Evidence Table H-5b. Dressings observational studies

| **Author, yearCountryOverall Quality Rating** | **Study Type** | **Confounders Assessed in Analysis** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **AgeSexRace** | **Ulcer Type/Severity at Baseline (Intervention Onset)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Meaume, 200788FranceFair | Observational | NR | Hospitalized in geriatric institutions; Acute or chronic wounds in the granulation phase; <100 cm2; and not presenting clinical infection | Any progressive neoplastic lesion;Known hypersensitivity to carboxymethylcellulose Receiving radiotherapy or chemotherapyTaking immunosuppressive drugs  | NR/NR/43/43PU N=7 | PU group onlyAge (Mean): 80 yearsFemale: 57.1% Race: NR | Location:Upper Limb: N=1Lower Limb: N=5Thorax: N=0Others: N=1 |
| Moody, 199189USPoor | Non comparative, single-treatment study | NR | Informed consent; Grade II or III PU or venous leg ulcer or other wound; male or female; 16 years or older | Lesion dry or crusted over; PU more than 1cm deep; insulin dependent diabetes; incontinent without a catheter; infection of lesion; fragile or excessively dry skin.  | NR/NR/10/7(Includes other types of wounds, PU N=9) | Age (Mean):78 yearsFemale: 10%Race: NR | Location:Sacrum: N=8Buttocks: N=1 |
| Parnell, 200590Country Not ReportedPoor | Observational | NR | At least one Stage II or Stage III; PU >1.0 cm2; Have used a low-air-loss support surface (Dyna Medics Corporation; Keller, Tex.) for at least the previous 14 days. PU with a treatment history that included enzymatic debridement had to be at least 7 days post-treatment. | Severe medical condition that could lead to death within the study period; current use of systemic steroids, chemotherapeutic agents, or other immunosuppressives; HIV-positive; hypersensitivity to fruit and vegetables or enzymes from fruits and vegetables; history of alcohol or drug abuse. Exclusion criteria for the study ulcer: Undermining or serious sinus tracts ≥1.0 cm; clinical or laboratory signs of infection; required topical medications; required debridement; ulcer present for more than 3 months before study enrollment. | NR/NR/10/10 | Age (Mean): NRFemale: NRRace: NR | Stage II: N=3, Stage III: N=7,  |
| Stoker, 199091UKPoor | Observational | NR | NR | NR | NR/NR/42/29(PU N=36) | Age (Mean): 70 yearsFemale: NRRace: NR | Stage I: N=1Stage II: N=16Stage III: N=15Stage IV: N=4Location: Left Heel: N= 3Right Heel: N=3 Left Buttock: N=6Right Buttock: N=5Buttock: N=6Sacrum: N=10Left Ankle: N=1Right Foot: N=1 |

|  |
| --- |
| **Evidence Table H-5b: Dressings** **Observational Studies, continued** |
| **Author, yearCountryOverall Quality Rating** | **Treatment A** | **Treatment B** | **Treatment C** | **Duration of Treatment/Followup** | **Study setting** | **Author, yearCountryOverall Quality Rating** | **Treatment A** |
| Viamontes, 200392USPoor | Observational | Patients in the database who had a PU, venous ulcer, diabetic ulcer, or traumatic wound that was treated with either the hydrocellular or soft-silicone dressing or both dressings on atleast one occasion | NR | NR/NR/1,891/1,891(PU N=4,200) | Local Wound Application: Dressing | Age (Mean):82 yearsFemale: NRRace: NR | Of 4,200 wounds included in the study 3,969 were PU (94%) |

| Evidence Table H-5b: Dressings Observational Studies, continued |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author, yearCountryOverall Quality Rating** | **Treatment A** | **Treatment B** | **Treatment C** | **Duration of Treatment/Followup** | **Study setting** |
| Meaume, 200788FranceFair | Dressing, Urgotul Duo a new dressing composed of an Urgotul interface (polyester textile support impregnated with hydrocolloid particles and Vaseline in contact with the wound bed) and a 100% viscose, gas permeable and neutral absorbent. | NA | NA | 4 weeks  | 11 Hospitals |
| Moody, 199189USPoor | Dressing, Kaltoclude- a pad of calcium sodium alginate fiber | NA | NA | 8-15 days | Hospital |
| Parnell, 200590Country Not ReportedPoor | Dressing: Hydrovase- a greaseless, glycerin hydrogel that contains a combination of endopeptidase enzymes and is designed to maintain a moist wound environment for a minimum of 24 hours.  | NA | NA | 12 weeks | Nursing homes |
| Stoker, 199091UKPoor | Dressing: Comfeel Pressure Relieving Dressing | NA | NA | Until wound healing was complete | Hospital |
|  |  |  |  |  |  |
| Viamontes, 200392USPoor | Hydrocellular dressing N (wounds)= 3,795 | Soft silicone dressingN (wounds)=352 | Both dressingsN (wounds)=53 | Data was gathered retroactively for a 5 year period | Nursing home |

| **Evidence Table H-5b: Dressings Observational Studies, 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** |
| Meaume, 200788FranceFair  | Treatment A: 14.2% healed | Treatment A: Mean PU surface area reduced by 74.8% | Treatment A: 1 PU healed after 21 days of treatment | NR | NR | NR | NR | Treatment A: In 100% of PU cases, perilesional skin was considered to be healthy" vs. 55% "healthy" at the start of the trial |
| Moody, 199189USPoor | N=4 PU healed | NR | NR | NR | NR | NR | All patients reported the dressing was comfortable | NR |
| Parnell, 200590Country Not ReportedPoor | Treatment a:50% (n=5) | Treatment A: NR, though authors report four Stage III ulcers "improved" | Treatment A: Average healing time:Stage II: 3.3 weeks (range 1-7 weeks)Stage III: 6.5 weeks  | NR | NR | NR | NR | NR |
| Stoker, 199091UKPoor | NR | Treatment A:Mean percent change per day in trial: Buttock: 3.1091 cm2 SD 9.5641Sacrum: -.0346 cm2 SD 2.0187Heel: -1.8405 cm2 SD 4.8918 | Treatment A: Mean % change (excluding two patients who healed within the first two weeks of the trial): 1.66% per day | NR | NR | NR | NR | NR |
| Viamontes, 200392USPoor | Treatment A: 1,996 of 3,792 (53%) wound closed completely. Treatment B:152 out of 351 (50%) wounds closed completely. Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers) | NR | Average treatment time (for all groups) 71.3 days (range 5-1386 days) | NR  | NR | NR | NR | NR |

| **Evidence Table H-5b: Dressings Observational Studies, continued** |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, yearCountryOverall Quality Rating** | **Harms: Pain**  | **Harms: Dermatologic Complications** | **Harms: Bleeding** | **Harms: Infection** | **Other Harms: Specify** | **Serve Adverse Events** | **Withdrawal due to Adverse Events** | **Overall Adverse Events Rate** | **Funding Source** |
| Meaume, 200788FranceFair | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Moody, 199189USPoor | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Parnell, 200590Country Not ReportedPoor | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Stoker, 199091UKPoor | Treatment A: Found the dressing uncomfortable n=1 | Treatment A: Rash related to dressing, n=1 | NR | NR | NR | NR | 2 patients (dressing uncomfortable and rash) | NR | Coloplast Ltd. |
| Viamontes, 200392USPoor | NR | Treatment A: 12 PU experienced skin strippingTreatment B:4 PU experienced skin stripping | NR | Treatment A:35 (n=76) Treatment B: 9% (n=23)23 out of 265 (9%) Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers) | Skin stripping: Treatment A: <1% (n=13)Treatment B: 2% (n=4) | NR | NA | 3% (n=116) | NR |

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