

# Dressings for venous leg ulcers: systematic review and meta-analysis

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## ABSTRACT

**Objective** To review the evidence of effectiveness of dressings applied to venous leg ulcers.

**Design** Systematic review and meta-analysis.

**Data sources** Hand searches of journals and searches of electronic databases, conference proceedings, and bibliographies up to April 2006; contacts with dressing manufacturers for unpublished studies.

**Studies reviewed** All randomised controlled trials that evaluated dressings applied to venous leg ulcers were eligible for inclusion. Data from eligible studies were extracted and summarised independently by two reviewers using a data extraction sheet. Methodological quality was assessed independently by two reviewers.

**Results** The search strategy identified 254 studies; 42 of these fulfilled the inclusion criteria. Hydrocolloids were no more effective than simple low adherent dressings used beneath compression (eight trials; relative risk for healing with hydrocolloid 1.02, 95% confidence interval 0.83 to 1.28). For other comparisons, insufficient evidence was available to allow firm conclusions to be drawn. None of the dressing comparisons showed evidence that a particular class of dressing healed more ulcers. Some differences existed between dressings in terms of subjective outcome measures and ulcer healing rates. The results were not affected by the size or quality of trials or the unit of randomisation. Insufficient data were available to allow conclusions to be drawn about the relative cost effectiveness of different dressings.

**Conclusions** The type of dressing applied beneath compression was not shown to affect ulcer healing. The results of the meta-analysis showed that applying hydrocolloid dressings beneath compression produced no benefit in terms of ulcer healing compared with applying simple low adherent dressings. No conclusive recommendations can be made as to which type of dressing is most cost effective. Decisions on which dressing to apply should be based on the local costs of dressings and the preferences of the practitioner or patient.

## INTRODUCTION

Multilayer compression bandaging has been identified as the gold standard in the treatment of venous leg ulcers.<sup>1-3</sup> Dressings are usually placed over the ulcer before compression bandages or hosiery are applied, with the intention of promoting healing and preventing the bandages

sticking to the wound. However, the evidence of any increased benefit provided by these dressings, which can contribute significantly to the cost of treating a venous leg ulcer, is less clear than for compression.

The range and type of dressings available have increased since the publication of a systematic review of dressings for venous ulcers by Bradley et al in 1999.<sup>4</sup> Large numbers of different wound dressings are available, with many ways of classifying them—for example, by physical composition or by describing them as passive, active, or reactive. However, the evidence for their use is equivocal. Whether any particular dressing or type of dressing affects the healing of ulcers needs to be established. In addition, many of these dressings are relatively expensive, with a difference of up to six times in unit cost between the more expensive and cheaper dressings.<sup>5</sup>

This study was based on a recently published Cochrane Collaboration review.<sup>6</sup> We aimed to assess the effectiveness of wound dressings used in the treatment of venous leg ulcers.

## METHODS

We sought to summarise all randomised controlled trials evaluating dressings in the treatment of venous leg ulcers. Two reviewers (SP and EAN) independently assessed trials for suitability; a third reviewer (JAM) arbitrated any disagreements. We excluded trials that included patients with wounds such as arterial and diabetic ulcers, unless the results for patients with venous ulcers were reported separately. We also excluded trials evaluating topical agents and skin grafting. To structure the many comparisons that can be made between dressings, and to avoid potential double counting of comparisons if we simply summarised the interventions by dressing types, we decided in advance to structure our comparisons as illustrated in box 1.

The primary outcome measure was time to complete ulcer healing or proportion of ulcers completely healed. We excluded composite outcome measures such as “number of ulcers healed or improved.”

We identified randomised controlled trials by searching Medline, Embase, and CINAHL, as well as the Cochrane Wounds Group specialised trials register up to April 2006. Box 2 shows details of all the databases searched and search terms used. We also sought grey literature by examining conference proceedings.

**Box 1 | Comparisons of dressing types****Hydrocolloids**

Versus foam  
 Versus alginate  
 Versus hydrogel  
 Versus paste  
 Versus simple/non-adherent dressings  
 Versus other dressings  
 Versus other hydrocolloids

**Foams**

Versus simple/non-adherent dressings  
 Versus silicone dressings  
 Versus other foams

**Alginate**

Versus simple non-adherent dressings  
 Versus foam  
 Versus other alginates

**Hydrogel**

Versus simple/non-adherent dressings  
 Versus other hydrogel dressings

We placed no restrictions in terms of language or year of publication. We also hand searched key journals, checked citations, and contacted experts in the field of wound care to enquire about ongoing and recently published trials.

Two reviewers acting independently decided on the inclusion or exclusion of trials. A third reviewer (JAM) adjudicated on any disagreements about inclusion or exclusion. We considered trials for inclusion if they were randomised controlled trials evaluating dressings in the treatment of venous leg ulcers. Trials had to report time to complete ulcer healing, proportion of ulcers completely healed, or reduction in area (healing rate). We excluded composite outcome measures that aggregated, for example, healing and improvement. We assessed the quality of the trials on the basis of factors that have been shown to minimise bias and confounding.<sup>7</sup> These were comparability of treatment groups at baseline; analysis of outcomes on an intention to treat basis, defined as all people who were allocated to a group being analysed in this intervention group regardless of the actual intervention used; completeness of follow-up; and the blinding and objectivity of outcome assessors.

We used Rev Man (4.1) to analyse data. All analysis was on an intention to treat basis, assuming withdrawals and losses to follow-up to be treatment failures. We estimated the relative risk of healing for each study; where similar interventions were compared in similar populations, we then considered using meta-analysis to estimate an aggregate relative risk. We assessed clinical heterogeneity by assessment of populations, concurrent treatment, trial setting, and outcome measures. Statistical heterogeneity was assessed by using the  $I^2$  test (we considered  $I^2$  values of 25% or less to indicate low heterogeneity and values of 75% or more to indicate high heterogeneity) and the  $\chi^2$  test (we

considered a significance level of  $P < 0.1$  to indicate heterogeneity<sup>8</sup>). In the absence of clinical and statistical heterogeneity, we used a fixed effect model. In the absence of clinical heterogeneity but the presence of statistical heterogeneity, we did a random effects meta-analysis. In the presence of clinical heterogeneity, we did a narrative review. A priori, we specified subgroup analyses to examine the robustness of the results on the basis of study size and the presence or absence of compression and allocation concealment.

**RESULTS**

We contacted 14 authors about methods, outcomes, and type of wounds, of whom three replied. Figure 1

**Box 2 | Details of search strategy****Search terms used in electronic searches**

(Venous Ulcer or Foot Ulcer or Skin Ulcer or Leg Ulcer or Varicose Ulcer) and (Dressing\* or Gauze\* or Hydrocolloid\* or Alginat\* or Hydrogel\* or Foam\* or Film) and (Search filter for RCTs)

**Conference proceedings examined**

- European Conference on Advances in Wound Management 1991-2003
- European Tissue Repair Society (ETRS) Conference 1993-2001
- American Symposia on Advanced Wound Care 1990-2001
- Symposium on Venous Leg Ulcers 1985
- British/Swedish Angiology Meeting 1991
- Wound Healing and Scarring 1996
- Meeting of the Venous Forum of the Royal Society of Medicine 1999
- 31st Annual Wound, Ostomy and Continence Nurses Conference 1999
- Wound Healing Society Educational Symposium 2000
- 7th Annual Conference of the Canadian Association of Wound Care 2001
- 4th Australian Wound Management Association Conference 2002
- Tissue Viability Society Conference 2003
- Ostomy Wound Management 2003
- Vascular Surgical Society of Great Britain and Ireland 2003
- RCN International Nursing Research Conference 2004
- 2nd World Union of Wound Healing Societies' Meeting 2004
- Wound Healing Society 16th Annual Meeting and Exhibition 2006

**Journals hand searched**

- *CARE—Science and Practice* 1979-90
- *Decubitus* 1987-93
- *Journal of the European Wound Management Association* 2001-April 2006
- *Journal of Tissue Viability* 1991-April 2006
- *Journal of Wound Care* 1991-April 2006
- *Phlebology* 1986-April 2006
- *Wound Repair and Regeneration* 1993-April 2006

\*Truncated

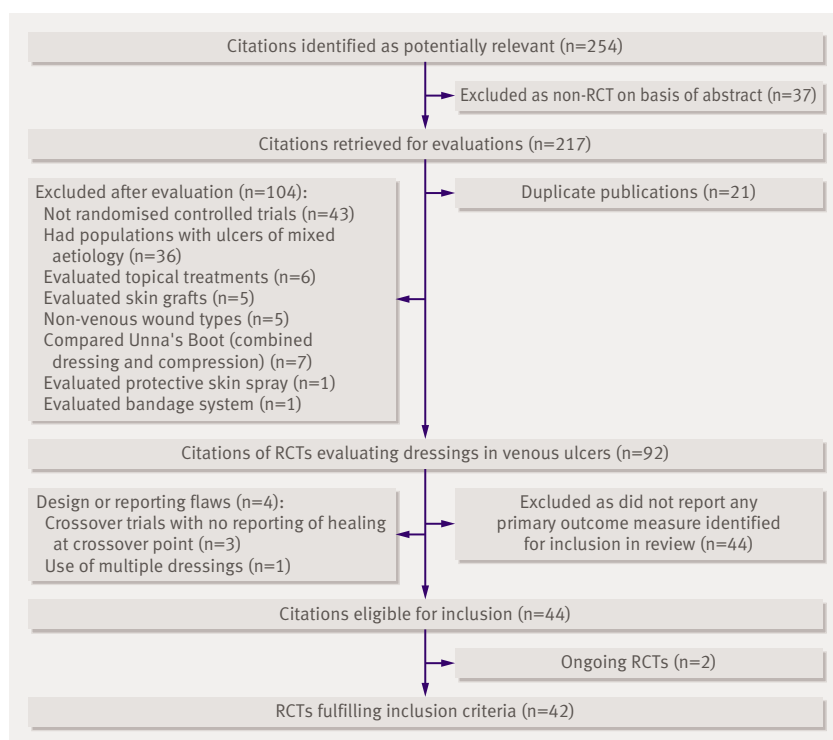


Fig 1 | Flow chart of identified trials. RCT=randomised controlled trial

shows the stages of the process of meta-analysis using the QUOROM statement.<sup>9</sup> Tables 1 to 3 show the characteristics of the included and excluded studies and the quality of the included studies.

Of 254 citations initially identified, 44 studies were eligible for inclusion. Two of these trials were ongoing (the VULCAN trial and the HALT trial).<sup>w1 w2</sup> We therefore included 42 trials (59 citations) involving 3001 participants. Some trials used the limb or ulcer as the unit of randomisation; 3037 ulcers or limbs were included in the trials. Most (31/42, 74%) of the trials had 100 or fewer participants, and 36% (15/42) had fewer than 50 participants.

Table 2 shows details of the methodological quality of the trials. Trials that we deemed to be of high quality gave clear inclusion/exclusion criteria, described the method of randomisation and blinding of treatment allocation, analysed on an intention to treat basis, had comparable treatment groups at the start of the trial, and used valid outcome measures.

No inclusion criteria were reported for 38% of studies. Only 11 (26%) trials stated the method of randomisation.<sup>w3-w13</sup> The others merely stated that treatment allocation was “randomised.” Most trials reported that the treatment groups were comparable at baseline. Most of the trials (31/42, 74%) reported the total number of ulcers healed during the trial. The remaining 26% (11/43) of trials used only the ulcer healing rate as an outcome measure. The duration of the trials ranged from four weeks to 48 weeks. The mean duration/follow-up was 14 weeks, and the median duration was eight weeks.

We used a random effects model to obtain aggregate outcomes for the relative risk of complete ulcer healing. This method allows for potential heterogeneity of the treatment effect between studies included in the meta-analysis. However, the conclusions from the analysis were the same with both fixed effects and random effects models, even allowing for the variations in precision between the two methods. The scope for subgroup analysis was limited owing to the small number of trials within each comparison. Table 4 shows the results of the meta-analysis.

### Hydrocolloid dressings

Twenty seven trials evaluated hydrocolloid dressings.

#### *Hydrocolloid versus low adherent dressings*

Nine trials (928 participants) compared hydrocolloid and low adherent dressings.<sup>w4 w7 w9 w10 w14-w18</sup> We excluded one trial from the meta-analysis, however, as it did not report the number of people whose ulcer had healed.<sup>w17</sup> The remaining eight trials included 792 people, and the pooled relative risk for healing with hydrocolloid was 1.02 (95% confidence interval 0.83 to 1.25) (fig 2).

We detected significant heterogeneity within this comparison ( $I^2=46.6\%$ ;  $\chi^2=13.11$ ,  $df=7$ ;  $P=0.07$ ). Retrospective exploration of the heterogeneity identified one trial that seemed to differ from the others.<sup>w7</sup> It included only small ulcers (wound area less than 5 cm<sup>2</sup>). Exclusion of this trial removed the statistical heterogeneity and did not affect the finding of no evidence of a difference in healing rate between hydrocolloids and simple low adherent dressings (relative risk=0.98, 0.85 to 1.12;  $I^2=0\%$ ).

#### *Hydrocolloid versus foam dressings*

Four trials (311 participants) reported the total number of ulcers healed at 12 weeks for hydrocolloid dressings compared with foam dressings.<sup>w5 w19-w21</sup> Meta-analysis showed a pooled relative risk for healing of 0.98 (0.79 to 1.22) (fig 3), indicating no evidence of a statistically significant difference in healing rates. We detected no heterogeneity within the comparison ( $I^2=0\%$ ;  $\chi^2=0.07$ ,  $df=3$ ,  $P=0.97$ ). One of the trials used the ulcer rather than the patient as the unit of randomisation for the intervention.<sup>w5</sup> Excluding this trial from the analysis did not affect the conclusions of the meta-analysis (relative risk=0.97, 0.74 to 1.28).

#### *Hydrocolloid versus alginate dressings*

Two trials (80 participants) compared hydrocolloid dressings with alginate dressings.<sup>w22 w23</sup> The pooled relative risk for ulcer healing for hydrocolloids compared with alginate dressings was 0.72 (0.48 to 1.69) at 6-13 weeks. We found high heterogeneity ( $I^2=52\%$ ;  $\chi^2=2.08$ ,  $df=1$ ;  $P=0.15$ ).

One trial reported cost data and concluded that the cost of materials for hydrocolloids was £67 cheaper than for alginates.<sup>w23</sup> However, no detail was given of how the costs were calculated, where the data included

Table 1 | Characteristics of included studies

Reference	Participants	Dressing	Outcomes reported
Andersen 2002 <sup>w3</sup>	Netherlands and Denmark; n=118, but 99 included in analysis; duration 8 weeks	I1: FD (n=58; 53 included in analysis); I2: FD (n=60; 46 included in analysis)	No healed—I1: 18/53 (34%; ITT 18/58, 31%); I2: 18/46 (39%; ITT 18/60, 30%). Mean time to healing—I1: 5.2 (SD 1.9) weeks; I2: 5.0 (SD 1.7) weeks
Arnold 1994 <sup>w15</sup>	UK and USA; n=70; No of ulcers=90; duration 10 weeks	I1: HC (n=35); I2: standard dressing (n=35)	No healed—I1: 11/35 (31%); I2: 14/35 (40%). Mean reduction in ulcer area—I1: 71% (SE 4.3); I2: 43% (SE 7.1)
Backhouse 1987 <sup>w16</sup>	UK; n=56; duration 12 weeks	I1: HC (n=28); I2: LA (n=28)	No healed—I1: 21/28 (75%); I2: 22/28 (78%)
Banerjee 1997 <sup>w31</sup>	UK; n=71; duration 17 weeks	I1: FD (n=36); I2: LA (n=35)	No healed—I1: 11/36 (30.5%); I2: 8/35 (23.0%)
Banks 1996 <sup>w20</sup>	UK; n=100; duration 13 weeks	I1: HC (n=50); I2: FD (n=50)	No healed—I1: 19/50 (38%); I2: 18/50 (36%)
Blair 1988 <sup>w4</sup>	UK; n=120 "consecutive ulcers," with 60 in each stage; duration 12 weeks	I1: HC; I2: Flamazine; control: LA	No healed—I1: HC 22/30 (73%), LA 23/30 (77%); I2: Flamazine 19/30 (63%), LA 24/30 (78%)
Bowszyc 1995 <sup>w5</sup>	Poland; n=80 (82 limbs); duration 12 weeks	I1: HC (n=40); I2: FD (n=40)	No healed—I1: 24/40 (60%); I2: 24/40 (60%)
Callam 1992 <sup>w32</sup>	UK; n=132 participants; duration 12 weeks	I1: FD (n=66); I2: LA (n=66)	No healed—I1: 31/66 (47%); I2: 23/66 (35%) (P=0.08)
Caprio 1994 <sup>w29</sup>	Italy; n=93 (98 ulcers); duration 8 weeks	I1: HC (n=49); I2: LCD (n=49)	No healed—I1: 25/49 (51%); I2: 20/49 (41%). Reduction in wound area (mm <sup>2</sup> /week)—I1: 152.7; I2: 103.66. Total mean cost (lira) dressing materials per patient (£=2400 lira)—I1: 102 607 (£42.75); I2: 142 527 (£59.37)
Charles 2002 <sup>w19</sup>	UK; n=91; duration 12 weeks	I1: FD (n=31); I2: HC (n=31); I3: HC (n=29)	No healed—I1: 18/31 (58%); I2: 17/31 (55%); I3: 17/29 (57%)
Eriksson 1984 <sup>w38</sup>	Sweden; n=53; part 2 excluded 9; duration 10 weeks	Part 1—I1: 0.9% normal saline; I2: HG; no detail of numbers provided for groups. Part 2—I1: porcine skin (n=11); I2: aluminium foil dressing (n=20); I3: zinc oxide and Tensoplast bandage (n=13)	Part 1—ulcer healing rate, states "no significant difference" between groups. Part 2—mean reduction in wound area, I1: 70%; I2: 10%; I3: 80%
Franks 2003 <sup>w35</sup>	UK; n=156; duration 24 weeks	I1: SD (n=75); I2: FD (n=81)	No healed—I1: 50/75 (66.7%); I2: 50/81 (61.7%)
Freak 1992 <sup>w17</sup>	UK; n=75; duration 6 weeks	I1: HC (n=25); I2: HC (n=25); I3: LA (n=25)	Reduction in mean ulcer area (cm <sup>2</sup> )—I1: 2.98 (SE 0.44); I2: 2.09 (SE 0.51); I3: 4.31 (SE 0.64); P<0.05. Median time to complete healing (life table)—I1: 6.85 weeks; I2: 4.25 weeks; I3: 6.17 weeks
Greguric 1994 <sup>w30</sup>	Croatia; n=110; duration "10 dressing changes"	I1: standard dressing (n=55); I2: HC (n=55)	No healed—I1: 0; I2: 3. Mean reduction in ulcer area (mm <sup>2</sup> /day)—I1: 21; I2: 32
Groenwald 1984 <sup>w6</sup>	South Africa; n=72; duration 8 weeks	I1: conventional treatment (n=36); I2: HC (n=36)	Reduction in ulcer size—I1: 22.62%; I2: 67.64%; P<0.001
Grotewohl 1994 <sup>w27</sup>	Germany; n=84, but only 63 participants reported; duration 28 days	I1: HG (n=39); I2: HC (n=24)	Reduction in ulcer area—I1: 44.6%; I2: 33.3%. Mean reduction in ulcer surface area—I1: 4.5 cm <sup>2</sup> ; I2: 2.1 cm <sup>2</sup>
Hansson 1998 <sup>w18</sup>	Sweden/Denmark/Netherlands/UK; n=153; duration 12 weeks	I1: HG (n=56); I2: HC (n=48); I3: LA (n=49)	No healed—I1: 8/56 (14%); I2: 5/48 (10%); I3: 7/49 (14%)
Hornemann 1987 <sup>w37</sup>	Germany; n=148; duration 4 weeks	I1: HG (n=73); I2: HG (n=75)	Median wound reduction—I1: 50%; I2: 20%
Limova 1996 <sup>w24</sup>	USA; n=31; duration 8 weeks	I1: HC (n=17); I2: HC (n=14)	No healed—I1: 10/17 (60%); I2: 2/14 (14%)
Limova 2003 <sup>w40</sup>	USA; n=20, but only 19 included in analysis; duration 6 weeks	I1: AD (n=10); I2: AD (n=9)	No healed—I1: 0/10 (0%); I2: 2/9 (22%)
Lindholm 1994 <sup>w28</sup>	Sweden; n=28; duration 6 weeks	I1: GD (n=14); I2: HC (n=14)	Reduction in wound area—I1: 19%; I2: 51%
Meredith 1988 <sup>w7</sup>	UK; n=50, but one excluded from analysis; duration 6 weeks	I1: HC (n=25); I2: LA (n=24)	No healed—I1: 19/25 (76%); I2: 6/24 (25%). Total area healed (cm <sup>2</sup> )—I1: 21.1; I2: 7.7. Cost of dressing—I1: £436.86; I2: £855.87
Moffatt 1992 <sup>w39</sup>	UK; n=60; duration 12 weeks	I1: AD (n=30); I2: LA (n=30)	No healed—I1: 26/30 (87%); I2: 24/30 (80%)
Moffatt 1992 <sup>w9</sup>	UK; n=60; duration 12 weeks	I1: HC (n=30); I2: LA (n=30)	No healed—I1: 13/30 (43%); I2: 7/30 (23%)
Mulder 1995 <sup>w34</sup>	UK; n=40 (39 reported); duration 16 weeks	I1: FD (n=19); I2: AD (n=20)	No healed—I1: 10/19 (53%); I2: 6/20 (30%)
Mulligan 1986 <sup>w8</sup>	UK; n=101 (97 reported); duration 6 weeks	I1: knitted fabric charcoal dressing (n=65); I2: conventional treatment decided by physician (n=35)	Mean ulcer reduction—I1: 28.7%; I2: 11.7%. Mean ulcer healing rate/week—I1: 1.2 cm; I2: 0.2 cm
Nelson 1995 <sup>w10</sup>	UK; n=200; duration 24 weeks	I1: LA (n=98); I2: HC (n=102)	No healed—I1: 44/98 (45%); I2: 49/102 (48%)
Ormiston 1985 <sup>w11</sup>	UK; n=61; duration 12 weeks	I1: HG and Melolin dressing (n=30; ITT=31); I2: standard treatment (gentian violet, Polyfax salmyxin, and bacitracin ointment plus gauze pad) (n=30)	No healed—I1: 12/31 (39%); I2: 7/30 (23%). Healing rate per week (cm <sup>2</sup> )—I1: 0.89 (SE 0.1); I2: 0.46 (SE 0.1); P=0.0001
Pessenhoffer 1992 <sup>w12</sup>	Austria; n=48; duration 40 weeks	I1: FD (n=25); I2: LA (n=23)	Relative change in ulcer size—I1: decrease 65.6% (SD 47.0); I2: increase 78.3% (SD 215.8)
Scurr 1994 <sup>w22</sup>	UK; n=40; duration 6 weeks	I1: AD (n=20); I2: HC (n=20)	No healed—I1: 6/20 (30%); I2: 2/20 (10%) Mean reduction in area—I1: 90.7% (SD 14.5); I2: 80.2% (SD 22.4)
Skog 1983 <sup>w42</sup>	Sweden and Norway; n=95 (74 reported); duration 6 weeks	I1: HG (n=38); I2: standard treatment (n=36)	Mean reduction in ulcer area—I1: decrease of 34%; I2: increase of 5%
Smith 1994 <sup>w23</sup>	UK; n=40; duration 6 weeks	I1: HC (n=22); I2: AD (n=18)	No healed—I1: 4/22 (18%); I2: 2/18 (11%). Change in ulcer area—I1: 57.1%; I2: 34.9%. Cost of treatment—I1: £431.73; I2: £364.08

Smith 1992 <sup>w14</sup>	UK; n=200; duration 16 weeks	I1: HC (n=99); I2: LA (n=101)	No healed—I1, small HC: 38/64 (56%); I2, small LA: 43/62 (69%); I1, large HC: 12/35 (34%); I2, large LA: 4/39 (10%). Cost of treatment—I1, small: £48.96; I2, small: £39.95; I1, large: £526.63; I2, large: £183.75
Stacey 1997 <sup>w41</sup>	Australia; n=113, with 133 limbs; duration 36 weeks	I1: zinc oxide ointment impregnated woven cotton bandage (Viscopaste bandage); I2: zinc oxide ointment impregnated knitted stockinet (Acoband); I3: AD (Kaltostat)	No healed—I1: Viscopaste 34/43 (86%); I2: Acoband 26/44 (66%); I3: Kaltostat 26/46 (57%)
Taddeucci 2004 <sup>w43</sup>	Italy; n=17, with 24 ulcers; duration 8 weeks	I1: hyaluronan derivative fleece dressing (n=12 ulcers); I2: LA (n=12 ulcers)	No healed—I1: 2/12 (16%); I2: 1/12 (8%). Reduction in ulcer area (cm <sup>2</sup> )—I1: 8.1 (n=12); I2: 0.4 (P<0.002)
Tarvainen 1988 <sup>w13</sup>	Finland; n=27; duration 8 weeks	I1: HG (n=14); I2: HG (n=13)	No healed—I1: 7/14 (50%); I2: 5/13 (39%)
Veraart 1994 <sup>w25</sup>	Netherlands; n=38; duration 8 weeks	I1: HC (Comfeel extra-absorbing dressing) (n=19); I2: HC (Granuflex/Duoderm CGF) (n=19)	No healed—I1: 12/19 (63%); I2: 10/19 (53%)
Vin 2002 <sup>w36</sup>	France; n=73; duration 12 weeks	I1: HG (n=37); I2: LA (n=36)	No healed—I1: 18/37 (49%); I2: 12/36 (33%). Mean reduction in wound area—I1: 54.4% (SE 10); I2: 36.5% (SE 11.4). Median reduction in wound area—I1: 82.4%; I2: 44.6%
Vincent <sup>w26</sup>	UK; n=29; duration 6 weeks	I1: HC (n=16); I2: HC (n=13)	Reduction in wound area—I1: 45%; I2: 57%
Weiss 1996 <sup>w33</sup>	USA; n=18; duration 16 weeks	I1: FD (n=10); I2: FD (n=8)	No healed—I1: 8/10 (80%); I2: 4/8 (50%). Mean time to healing—I1: 5.6 weeks; I2: 6.5 weeks
Wunderlich 1991 <sup>w44</sup>	Germany; n=40, of which 38 produced "evaluable" data; duration 6 weeks	I1: 5 days' cleaning with enzymatic debrider and then application of polyamide active charcoal dressing with 0.15% silver; I2: 5 days' cleaning using mechanical and enzymatic debridement and then dressing according to stage of healing. Granulation=paraffin oil or PVI (polyvinyl iodine) cream; epithelialisation=Fettgaze or oil in water emulsion	No healed—I1: 6/19 (31.6%, ITT=30%); I2: 2/20 (10.5%, ITT=10%). Reduction in wound area—I1: 60%; I2: 75%
Zuccarelli 1992 <sup>w21</sup>	France; n=40, but only 38 analysed; duration 12 weeks	I1: FD (n=19); I2: HC (n=19)	No healed—I1: 9/19 (47%); I2: 9/19 (47%)

AD=alginate dressing; FD=foam dressing; HC=hydrocolloid; HG=hydrogel; GD=gauze dressing; I1=intervention 1; I2=intervention 2; I3=intervention 3; ITT=intention to treat; LA=low adherent; LCD=lyophilised collagen dressing; SD=silicone dressing.

in the costs came from (from patients or from drug tariff data), or the type and extent of discounting used.

#### *Hydrocolloid versus hydrocolloid*

Three trials (98 participants) compared various hydrocolloid dressings.<sup>w24-w26</sup> We could include only two in the meta-analysis, as one did not report the total number of ulcers healed.<sup>w26</sup> The meta-analysis showed high heterogeneity ( $I^2=69.7\%$ ;  $\chi^2=3.3$ ,  $df=1$ ;  $P=0.07$ ) and no statistical difference between the dressings (relative risk=1.56, 0.67 to 3.63).

#### *Hydrocolloid versus other dressings*

Two trials (237 participants) compared hydrocolloid and hydrogel dressings.<sup>w18 w27</sup> One trial allocated treatment "according to the principle of random selection."<sup>w27</sup> The analysis was not intention to treat. The outcomes reported were percentage reduction in ulcer area at 28 days (44.6% hydrogel *v* 33.3% hydrocolloid) and the reduction of the ulcer surface area at 28 days (4.5 cm<sup>2</sup> hydrogel *v* 2.1 cm<sup>2</sup> hydrocolloid). The total number of ulcers healed in each group was not reported. The other trial had three arms and was also included in the hydrocolloid versus low adherent dressings comparison.<sup>w18</sup>

One trial (28 participants) compared hydrocolloid and gauze.<sup>w28</sup> It reported a relative reduction in ulcer area of 19% for the gauze group and 51% for the hydrocolloid group. No statistical analysis of the results was reported.

One trial (93 participants with 98 ulcers) compared hydrocolloid dressing (Duoderm E) and a lyophilised

collagen dressing.<sup>w29</sup> The unit of randomisation was the ulcer and not the patient. No statistical differences between the dressings were reported.

One trial (110 participants) compared hydrocolloid dressing (Varihesive E) and magnesium sulphate paste beneath a gauze dressing.<sup>w30</sup> The duration of the trial was for 10 dressing changes, but no details were given on trial length. The trial reported three ulcers healed in the hydrocolloid group and no ulcers healed in the other group.

#### Foam dressings

##### *Foam versus low adherent dressings*

Three trials (253 participants) compared foam dressings with low adherent dressings.<sup>w12 w31 w32</sup> One trial did not report the total number of ulcers healed and so could not be included in the meta-analysis.<sup>w12</sup> For the other two studies, the pooled relative risk was 1.35 (0.93 to 1.94), with no statistical heterogeneity ( $I^2=0\%$ ;  $\chi^2=0.0$ ,  $df=1$ ;  $P=0.99$ ).

##### *Foam versus foam dressings*

Two trials (136 participants) compared various foam dressings.<sup>w3 w33</sup> The aggregate relative risk of healing for the two studies was 1.2 (0.77 to 1.87), with no statistical heterogeneity ( $I^2=0\%$ ,  $\chi^2=0.88$ ,  $df=1$ ;  $P=0.35$ ).

##### *Foam versus alginate dressings*

One trial (40 participants) compared foam dressings with alginate dressings.<sup>w34</sup> No statistically significant difference was found between the dressings. The reported hazard ratio for healing was 1.75 (0.79 to 3.88).

Table 2 | Methodological quality of included studies

Study	Baseline comparability	Inclusion and exclusion criteria	Method of randomisation	Allocation concealment	Sample size calculation	ITT	Blinding of outcome
Andersen 2002 <sup>w3</sup>	Yes	Yes	Yes	Adequate	No	No	Unclear
Arnold 1994 <sup>w15</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Backhouse 1987 <sup>w16</sup>	Yes	No	No	Unclear	No	Yes	Unclear
Banerjee 1997 <sup>w31</sup>	No	Yes	No	Unclear	No	Yes	Unclear
Banks 1996 <sup>w20</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Blair 1988 <sup>w4</sup>	Yes	Yes	Yes	Adequate	No	Yes	Unclear
Bowszyc 1995 <sup>w5</sup>	Yes	Yes	Yes	Unclear	No	No	Unclear
Callam 1992 <sup>w32</sup>	Yes	Yes	No	Adequate	No	Yes	Yes
Caprio 1994 <sup>w29</sup>	No	Yes	No	Unclear	No	Yes	Unclear
Charles 2002 <sup>w19</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Eriksson 1984 <sup>w38</sup>	Yes	No	No	Unclear	No	No	Unclear
Franks 2003 <sup>w35</sup>	No	Yes	No	Unclear	No	Yes	Unclear
Freak 1992 <sup>w17</sup>	Yes	No	No	Unclear	No	Yes	Unclear
Greguric 1994 <sup>w30</sup>	Yes	No	No	Unclear	No	Yes	Unclear
Groenwald 1984 <sup>w6</sup>	No	No	Yes	Unclear	No	Yes	Unclear
Grotewohl 1994 <sup>w27</sup>	No	No	No	Unclear	No	No	Unclear
Hansson 1998 <sup>w18</sup>	No	Yes	No	Unclear	No	Yes	Unclear
Hornemann 1987 <sup>w37</sup>	No	No	No	Unclear	No	Yes	Unclear
Limova 1996 <sup>w24</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Limova 2003 <sup>w40</sup>	No	No	No	Unclear	No	No	Unclear
Lindholm 1994 <sup>w28</sup>	No	Yes	No	Unclear	No	Yes	Unclear
Meredith 1988 <sup>w7</sup>	Yes	Yes	Yes	Unclear	No	No	Unclear
Moffatt 1992 <sup>w39</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Moffatt 1992 <sup>w9</sup>	Yes	Yes	Yes	Unclear	Yes	Yes	Unclear
Mulder 1995 <sup>w34</sup>	No	No	No	Unclear	No	No	Unclear
Mulligan 1986 <sup>w8</sup>	Yes	Yes	Yes	Unclear	No	No	Unclear
Nelson 1995 <sup>w10</sup>	Yes	Yes	Yes	Adequate	Yes	Yes	Unclear
Ormiston 1985 <sup>w11</sup>	Yes	No	Yes	Adequate	No	No	Unclear
Pessenhoffer 1992 <sup>w12</sup>	No	No	Yes	Unclear	No	Yes	Unclear
Scurr 1994 <sup>w22</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Skog 1983 <sup>w42</sup>	Yes	No	No	Unclear	No	No	Unclear
Smith 1994 <sup>w23</sup>	Yes	No	No	Unclear	No	Yes	Unclear
Smith 1992 <sup>w14</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Stacey 1997 <sup>w41</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Taddeucci 2004 <sup>w43</sup>	No	No	No	Unclear	No	Yes	Unclear
Tarvainen 1988 <sup>w13</sup>	Yes	Yes	Yes	Adequate	No	Yes	Unclear
Veraart 1994 <sup>w25</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Vin 2002 <sup>w36</sup>	Yes	Yes	No	Unclear	No	Yes	Unclear
Vincent <sup>w26</sup>	Yes	No	No	Unclear	No	Yes	Unclear
Weiss 1996 <sup>w33</sup>	No	No	No	Unclear	No	Yes	Unclear
Wunderlich 1991 <sup>w44</sup>	Yes	Yes	No	Unclear	No	No	Unclear
Zuccarelli 1992 <sup>w21</sup>	Yes	Yes	No	Unclear	No	No	Unclear

ITT=intention to treat.

*Foam versus silicone dressings*

One trial (156 participants) compared foam dressings against silicone dressings.<sup>w35</sup> No statistically significant difference was found between the dressings. The reported hazard ratio for healing was 1.17 (0.79 to 1.72).

*Hydrogel dressings**Hydrogel versus low adherent dressings*

Two trials (151 participants) compared hydrogel dressings with low adherent dressings.<sup>w11 w36</sup> The aggregate

relative risk for healing with hydrogel compared with low adherent dressings was 1.53 (0.96 to 2.42;  $I^2=0\%$ ,  $\chi^2=0.07$ ,  $df=1$ ;  $P=0.79$ ).

*Hydrogel versus hydrogel*

Two trials (175 participants) compared different hydrogels.<sup>w13 w37</sup> However, we were unable to do a meta-analysis as only one trial reported the total number of ulcers healed, and this found no statistically significant difference between the two groups.<sup>w13</sup>

**Table 3 | Reasons for exclusion of studies**

Study	Reason for exclusion
Agren 1990 <sup>w45</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Alcaraz 2003 <sup>w46</sup>	Non-randomised study
Alicandro 2003 <sup>w47</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Armstrong 1995 <sup>w48</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Armstrong 1997 <sup>w49</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Bale 1994 <sup>w50</sup>	Includes arterial ulcers, with no separate reporting by ulcer type
Bale 1998 <sup>w51</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Ballard 2002 <sup>w52</sup>	Non-randomised study
Banks 1995 <sup>w53</sup>	No reporting of ulcer healing
Banks 1997 <sup>w54</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Barnett 1988 <sup>w55</sup>	Review paper
Bartoletti 1997 <sup>w56</sup>	No reporting of ulcer healing
Berry 1993 <sup>w57</sup>	Evaluation of dressings for pilonidal sinus
Bianchi 2001 <sup>w58</sup>	Review article and case study
Bonnetblanc 2004 <sup>w59</sup>	Evaluation of protective spray not dressing
Brandrup 1990 <sup>w60</sup>	Includes arterial ulcers with no separate reporting by ulcer type
Brown-Etris 2004 <sup>w61</sup>	No reporting of ulcer healing
Bull 1995 <sup>w62</sup>	No reporting of ulcer healing
Burgess 1993 <sup>w63</sup>	No reporting of ulcer healing
Burgos 1989 <sup>w64</sup>	Evaluation of topical growth factors applied via dressings
Capillas 2000 <sup>w65</sup>	Reports cost to heal 1 cm <sup>2</sup> ulcer; authors unable to provide more data
Casoni 2002 <sup>w66</sup>	Evaluation of compression
Chaloner 1992 <sup>w67</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Chaloner 1996 <sup>w68</sup>	Did not report healing outcomes
Charles 2004 <sup>w69</sup>	Non-randomised study
Cherry 1996 <sup>w70</sup>	Study examining topical application
Cherry 2001 <sup>w71</sup>	Evaluation of topical application
Colletta 2003 <sup>w72</sup>	Non-randomised study
Collier 1992 <sup>w73</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Cordts 1992 <sup>w74</sup>	Evaluates compression
Creese 1986 <sup>w75</sup>	Non-randomised study
Daniels 2002 <sup>w76</sup>	Non-randomised study
Davis 1992 <sup>w77</sup>	Evaluates compression
Diem 1987 <sup>w78</sup>	Non-randomised study
Dmochowska 1999 <sup>w79</sup>	No reporting of total number of ulcers healed or ulcer healing rates
Egan 1983 <sup>w80</sup>	Intervention is preparation for skin grafting; does not report healing
Eriksson 1986 <sup>w81</sup>	Evaluates double layer bandage system
Falanga 1998 <sup>w82</sup>	Evaluates skin graft
Farina 1997 <sup>w83</sup>	Does not report ulcer healing
Fivenson 2003 <sup>w84</sup>	Non-randomised study
Floden 1978 <sup>w85</sup>	Does not report ulcer healing
Frank 1979 <sup>w86</sup>	Does not report ulcer healing
Franken 1999 <sup>w87</sup>	Description of trial methods; no results
Franks 1993 <sup>w88</sup>	Letter; does not report outcome data
Friedman 1984 <sup>w89</sup>	Non-randomised study
Gamborg-Nielson 1989 <sup>w90</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Gibson 1985 <sup>w91</sup>	Arterial ulcers only
Goldman 2003 <sup>w92</sup>	Non-randomised study
Halbert 1992 <sup>w93</sup>	Non-randomised study
Handfield-Jones 1988 <sup>w94</sup>	Crossover study with no report of ulcer healing at crossover point
Harcup 1986 <sup>w95</sup>	No breakdown of numbers randomised to each group
Hart 1998 <sup>w96</sup>	No breakdown of numbers allocated to groups; no reply to query
Hermans 2000 <sup>w97</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Hoffman 2000 <sup>w98</sup>	Non-randomised study
Holloway 1989 <sup>w99</sup>	No data on ulcer healing
Hutchinson 1992 <sup>w100</sup>	Outcome measure "healed or improved;" no reply from author

Jasiel 1996 <sup>w101</sup>	Study examining absorbency of two dressings
Johnson 1992 <sup>w102</sup>	Study of dressings for pressure sores
Jones 2003 <sup>w103</sup>	No report of healing rates or total number of ulcers healed
Kalis 1993 <sup>w104</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Kammerlander 2000 <sup>w105</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Karlsmark 2003 <sup>w106</sup>	Non-randomised study
Kero 1987 <sup>w107</sup>	Non-randomised study
Kerstein 2000 <sup>w108</sup>	Non-randomised study
Kikta 1988 <sup>w109</sup>	Evaluation of compression
Koksal 2003 <sup>w110</sup>	Evaluation of compression
Kucharzewski 2003 <sup>w111</sup>	Evaluation of topical treatments
Lansdown 2003 <sup>w112</sup>	Non-randomised study
Larsen 1995 <sup>w113</sup>	No reporting of ulcer healing
Larsen 1997 <sup>w114</sup>	No reporting of ulcer healing
Larsen 2001 <sup>w115</sup>	No reporting of ulcer healing
Laudanska 1988 <sup>w116</sup>	Study endpoint combined complete healing and "very superficial"
Leaper 1991 <sup>w117</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Lindholm 1993 <sup>w118</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Lindholm 1995 <sup>w119</sup>	No reporting of ulcer healing
Ljunberg 1998 <sup>w120</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Llewellyn 1995 <sup>w121</sup>	Non-randomised study
Loiterman 1991 <sup>w122</sup>	Non-randomised study
Margolis 1993 <sup>w123</sup>	Non-randomised study
Mayrovitz 1992 <sup>w124</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
McMullen 1991 <sup>w125</sup>	Non-randomised study
Meaume 2002 <sup>w126</sup>	Non-randomised study
Meaume 2004 <sup>w127</sup>	No reporting of ulcer healing
Mekkes 1992 <sup>w128</sup>	No reporting of ulcer healing
Mian 1992 <sup>w129</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Milward 1991 <sup>w130</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Moody 2003 <sup>w131</sup>	No reporting of ulcer healing
Mulder 1993 <sup>w132</sup>	No reporting of ulcer healing
Mulder 1994 <sup>w133</sup>	States "statistically significant" differences but no results reported
Nowak 1995 <sup>w134</sup>	No reporting of ulcer healing
Nyfors 1982 <sup>w135</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Ohlsson 1994 <sup>w136</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Palmeri 1992 <sup>w137</sup>	Comparing topical agents
Perez 2000 <sup>w138</sup>	No reporting of ulcer healing
Petres 1993 <sup>w139</sup>	No reporting of ulcer healing
Polignano 2002 <sup>w140</sup>	No reporting of ulcer healing
Poole 1994 <sup>w141</sup>	No reporting of ulcer healing
Poskitt 1987 <sup>w142</sup>	Study of skin grafts.
Price 2003 <sup>w143</sup>	Non-randomised study
Price 2004 <sup>w144</sup>	No reporting of ulcer healing
Rainey 1993 <sup>w145</sup>	No reporting of ulcer healing
Reynolds 2004 <sup>w146</sup>	Reports "ulcer improved or healed"
Robinson 1993 <sup>w147</sup>	No reporting of ulcer healing
Robinson 1995 <sup>w148</sup>	Non-randomised study
Robinson 1996 <sup>w149</sup>	Report of trial design
Robinson 1997 <sup>w150</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Robledillo 2002 <sup>w151</sup>	Non-randomised study
Rubin 1990 <sup>w152</sup>	Evaluation of compression
Rundle 1981 <sup>w153</sup>	No reporting of ulcer healing
Russell 2004 <sup>w154</sup>	Reports only composite outcome of "ulcer healed or improved"
Samson 1992 <sup>w155</sup>	No reporting of ulcer healing; no reply to query
Samson 1993 <sup>w156</sup>	Non-randomised study
Sayag 1996 <sup>w157</sup>	Trial of treatments for pressure ulcers
Scalise 2003 <sup>w158</sup>	Report of trial design

Schmutz 1996 <sup>w159</sup>	Report of trial design
Schulze 2001 <sup>w160</sup>	No reporting of ulcer healing
Scurr 1993 <sup>w161</sup>	Non-randomised study
Serafica 2003 <sup>w162</sup>	Non-randomised study
Sibbald 2004 <sup>w163</sup>	No reporting of ulcer healing
Sikes 1985 <sup>w164</sup>	Evaluation of compression
Sironi 1993 <sup>w165</sup>	No reporting of ulcer healing
Sironi 2003 <sup>w166</sup>	No reporting of ulcer healing
Skene 1992 <sup>w167</sup>	Reports development of prognostic index to predict time to healing
Slezak 2004 <sup>w168</sup>	Non-randomised study
Smith 1993 <sup>w169</sup>	Duplicate publication of Smith 1994 <sup>w23</sup>
Smith 2003 <sup>w170</sup>	Non-randomised study
Stewart 1987 <sup>w171</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Strömberg 1984 <sup>w172</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Teepe 1993 <sup>w173</sup>	Study examining skin grafts
Thomas 1988 <sup>w174</sup>	Review article
Thomas 1989 <sup>w175</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Thomas 1997 <sup>w176</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Torres 2003 <sup>w177</sup>	Non-randomised study
Tosti 1983 <sup>w178</sup>	Unclear if a randomised controlled trial; no reply to query
Varghese 1986 <sup>w179</sup>	Non-randomised study
Viamontes 2003 <sup>w180</sup>	Non-randomised study
Vin 1997 <sup>w181</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Warburg 1994 <sup>w182</sup>	Study of skin grafting
Watts 1988 <sup>w183</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Watts 1993 <sup>w184</sup>	Study of pressure ulcers and cavity wounds
Wayman 2000 <sup>w185</sup>	No reporting of ulcer healing
Westerhof 1990 <sup>w186</sup>	No reporting of ulcer healing
Westerhoff 1993 <sup>w187</sup>	No reporting of ulcer healing
Westerhoff 1995 <sup>w188</sup>	Report of imaging technique
Westh 1998 <sup>w189</sup>	No reporting of ulcer healing
Williams 1981 <sup>w190</sup>	Study of pilonidal sinus
Winter 1990a <sup>w191</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Winter 1990b <sup>w192</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Wollina 1997 <sup>w193</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Worsley 1991 <sup>w194</sup>	Includes ulcers of mixed aetiology; no reporting by ulcer type
Zeegelaar 1994 <sup>w195</sup>	No reporting of ulcer healing
Zeegelaar 2001 <sup>w196</sup>	Non-randomised study

### *Hydrogel versus miscellaneous dressings*

One trial (53 participants) consisted of two parts.<sup>w38</sup> Part 1 compared 0.9% normal saline with Debrisan paste. This phase lasted two weeks, and the authors reported relative change in wound area. Part 2 of the study compared porcine skin (Skin-tec, Astra-Syntex, Sweden), aluminium foil dressing (Metallina, Lohmann GmbH, Germany), and a non-compressive double layer paste bandage. The authors gave no data on the total number of ulcers healed; they reported mean relative reduction in wound area.

### **Alginate dressings**

#### *Alginate versus low adherent dressings*

One trial (60 participants) compared alginate with low adherent dressings.<sup>w39</sup> It found no statistically significant difference between the two dressings (26/30 healing in the alginate group compared with 24/30 in the low adherent group; relative risk=1.08, 0.86 to 1.36).

### *Alginate versus alginate*

One trial (20 participants) compared different alginate dressings (Tegagen HG and Sorbsan).<sup>w40</sup> The study reported the total number of ulcers healed at eight weeks and found no statistically significant differences between the two groups (relative risk for healing with Tegagen=0.1, 0.01 to 1.86).

Three trials compared alginates with hydrocolloids,<sup>w20 w22 w23</sup> and one trial compared alginate with a foam dressing.<sup>w34</sup> These are summarised in the hydrocolloid and foam sections.

One trial (113 patients with 133 ulcerated limbs) compared alginate dressings in a three treatment arm trial.<sup>w41</sup> The allocation was on the basis of the limb and not the patient. The treatments were zinc oxide impregnated cotton bandage (Viscopaste, n=43), zinc oxide impregnated stockinet (Acoband, n=44), and alginate dressing (Kaltostat, n=46). The study reported the total number of limbs healed. These were 34/43

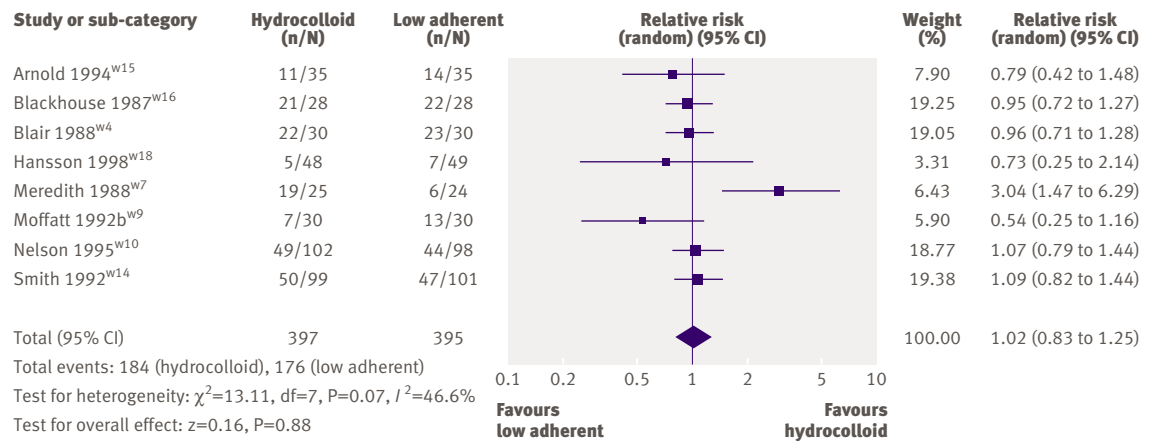


Fig 2 | Hydrocolloid dressings versus low adherent dressings

(86%) in the Viscopaste arm, 26/44 (66%) in the Aco-band arm, and 26/46 (57%) in the alginate arm. The relative risk of healing with the zinc paste bandage compared with the alginate dressing was 0.82 (0.61 to 1.1).

#### Miscellaneous dressings

One trial compared a cadoximer iodine powder and “standard” treatment as determined by the clinician.<sup>w42</sup> The trial reported a mean percentage ulcer reduction of 34% in the cadoximer group compared with 5% in the standard group.

One trial compared a hyaluronan derivative fleece dressing with paraffin gauze dressing.<sup>w43</sup> It found no statistically significant difference in the numbers of ulcers healed. Two (16%) of 12 ulcers healed in eight weeks in the fleece dressing group compared with 1/12 (8%) in the paraffin gauze group ( $\chi^2=0.39$ ,  $df=1$ ;  $P=0.53$ ). It also reported a statistically significant reduction in ulcer area—8.1 cm<sup>2</sup> for the fleece dressing compared with 0.4 cm<sup>2</sup> for paraffin gauze ( $P<0.002$ ).

One trial compared a polyamide active charcoal dressing with a dressing applied “according to the stage of healing.”<sup>w44</sup> It found no statistically significant difference in the numbers healed at six weeks: 6/19 (31.5%) in the charcoal dressing group compared with 2/20 (10.5%) for the alternative ( $\chi^2=2.78$ ,  $df=1$ ;  $P=0.095$ ).

#### DISCUSSION

This review updates a systematic review published in 1999<sup>4</sup> and a more limited review published in 2005,<sup>10</sup> which included only 16 studies, compared with 42 in our review. The results from our meta-analysis showed no statistically significant difference in terms of total ulcers healed between any of the dressing types. In some cases this may be due to low power to detect a difference. The meta-analysis of hydrocolloid dressings versus low adherent dressings had more than 700 participants. This means that we can be confident that hydrocolloids confer no significant clinical benefit over simple, low adherent dressings when used

beneath compression. Given the potential disadvantages of using hydrocolloid rather than a low adherent simple dressing, in terms of increased cost and greater exposure to allergens in the preservative, the simple non-adherent dressing should be preferred.

One consideration when reviewing these results must be that an intention to treat perspective was used, which assumed that losses to follow-up failed to heal. This could have underestimated the healing rates.

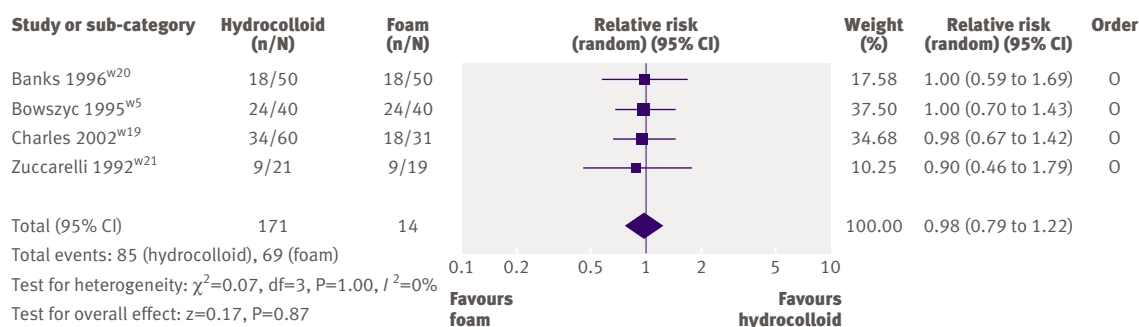
#### Quality of included trials

Most of the trials included in this review had a small sample size (range 13–200, mean 76, median 70) and therefore had low power to detect clinically important differences. Only one study reported an a priori sample size calculation.<sup>w9</sup> This was a concern, as small trials are at a higher risk of publication bias than large trials. Although the results for healing in these trials were usually inconclusive, and this might indicate that few trials in this area remain unpublished because of the direction of their findings, most trials were not inconclusive in their conclusions. They reported several outcome measures, usually subjective, such as dressing performance (ease of use, patient “comfort”), and often concluded that evidence existed for one dressing performing better than the other.

Most of the trials in this review were funded by dressing manufacturers, and we cannot be certain whether unpublished trials exist, or if, in the published trials, outcome measures have been selectively reported. Each comparison included too few trials to allow a funnel plot to be drawn.

We also found problems in terms of reporting of trials. Only three studies stated the method of randomisation and blinding of allocation,<sup>w4 w10 w11</sup> and only one reported blinding of assessment.<sup>w19</sup> Although blinding of trial participants to many wound dressings is difficult, as they often differ in appearance, blinding of the assessment of treatment can usually be achieved.

The lack of blinding of outcome assessors has implications in the light of a recent study that reported statistically significant differences in the subjective



**Fig 3 | Hydrocolloid dressings versus foam dressings**

assessment of wound progress when the assessors were not blind to the dressing allocated, in contrast to an assessment by blinded outcome assessors in which no difference in wound progress was found.<sup>11</sup> Evidence also exists to suggest that inadequate methodological reporting has an association with overestimation of treatment effects.<sup>12</sup>

The trials were of relatively short duration (range 4–48, mean 14, median 8 weeks). Venous ulcers usually take months to heal,<sup>13</sup> so trials with short durations fail to capture most healing events, further eroding power to detect clinically important differences as statistically significant.

#### External validity of included trials

The external validity of many of these trials is threatened by the fact that they limited inclusion by ulcer size. Of the 23 studies that reported details of baseline ulcer area, 15 included only ulcers of less than 10 cm<sup>2</sup> and eight included only ulcers of greater than 10 cm<sup>2</sup>. Only one trial used life table analysis, summarising both how many people's ulcers healed and how quickly they healed.<sup>w9</sup> Many studies used rate of reduction in ulcer area as an outcome measure; however, this is not necessarily a predictor of healing, particularly when used over a short period. In addition, the use of change in wound area raises questions of validity, especially when initial ulcer size varies, as the percentage change will be greater for smaller wounds. The use of rates of reduction in area (often called ulcer healing rates) can therefore be misleading.<sup>14</sup>

Other outcome measures used included patient derived and nurse derived subjective measures such as “satisfaction” and pain. The use of subjective outcomes in trials can lead to bias, especially if the tools used are not tested for reliability and validity and if blinding to treatment allocation is not used. Bias can result from subconscious preferences of treatments by the assessors, patients, or both, or selective reporting of positive outcomes.

#### Cost and quality of life data

Cost and quality of life data used in the studies were also generally poor quality or lacking. When quality of life measures were reported they tended to be linear analogue scales or simple Likert-type scales. The inclusion of more sophisticated measures of quality of life when evaluating dressings is an area that needs to be tackled. This is particularly important as it may be one of the few ways to distinguish between dressings. The impact of venous ulcers on quality of life has been studied,<sup>15–20</sup> but within randomised controlled trials quality of life data were very poor or omitted altogether.

The poor reporting of cost data was a particular concern. Where such data were collected,<sup>w7 w14 w29</sup> the reporting did not conform to rigorous guidelines for economic evaluations.<sup>21</sup> The trials simply totalled the monetary cost of the dressings and did not examine their cost effectiveness. This was illustrated in the hydrocolloid versus alginate comparison, where costs were reported for the interventions but insufficient detail was provided on their derivation.

#### Clinical implications

Although a wide variety of dressings are available, and used on venous leg ulcers, we found insufficient evidence to justify the use of a particular dressing or dressing type in preference to any other. In particular, the use of hydrocolloid dressings rather than simple, low adherent dressings should be questioned. In the absence of clear evidence of differences in clinical effectiveness, the optimum use of resources demands that the least expensive dressing should be used, although the preferences of patients and nurses may be important where little difference in cost exists.

**Table 4 | Meta-analysis results**

Comparison	No of trials (total No of participants)	Pooled relative risk (95% CI)
Hydrocolloid v low adherent	8 (792) (1 trial excluded <sup>w17</sup> )	1.02 (0.83 to 1.25)
Hydrocolloid v foam	4 (311)	0.98 (0.79 to 1.22)
Hydrocolloid v alginate	3 (80)	0.72 (0.15 to 3.42)
Hydrocolloid v hydrocolloid	3 (98)	1.56 (0.67 to 3.63)
Foam v low adherent	2 (203) (1 trial excluded <sup>w12</sup> )	1.35 (0.93 to 1.94)
Foam v foam	2 (136)	1.2 (0.77 to 1.87)
Hydrogel v low adherent	2 (151)	1.53 (0.96 to 2.42)
Hydrogel v hydrogel	2 (175)	NA

NA=not applicable.

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

Dressings are applied over ulcers with a view to aiding healing and improving patients' comfort

A wide variety of brands and types of dressing are available, but the evidence for their effectiveness is equivocal

**WHAT THIS STUDY ADDS**

Insufficient evidence of effectiveness exists to recommend one type of dressing in preference to another

Hydrocolloid dressings offer no healing benefit compared with simple dressings under compression

In the absence of evidence for healing benefit, cost should be a factor in the choice of dressings

Cost effectiveness studies examining dressings for venous leg ulcers are urgently needed, as dressing frequency drives costs by influencing the amount of time taken by clinicians to treat ulcers.

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**Competing interests:** A trial by EAN was included in the review.

**Ethical approval:** Not needed.

**Provenance and peer review:** Non-commissioned; externally peer reviewed.

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