | NR | NR |
| Banks, 1994(a)50UKPoor | 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: NRTreatment B: Authors report Two patients were withdrawn at their own request because discomfort they experienced with the dressing. | NR |
| Banks, 1994(b)48UK Fair | Treatment A:77% complete wound healingTreatment B:62.5% complete wound healing | Treatment A:No dataTreatment B:6.1% greatly improved | Treatment A:13.36 daysTreatment B:12.69 days | NR | NR | NR | NR |  |
| Belmin, 200249 France Fair | Treatment A:5.1% complete wound healingTreatment B:15.1% complete wound healing(p=0.162) | Wound surface area mean: Treatment A: 5.0cm2, 66% improvementTreatment B: 7.4cm2, 42% improvement(p<0.0001) | NR | NR | NR | NR | NR | NR |
| Bito, 201250JapanGood | Treatment A:52%Treatment B:46% | NR | Treatment A:60 daysTreatment B:58 days  | NR | NR | NR | NR | NR |
| Brod, 199051USPoor | Treatment A: 52%Treatment B:62% (p=0.54) | NR | Treatment A: 0.18cm2/weekMedian time to complete healing: 32 daysTreatment 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, 200852USFair | 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, 199853MalaysiaPoor | NR | Treatment A: mean reduction of 34% from baseline surface areaTreatment B:mean 9% increase to baseline surface areap=0.2318 | NR | Treatment A: NRTreatment B: One subject developed infection | NR | NR | Overall comfort Treatment A: 0% uncomfortableTreatment B:50% uncomfortable (p<0.01) | Exudate handling good/excellent:Treatment A: 69%Treatment B: 44%(p<0.019)  |
| Chuangsuwanich, 201154ThailandFair | NR | Treatment A: Mean surface area at 8th week 7.96 cm2Treatment 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, 199655MultinationalPoor | NR | Treatment A: – 35%Treatment B:7%(p=0.03) | NR | NR | NR | NR | NR | NR |
| Colwell, 199356USPoor | Treatment A: 22%Treatment B: 2% | Treatment A: 0.73 cm reductionTreatment B: 0.67 cm increase | NR | NR | NR | NR | NR | NR |
| Darkovich, 199057USPoor | Treatment A: 43%Treatment B: 24% | Treatment A: 68% (7.5cm2) wound area difference from baselineTreatment B: 40% (3.7cm2) difference from baseline | Treatment A: 8.1% wound area/dayTreatment B:3.1% wound area/day | NR | NR | NR | NR | NR |
| Day, 199558US, UK, CanadaFair  | 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 daysTreatment 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, 198759USPoor | Treatment A:87% healedTreatment B:69% healed | Treatment A:15.7% healingTreatment B; 19.2% healing | Treatment A:0.72cm2/dayMean healing days: 10Treatment B:0.55cm2/dayMean healing days: 8.7 | NR | NR | NR | NR | NR |
| Honde, 199460FranceFair | 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 daysTreatment 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, 200561TurkeyPoor | Treatment A:84% of wounds became epithelializedTreatment B:54.2% of wounds became epithelialized(p=0.04) | NR | Treatment A:0.12cm2/daysHealing time was 48 daysTreatment B:0.08cm2/days Healing time was 45.23 days(p=0.06) | NR | NR | NR | NR | NR |
| Kerihuel, 201062FranceGood | NR | Treatment A:26.9% wound reductionTreatment B:18.5% wound reduction | NR | NR | NR | NR | NR | NR |
| Kim, 199663KoreaPoor | Treatment A:80% complete wound healingTreatment B:77.8% complete wound healing | NR | Treatment A: 9.1mm2/dayTreatment B:7.9mm2/day | NR | NR | NR | NR | NR |
| Kloth, 200264US Fair | Treatment A: 48% wound closure Treatment B:36% wound closure | Treatment A:69% decrease in mean surface areaTreatment B:50% decrease in mean surface area | Treatment A:0.52cm2 per weekTreatment B:0.23cm2 per week (p=0.02) | NR | NR | NR | NR | NR |
| Kraft, 199365USPoor | Treatment A:42% healed Treatment B:21% healed | NR | NR | NR | NR | NR | NR | NR |
| Kurzuk-Howard, 198566USPoor | 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 infectionTreatment 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, 199967DenmarkPoor | Treatment A:29% complete wound healingTreatment B:0% complete wound healing | NR | NR | Treatment A: NRTreatment B: 40% developed necrotic tissue with infection | NR | NR | Treatment A: Median of 2 patients reported painTreatment B: Median of 2 patients reported pain | NR |
| Meaume, 200568FranceFair | NR | Treatment A:Absolute decrease: 7.2cm2wound reduction: 31.6%Treatment B:Absolute decrease: 0.8cm2wound reduction: 13.9% | Treatment A:0.26cm2/dayTreatment B:0.03cm2/day | NR | NR | NR | Treatment A: NRTreatment B: Pain during dressing and erythema, pain reported | NR |
| Meaume, 200369FinlandFair | Treatment A:44.4% healedTreatment B:50% healed | Treatment A:38.8% showed improvementTreatment B:NR | NR | NR | NR | Treatment A: 0% developed new ulcersTreatment B: 10% developed new ulcers | NR | NR  |
| Motta, 199970USPoor | Treatment A:40% healedTreatment B:40% healed | Treatment A:79.2% wound improvementTreatment B:88.6% wound improvement | Treatment A:0.15cm/dayTreatment B:0.35cm/day | NR | NR | NR | NR | NR |
| Mulder, 199371USPoor | NR | NR | Treatment A vs. Treatment B vs. Treatment C:Mean reduction/week8% vs. 3.3% vs. 5.1% (p=0.89) | Treatment A: 1 case of inflammationTreatment B:NR | NR | NR | NR  | NR |
| Neill, 198972USPoor | Treatment A:31% healedTreatment B:22% healed | 50% or more reduction in size: Treatment A:50%Treatment B: 46% | NR  | Treatment A: No infection occurredTreatment B: NR | NR | NR | NR | NR |
| Oleske, 198673USPoor | Treatment A:1 ulcer healedTreatment 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 infectionTreatment 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, 200974USPoor | Treatment A:55.5% healedTreatment B:37.5% healed | NR | NR | Treatment A: 5.56% showed signs of infectionTreatment B: No infections reported  | NR | NR | NR | NR |
| Price, 200075UKGood | Treatment A:12% complete wound healingTreatment B:8% complete wound healing | Reduction of initial wound area: Treatment A:75%Treatment B:40% | Treatment A:66.7cm2/weekTreatment B:63.3cm2/week | NR | NR | NR | Treatment A: No difference in pain scores from baseline to end of studyTreatment B: No difference in pain scores from baseline to end of study.  | NR |
| Sebern, 198676Sebern, 198977USPoor | Grade IITreatment A: 64%Treatment B: 0%(p<0.01) | Grade IIMedian improvement: Treatment A: 100%Treatment B: 52% (p<0.05) | NR | Treatment A: No sepsis reportedTreatment B: No sepsis reported | NR | NR | NR | NR |
| Seeley, 199978USFair | Treatment A:40% of all PU healedTreatment 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 0.15Treatment B: mean wound pain 0.47 | NR |
| Small, 200279South AfricaGood | Treatment A: 53.6%Treatment B:30% | NR | NR | Treatment A: 1 infectionTreatment B: 1 infection | NR | NR | NR | NR |
| Thomas, 199780UKPoor | Treatment A: 33%Treatment B: 20% | Treatment A: 47%Treatment B: 10% | NR | NR | NR | NR | NR | NR |
| Thomas, 199881USPoor | Treatment A: 63%Treatment B: 64% | NR | Treatment A: 5.3 weeksTreatment B:5.2 weeks (p=0.87) | NR | NR | NR | NR | NR |
| Thomas, 200582USGood | Treatment A: 57%Treatment B:44% (p=0.46) | NR | NR | NR | NR | NR | NR | NR |
| Whitney, 200183USFair | Treatment A: 53%Treatment B:43% | NR | Mean linear rate of healing:Treatment A: 0.012cm2 per dayTreatment B:0.004 cm2 per day(p=0.01) | NR | NR | NR | NR | NR |
| Winter, 199084UKPoor | Treatment A: 63% (n=12)Treatment B: 19% (n=3) | NR | NR | NR | NR | NR | NR | NR |
| Xakellis, 199285USFair  | 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, 200786Turkey Fair | Treatment A: 20%Treatment B:0% (p<0.05 ) | Decrease in ulcer size: (mean)Treatment A: 56% reductionTreatment 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, 200487USPoor | 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, yearCountryOverall 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, 198943SwedenFair | 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=1Wet saline gauze: N=0 |
| Bale, 199744UKFair | NR | Treatment A:Skin rash, N=1Treatment B:Skin rash, N=0 | NR | NR | NR | NR | NR | NR |
| Bale, 1998(b)45UK 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)46UKPoor | 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)50UKPoor | Treatment A: NRTreatment 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)48UK (Wales)Poor | NR | NR | NR | NR | Treatment A: Wound deterioration, n=1Wound/dressing-related problems n=1Treatment B:Wound deterioration, n=3Wound/dressing related problems, n=1 | NR | Treatment A:3Treatment B:4  | 20.6% |
| Belmin, 200249France 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=1Treatment B: N=0 | Treatment A: n=1Treatment 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, 201250JapanGood | NR | Treatment A: 6 cases of eczema, maceration, or rash with the covered skinTreatment B:Cases of eczema, maceration, and rash reported N not given  | NR | NR | NR | None related to treatment | NR | NR |
| Brod, 199051USPoor | NR | NR | NR | NR | NR | NR | Treatment A: NRTreatment B: n=1  | 2.3% |
| Brown-Etris, 200852USFair | NR | NR  | NR | NR | NR | NR | NR | NR |
| Chang, 199853MalaysiaPoor | 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 reportedTreatment B: 1 infection reported | Adherence to wound bed: Treatment A: 100%Treatment B: 44%(p<0.01) | NR | Treatment A: NRTreatment B: 1 subject in gauze group developed wound infection and withdrew | NR |
| Chuangsuwanich, 201154ThailandFair  | NR | NR | NR | NR | NR | NR | NR | NR |
| Colin, 199655MultinationalPoor | Treatment A: No pain reportedTreatment 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=1Treatment B: NR | NR | NR | NR |
| Colwell, 199356USPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Darkovich, 1990 57USPoor  | NR | NR | NR | NR | Wound deterioration: Treatment A: 1.5%Treatment B: 10% | NR | NR | NR |
| Day, 199558US, UK, CanadaFair  | 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 DeteriorationTreatment A: 4%Treatment B: 31% | Treatment A: NRTreatment B: Minor bleeding reported | NR | Erythema, severe pain, increase in necrotic tissue, wound size, and depth:Treatment A: 4%Treatment B: 31% | Treatment A: NRTreatment 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: NRTreatment B: n=7 patients | 10% |
| Gorse, 198759USPoor | NR | NR | NR | Treatment A: Rate of wound increase: 2.89cm2/dayTreatment B: Rate of wound increase: 0.75cm2/day | NR | NR | NR | NR |
| Honde, 199460FranceFair | 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, 200561TurkeyPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Kerihuel, 201062FranceGood  | 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, 199663KoreaPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Kloth, 200264USFair | NR | NR | NR | NR | NR | NR | NR | NR |
| Kraft, 199365USPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Kurzuk-Howard, 198566USPoor | NR | NR | NR | Treatment A: 1 patientTreatment B: NR | NR | NR | NR | NR |
| Matzen, 199967DenmarkPoor | NR | NR | NR | NR | NR  | NR | 9 | 28.1% |
| Meaume, 200568FranceFair | 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, 200369FinlandFair | 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, 199970USPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Mulder, 199371USPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Neill, 198972USPoor | NR | Treatment A: mild skin irritation, perilesional erythema, and eczema reportedTreatment B:NR | NR | NR | Treatment A: NRTreatment B: One sore enlarged by 216% | NR | Treatment A: 9 Treatment B: 1 | 18% vs. 2% |
| Oleske, 198673USPoor | 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 infectionTreatment 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, 200974USPoor | 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, 200075UKGood | Treatment A: No pain reported due to dressingTreatment B: No pain reported due to treatment | NR | NR | NR | Undermining, no difference reported in the occurrence of undermining | NR | NR | NR |
| Sebern, 198676Sebern, 198977USPoor | 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: 0Treatment B: 0 | 11 ulcers developed necrosis and eschar after being randomly assigned treatment | NR  | NR | NR |
| Seeley, 199978USFair | Treatment A: mean wound pain 0.15Treatment 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, 200279South AfricaGood | NR | NR | NR | NR | NR | NR | NR | NR |
| Thomas, 199780UKPoor | NR | NR | NR | NR | Minor trauma or erythema removal during dressing change, maceration, bleeding, and wound dehydrationTreatment A: n=7Treatment B: n=10Note: leg ulcer group and PU group data combined.  | Five patients died during the study for reasons unrelated to the treatments | NR |  NR |
| Thomas, 199881USPoor | NR | NR | NR | NR | Worsening of Ulcer: Treatment A: 6% (n=1)Treatment B: 7% (n=1) | NR | 2 | 7% (n=2) |
| Thomas, 200582USGood | NR | NR | NR | NR | NR | NR | NR | NR |
| Whitney, 200183USFair | NR | Treatment A: 1 patient had maceration of wound due to treatmentTreatment 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, 199084UKPoor | NR | Treatment A: Rash, inflammation, or allergic reaction to dressing 1Treatment B:Rash, inflammation, allergic reaction to dressing, 1 | NR | Treatment A: N=5 Treatment B: N=4  | Wound deterioration:Treatment A: N=3Treatment 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, 199285USFair  | NR | NR | NR | NR | NR | NR | NR | NR |
| Yapucu Gunes, 200786TurkeyFair | NR | NR | NR | NR | NR | NR | NR | NR |
| Yastrub, 200487USPoor | NR | NR | NR | NR | NR | NR | NR | NR |

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