

Treatment for Pressure Ulcers: A Comparative Effectiveness Review

Appendixes

Appendix A. Exact Search Strategy

The following databases have been searched for relevant information:

Medline

Searched: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) 1946 to August Week 5 2011
 Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations September 12, 2011
 Date Searched: September 14, 2011

1	Pressure Ulcer/dh, dt, nu, rt, rh, su, th, ae, co, in, mo, po, to	4917
2	pressure ulcer/ and (treatment or healing or management or therapy).hw.	1818
3	((pressure ulcer\$ or pressure sore\$ or bed sore\$ or bedsore\$ or decubitus ulcer\$) adj5 (treat\$ or heal\$ or manag\$ or therap\$)).ti,ab.	2244
4	1 or 2 or 3	6047
5	limit 4 to yr="1985 -Current"	4876
6	remove duplicates from 5	4668

EMBASE

Searched: Embase (Elsevier)
 Date Searched: September 14, 2011

6	((('pressure ulcer?' OR 'pressure sore?' OR 'bed sore?' OR bedsore? OR decubitus) NEAR/5 (treat* OR heal* OR manag* OR therap* OR surger*)):ab,ti AND [embase]/lim OR ('decubitus'/mj AND ('radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de) AND [embase]/lim) AND (1985:py OR 1986:py OR 1987:py OR 1988:py OR 1989:py OR 1990:py OR 1991:py OR 1992:py OR 1993:py OR 1994:py OR 1995:py OR 1996:py OR 1997:py OR 1998:py OR 1999:py OR 2000:py OR 2001:py OR 2002:py OR 2003:py OR 2004:py OR 2005:py OR 2006:py OR 2007:py OR 2008:py OR 2009:py OR 2010:py OR 2011:py)	1,739
5	((('pressure ulcer?' OR 'pressure sore?' OR 'bed sore?' OR bedsore? OR decubitus) NEAR/5 (treat* OR heal* OR manag* OR therap* OR surger*)):ab,ti AND [embase]/lim OR ('decubitus'/mj AND ('radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de) AND [embase]/lim)	2,263
4	'decubitus'/mj AND ('radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de) AND [embase]/lim	1,528

3	((('pressure ulcer?' OR 'pressure sore?' OR 'bed sore?' OR 'bedsore?' OR 'decubitus') NEAR/5 (treat* OR heal* OR manag* OR therap* OR surger*)):ab,ti AND [embase]/lim	1,439
2	'radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de AND [embase]/lim	2,565,030
1	'decubitus'/mj AND [embase]/lim	3,001

CINAHL

Searched: EBSCOHost CINAHL Plus with Full Text
Date Searched: September 14, 2011

S6	S1 or S2 or S5	Limiters - Published Date from: 19850101-20111231 Search modes - Boolean/Phrase	1197
S5	S3 or S4	Limiters - Search Only Pre-CINAHL Search modes - Boolean/Phrase	22
S4	(AB "pressure ulcer*" or AB "pressure sore*" or AB "bed sore*" or AB "bedsore*" or AB "decubitus ulcer*") and (AB "treat*" or AB "heal*" or AB "manag*" or AB "therapy" or AB "therapies")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	658
S3	(TI "pressure ulcer*" or TI "pressure sore*" or TI "bed sore*" or TI "bedsore*" or TI "decubitus ulcer*") and (TI "treat*" or TI "heal*" or TI "manag*" or TI "therapy" or TI "therapies")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	449
S2	(MM "Pressure Ulcer") and (MW "treatment" or MW "healing" or MW "management" or MW "therapy" or MW "therapeutic")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	
S1	(MH "Pressure Ulcer/CO/DH/DT/MO/NU/RT/RH/SU/TH")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	1013

EBM REVIEWS

Searched:
EBM Reviews - Cochrane Database of Systematic Reviews 2005 to August 2011,
EBM Reviews - Database of Abstracts of Reviews of Effects 3rd Quarter 2011,
EBM Reviews - Cochrane Central Register of Controlled Trials 3rd Quarter 2011,
EBM Reviews - Health Technology Assessment 3rd Quarter 2011,
EBM Reviews - NHS Economic Evaluation Database 3rd Quarter 2011
Date Searched: September 14, 2011

1	Pressure Ulcer/dh, dt, nu, rt, rh, su, th, ae, co, in, mo, po, to	262
2	Pressure ulcer/ and (treatment or healing or management or therapy).hw.	184
3	((pressure ulcer\$ or pressure sore\$ or bed sore\$ or bedsore\$ or decubitus ulcer\$) adj5 (treat\$ or heal\$ or manag\$ or therap\$)).ti,ab.	363
4	1 or 2 or 3	501
5	limit 4 to yr="1985 -Current"	470
6	remove duplicates from 5	466

ClinicalTrials.gov
Searched 09/15/2011

((NOT ("Recruiting" OR "Not yet recruiting" OR "Available")) [OVERALL-STATUS] AND pressure ulcer* OR decubitus ulcer* OR pressure sore* OR bedsore* OR bed sore* [DISEASE]) [ALL-FIELDS]
Results = 184

Current Controlled Trials
Searched 09/15/2011

Search box: pressure ulcer*, decubitus ulcer*, pressure sore*, bedsore*, bed sore*
Selected all registries with the exception of Nih's ClinicalTrials.gov
Results = 8, which were then edited to treatment trials

ClinicalStudyResults.org
Searched 09/15/2011

Studies Indications or Disease: two searches:
#1: Ulcers, Pressure
#2: Ulcers, Diabetic and Decubitus (bedsores)
Results: neither search returned any results

WHO ICTRP
Searched 09/15/2011

Search terms:
Condition search box, two separate searches: decubitus ulcers, pressure ulcers
Recruitment status: ALL
Results = 79, which were then edited to treatment trials
Notes: search interface gave inconsistent and unexpected results, based on documentation.

ProQuest CSA CONFERENCE PAPERS INDEX
Searched: ProQuest CSA Conference Papers Index
Date Searched: 09/19/2011

Search Query #9 KW=(pressure ulcer* or pressure sore* or bed sore* or bedsore* or decubitus ulcer*) and KW=(treat* or heal* or surger* or surgical* or diet* or nutrition* or manag* or therap* or pressure or mattress* or cushion* or surface* or gel* or bandage* or dressing* or foam* or maggot* or debrid* or silver or saline or vibration* or cream*) and not Q1=(screening or prevention or risk assessment or classification or diabetes mellitus or training or quality of life or animal studies) ([Copy Query](#))

241 Published Works results found in Conference Papers Index
Date Range: 1985 to 2012

ProQuest Dissertations & Theses
Searched 09/16/2011

Search terms:
(decubitus ulcer* or pressure ulcer* or pressure sore* or bedsore* or bed sore*) AND (treat* or therap* or manag* or heal*)

Details of the Search Process

A research Librarian, developed a list of databases to be searched and tested database specific search strategies in collaboration with the research team . Additional references were found by hand-searching the bibliographies of review articles and included studies; letters to the editor and commentaries; and Technical Expert Panel input.

All citations were imported into Thomson Reuters' EndNote X3 (citation management) and then *Distiller Systematic Review Software* (screening of abstracts and full text, kappa calculation, data extraction, exclusion reports, and table construction).

Search Strategy Development Notes

A combination of controlled vocabulary and keywords were employed in the search strategies, with age, study methodology, and date (2002-) limits applied. No language limit was used. Details of the search strategies are given in Appendix A.

List of Databases Searched

Name	Date Searched	Platform Provider
Bibliographic Database Search		
Medline	1947-02/28/2011; Update Search 04/04/2012	OvidSP
Embase	1976-04/11/2011; Update Search 04/04/2012	Elsevier
Cochrane Library/EBM Reviews: Cochrane Central Register of Controlled Trials (CCRCT)	1991-04/11/2011; Update Search 04/04/2012	OvidSP
Cochrane Library/EBM Reviews: Cochrane Database of Systematic Reviews (CDSR)	2005-04/11/2011; Update Search 04/04/2012	OvidSP
Cochrane Library/EBM Reviews: Database of Abstracts of Reviews of Effects (DARE)	1991-04/11/2011; Update Search 04/04/2012	OvidSP
Citation Database Search		
Scopus	1960-04/11/2011; Update Search 04/04/2012	Elsevier
Subject Specific Database Search		
PsycINFO	1806-04/12/2011; Update Search 04/04/2012	OvidSP

Grey Literature (Unpublished Literature) Strategy

In addition to searching bibliographic, citation, and subject-specific databases, additional materials were sought by searching for regulatory information, clinical trial registries, and conference proceedings. Including the following databases and websites:

Name	Date Searched	Platform Provider
Clinical Trial Registries		
Clinicaltrials.gov	Original Search 03/02/2011 Update Search 04/06/2012	US National Institutes of Health
Regulatory Agencies		
Drug Approval Package	Original Search 03/02/2011 Update Search 04/06/2012	US Federal Drug Administration
European Public Assessment Reports	Original Search 03/02/2011 Update Search 04/06/2012	European Medicines Agency
Summary Basis of Decision (SBD): Drugs	Original Search 03/02/2011 Update Search 04/06/2012	Health Canada
Conference Proceedings		
Scopus	1960-April 11, 2011; Update Search 04/04/2012	Elsevier

Scientific Information Packets (SIPs)

The Effective Health Care Program Scientific Resource Center requested information about published and unpublished Phase II and above clinical studies, post-marketing studies, and observational studies from pharmaceutical companies. The SIP request deadline had not yet passed when this draft report was written, the final report will be updated with all relevant information derived from SIP submissions.

Appendix B. Pressure Ulcer Treatment: Inclusion Criteria by PICOTS and Key Question

	Inclusion Criteria	Exclusion Criteria
Populations	Adults aged 18 years and older being treated for existing decubitus ulcers. Subgroups include: sex, race/ethnicity, socioeconomic status, and diverse specific medical comorbidities (e.g., diabetes, end-stage renal disease, dementia), and patients with specific known risk factors for pressure ulcers (e.g., nutritional status, incontinence, peripheral vascular disease, mobility limitations, functional ability).	Wrong population. Children, adolescents, and patients with non pressure-related ulcers, including but not limited to venous ulcers and diabetic foot ulcers, because treatment considerations for these patients may differ significantly from those for pressure ulcers.
Interventions	Treatment for pressure ulcers including but not limited to: support surfaces, nutritional supplementation, wound debridement and cleansing, wound dressings, biologic agents, and surgical repair. Adjunctive therapies including ultrasound, electrical stimulation, vacuum-assisted closure, and hyperbaric oxygen therapy. <ul style="list-style-type: none"> For efficacy and effectiveness assessments, all studies of interventions for treatment of pressure ulcers meeting the requirements of the PICOTS and Key Questions were included. 	Wrong intervention. Studies of interventions without comparators were excluded but included in KQ2 to evaluate harms.
Comparisons	Usual care, placebo, no treatment, different treatment interventions	Studies with no comparator (included for harms only)
Outcomes	Clinical outcomes: <ul style="list-style-type: none"> Complete wound healing wound surface area reduction pain prevention of sepsis, prevention of osteomyelitis, recurrence rate and harms of treatment care settings, (including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training) 	Non- clinical outcomes, cost, comfort, and nursing time.
Settings	Patient-care settings, such as home, nursing facility, or hospitals.	Hospice care facilities.
Timing	No minimum follow up time was required.	Studies published prior to 1985.
Study designs	Randomized and non randomized trials, retrospective and prospective cohort studies, case-control studies, and multicenter intervention series with a population of 100 patients or more.	Single case reports, intervention series with sample sizes less than 100 patients conducted at single sites, articles with no original data; review articles, letter, and editorials. Systematic reviews used for background only.
Treatment Key Questions		
Population Interventions Comparators Outcomes Timing Settings	KQ1:1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection? <ul style="list-style-type: none"> For efficacy and effectiveness assessments, all studies of interventions for treatment of pressure ulcers meeting the requirements of the PICOTS 	Wrong population. Wrong interventions. Studies without a comparator or studies that reported outcomes only as an adverse event were excluded, but used in the assessment of harms.

	Inclusion Criteria	Exclusion Criteria
	<p>and Key Questions were included.</p> <ul style="list-style-type: none"> No minimum followup time was required. 	Wrong outcomes. Hospice care facilities.
Population/ patient, ulcer characteristics	1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?	None.
Population/ patient, characteristics	1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age; race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?	Wrong population.
Settings	1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?	Hospice care facilities.
Harms Key Questions		
Population Interventions Comparators Outcomes Timing Settings	KQ 2. What are the harms of treatments for pressure ulcers?	Wrong population. Wrong intervention. Hospice care facilities.
Population/Patient, ulcer characteristics	2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?	Wrong population.
Population/ patient, characteristics	2b. Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?	Wrong population.
Settings	2c. Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?	Hospice care facilities.

Appendix C. Stages of Pressure Ulcer

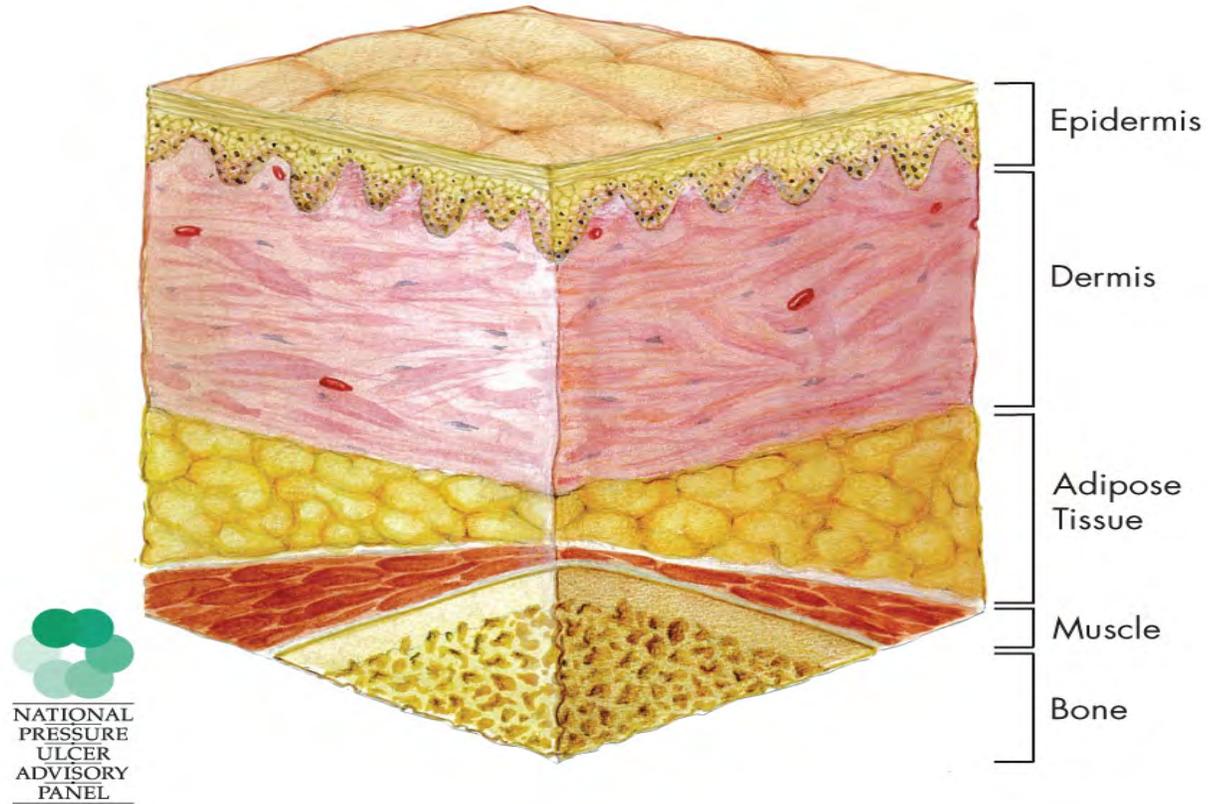
Stages of Pressure Ulcer Equivalency

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
I	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.	I	Red area: a. Present longer than 30 minutes, but less than 24 hours b. Present longer than 24 hours	NA	No Equivalent	I	Pressure sore is an acute inflammatory response involving the epidermis. An irregular, ill-defined area of soft-tissue erythema accompanies by in duration and heat persists for more than 24 hours. The epidermis remains intact, and the ulcer is reversible.	I	Persistent erythema of the skin
II	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister	II	Epidermis and/or dermis ulcerated with no subcutaneous fat observed	I	Limited to epidermis exposing dermis	II	Pressure sore is a break in or blistering of the epidermis surrounded by erythema and in duration. Potentially, it also is reversible.	II	Blister formation or superficial subcutaneous ulcer

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
III	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.	III	Subcutaneous fat observed, no muscle observed	II, III	Full-thickness of dermis to junction of subcutaneous fat Fat obliterated, limited by deep fascia undermining of skin	III	Pressure ulcer is an inflammatory fibroblastic response extending through the dermis to the junction with subcutaneous fat. Clinically presents as an irregular, shallow ulcer that has subcutaneous fat at its base and is surrounded by erythema, induration, and heat.	III	Deep subcutaneous ulcer-ulceration progress through the dermis

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
IV	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.	IV-V	Muscle/ fascia observed, but no bone observed Bone observed, but no involvement of joint space	IV	Bone at the base of ulceration	IV – muscle V – exposed bone	Pressure ulcer extends through the full thickness of skin into the deep fascia and / or muscle. Its draining, necrotic base is often foul-smelling, and under-mining of the surface tissues may be excessive. Pressure ulcer penetrates the underlying bone, causing osteomyelitis. It has no anatomic limit and is surrounded by erythema and induration. Clinically, it presents as an extensive ulcer with exposed bone, joint, muscle, and/or fascia at its base.	IV	
X									
		VI	Involvement of joint space	V	Closed large cavity through a small sinus			V	

Stages of Pressure Ulcer Equivalency: Layers of tissue affected



9297 NPUAP (2007). Support Surfaces Standards Initiative - Terms and Definitions Related to Support Surfaces. N. P. U. A. Panel, National Pressure Ulcer Advisory Panel: 10, Permission for use pending.

Appendix D. Included Studies List

Support:

1. Allman RM, et al. Air-fluidized beds or conventional therapy for pressure sores. A randomized trial. *Annals of Internal Medicine*. 1987 Nov;107(5):641-8. PMID: 3310792.
2. Branom R, Rapp L. "Constant force technology" versus low-air-loss therapy in the treatment of pressure ulcers. [Erratum appears in *Ostomy Wound Manage* 2001 Nov;47(11):6]. *Ostomy Wound Management*. 2001 Sep;47(9):38-46. PMID: 11889743.
3. Caley. randomized prospective trial of two types of low-air-loss therapy, caley. *Clinical Symposium on Pressure Ulcer and Wound Management*. 1994:1-2.
4. Clark M, Donald IP. A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. *Proceedings of the 7th European European Conferences on Advances in Wound Management 18-20 November; 1997; Harrogate, UK*.
5. Day A, Leonard F. Seeking quality care for patients with pressure ulcers. *Decubitus*; 1993. p. 32-43.
6. Devine B. Alternating pressure air mattresses in the management of established pressure sores. *Journal of Tissue Viability*. 1995;5(3):94-8.
7. Evans D, Land L, Geary A. A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system. *Journal of Wound Care*. 2000 Apr;9(4):181-6. PMID: 11933303.
8. Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers. *Journal of the American Medical Association*. 1993;269(4):494-7. PMID: 8338511.
9. Groen HW, Groenier KH, Schuling J. Comparative study of a foam mattress and a water mattress. *Journal of Wound Care*. 1999 Jul;8(7):333-5. PMID: 10776222.
10. Izutsu T, et al. Effect of rolling bed on decubitus in bedridden nursing home patients. *Tohoku Journal of Experimental Medicine*. 1998 Feb;184(2):153-7. PMID: 9605022.
11. Jackson BS, et al. The effects of a therapeutic bed on pressure ulcers: an experimental study. *Journal of Enterostomal Therapy*. 1988 Nov-Dec;15(6):220-6. PMID: 3204209.
12. Keogh A, Dealey C. Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. *Journal of Wound Care*. 2001 Feb;10(2):15-9. PMID: 12964222.
13. Land L, et al. A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. *Journal of Tissue Viability*. 2000 Jan;10(1):6-11. PMID: 10839090.
14. Makhos M, et al. Promote pressure ulcer healing in individuals with spinal cord injury using an individualized cyclic pressure-relief protocol. *Advances in Skin & Wound Care*. 2009 Nov;22(11):514-21. PMID: 20026933.
15. Malbrain M, et al. A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. *Journal of Tissue Viability*; 2010. p. 7-15.
16. Mulder G, et al. A study of pressure ulcer response to low air loss beds vs. conventional treatment. *Journal of Geriatric Dermatology* 1994;2(3):87-91.
17. Munro BH, Brown L, Heitman BB. Pressure ulcers: one bed or another? *Geriatric nursing (New York, N.Y.)*. 1989;10(4):190-2.
18. Nixon J, et al. Pressure relieving support surfaces: A randomised evaluation. *Health Technology Assessment*. 2006;10(22):iii-101. PMID: 16750060.
19. Ochs RF, et al. Comparison of air-fluidized therapy with other support surfaces used to treat pressure ulcers in nursing home residents. *Ostomy Wound Management*. 2005 Feb;51(2):38-68. PMID: 15699554.
20. Rosenthal MJ, et al. Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments. *Archives of Physical Medicine & Rehabilitation*. 2003 Dec;84(12):1733-42. PMID: 14669176.

21. Russell L, et al. A comparison of healing rates on two pressure-relieving systems. *British Journal of Nursing*. 2000 Dec 8-2001 Jan 10;9(22):2270-80. PMID: 12271193.
22. Russell L, et al. Randomised controlled trial of two pressure-relieving systems. *Journal of Wound Care*. 2000 Feb;9(2):52-5. PMID: 11933280.
23. Russell L, et al. Randomized comparison trial of the RIK and the Nimbus 3 mattresses. *British Journal of Nursing*. 2003 Feb 27-Mar 12;12(4):254, 6-9. PMID: 12671572.
24. Strauss MJ, et al. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. *Journal of Family Practice*. 1991 Jul;33(1):52-9. PMID: 2056290.
7. Frias Soriano L, et al. The effectiveness of oral nutritional supplementation in the healing of pressure ulcers. *Journal of Wound Care*. 2004 Sep;13(8):319-22. PMID: 15469215.
8. Houston S, et al. Adverse effects of large-dose zinc supplementation in an institutionalized older population with pressure ulcers [4]. *Journal of the American Geriatrics Society*. 2001;49(8):1130-2. PMID: 11555083.
9. Lee SK, et al. Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial. *Advances in Skin & Wound Care*. 2006 Mar;19(2):92-6. PMID: 16557055.
10. Meaume S, et al. Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial. *Journal of Nutrition, Health & Aging*. 2009 Aug;13(7):623-30. PMID: 19621198.

Nutrition:

1. Barnes P, Jr., Sauter TE, Zaheri S. Subnormal prealbumin levels and wound healing. *Texas Medicine*. 2007 Aug;103(8):65-8. PMID: 19113064.
2. Benati G, Delvecchio S, Cilla D, et al. Impact on pressure ulcer healing of an arginine-enriched nutritional solution in patients with severe cognitive impairment. *Archives of Gerontology & Geriatrics - Supplement*. 2001;7:43-7. PMID: 11431045.
3. Breslow, R. A., J. Hallfrisch, et al. (1993). "The importance of dietary protein in healing pressure ulcers." *Journal of the American Geriatrics Society* 41(4): 357-362.
4. Brewer S, et al. Effect of an arginine-containing nutritional supplement on pressure ulcer healing in community spinal patients. *Journal of Wound Care*. 2010 Jul;19(7):311-6. PMID: 20616774.
5. Cereda E, et al. Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial. *Journal of the American Geriatrics Society*. 2009 Aug;57(8):1395-402. PMID: 19563522.
6. Desneves KJ, et al. Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomised controlled trial. *Clinical Nutrition*. 2005 Dec;24(6):979-87. PMID: 16297506.
11. Myers SA, et al. Consistent wound care and nutritional support in treatment. *Decubitus*. 1990 Aug;3(3):16-28. PMID: 2119183.
12. Ohura T, et al. Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial). *Wound Repair & Regeneration*. 2011 May-Jun;19(3):330-6. PMID: 21539650.
13. Ter Riet G, Kessels AGH, Knipschild PG. Randomized clinical trial of ascorbic acid in the treatment of pressure ulcers. *Journal of Clinical Epidemiology*. 1995;48(12):1453-60.
14. Van Anholt RD, et al. An arginine- and micronutrient-enriched nutritional supplement accelerates pressure ulcer healing and reduces wound care in non-malnourished patients. *EWMA Journal*; 2010. p. 45.
15. Yamamoto T, et al. Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds?... European Pressure Ulcer Advisory Panel. *Wounds: A Compendium of Clinical Research & Practice*. 2009;21(6):153-7.

Local Wound Care:

1. Agren MS, Stromberg HE. Topical treatment of pressure ulcers. A randomized comparative trial of Varidase and zinc oxide. *Scandinavian Journal of Plastic & Reconstructive Surgery*. 1985;19(1):97-100. PMID: 3895409.

2. Alm A, Hornmark AM, Fall PA, et al. Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze compresses. *Acta Dermato-Venereologica. Supplementum*. 1989;149:1-10. PMID: 2694713.
3. Alvarez OM, Fernandez-Obregon A, Rogers RS, et al. Chemical debridement of pressure ulcers: a prospective, randomized, comparative trial of collagenase and papain/urea formulations. *Wounds: A Compendium of Clinical Research & Practice*. 2000;12(2):15-25.
4. Bale S, Hagelstein S, Banks V, et al. Costs of dressings in the community. *Journal of Wound Care*. 1998 Jul;7(7):327-30. PMID: 9791356.
5. Banks V, Bale S, Harding K. The use of two dressings for moderately exuding pressure sores. *Journal of Wound Care*. 1994(b);3(3):132-4. PMID: 1995009486. Language: English. Entry Date: 19950401. Revision Date: 20091218. Publication Type: journal article.
6. Banks V, Bale SE, Harding KG. Comparing two dressings for exuding pressure sores in community patients. *Journal of Wound Care*. 1994(a);3(4):175-8. PMID: 1995009494. Language: English. Entry Date: 19950401. Revision Date: 20091218. Publication Type: journal article.
7. Belmin J, Meaume S, Rabus M-T, et al. Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects: a multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid dressings alone. *Journal of the American Geriatrics Society*. 2002 Feb;50(2):269-74. PMID: 12028208.
8. Brod M, McHenry E, Plasse TF, et al. A randomized comparison of poly-hema and hydrocolloid dressings for treatment of pressure sores. *Archives of Dermatology*. 1990 Jul;126(7):969-70. PMID: 2193631.
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Appendix E. Excluded Studies List

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The Pressure Sore Alleviation Project. *Journal of Tissue Viability*; 2002. p. 77. **exclusion reason** - wrong intervention

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The effect of stochastic electrical noise on hard-to-heal wounds. *Journal of Wound Care*; 2011. p. 96-103. **exclusion reason** - unable to find

Tratamiento de las Úlceras con acupuntura Acupuncture treatment in ulcers. *gora de Enfermeria*; 2011. p. 27-30. **exclusion reason** - not relevant

Appendix F. Quality Assessment Methods

Individual studies were rated as “good,” “fair” or “poor” as defined below¹:

For Controlled Trials:

Each criterion was give an assessment of yes, no, or unclear.

1. Was the assignment to the treatment groups really random?

Adequate approaches to sequence generation:

- Computer-generated random numbers
- Random numbers tables

Inferior approaches to sequence generation:

- Use of alternation, case record numbers, birth dates or week days
- Randomization reported, but method not stated
- Not clear or not reported
- Not randomized

2. Was the treatment allocation concealed?

Adequate approaches to concealment of randomization:

- Centralized or pharmacy-controlled randomization (randomization performed without knowledge of patient characteristics).
- Serially-numbered identical containers
- On-site computer based system with a randomization sequence that is not readable until allocation
- Sealed opaque envelopes

Inferior approaches to concealment of randomization:

- Use of alternation, case record numbers, birth dates or week days
- Open random numbers lists
- Serially numbered non- opaque envelopes
- Not clear or not reported

3. Were the groups similar at baseline in terms of prognostic factors?

4. Were the eligibility criteria specified?

5. Were outcome assessors and/or data analysts blinded to the treatment allocation?

6. Was the care provider blinded?

7. Was the patient kept unaware of the treatment received?

8. Did the article include an intention-to-treat analysis, or provide the data needed to calculate it (i.e., number assigned to each group, number of subjects who finished in each group, and their results)?

9. Did the study maintain comparable groups?

10. Did the article report attrition, crossovers, adherence, and contamination?

11. Is there important differential loss to followup or overall high loss to followup?

For Cohort Studies:

Each criterion was give an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?

2. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?

3. Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?

4. Were outcome assessors and/or data analysts blinded to treatment?

5. Did the article report attrition?

6. Did the study perform appropriate statistical analyses on potential confounders?

7. Is there important differential loss to followup or overall high loss to followup?

8. Were outcomes pre-specified and defined, and ascertained using accurate methods?

For Case-Control Studies:

Each criterion was given an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) cases using pre-defined criteria?
2. Were the controls derived from the same population as the cases, and would they have been selected as cases if the outcome was present?
3. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?
4. Did the study report the proportion of cases and controls who met inclusion criteria that were analyzed?
5. Did the study use accurate methods for identifying outcomes?
6. Did the study use accurate methods for ascertaining exposures and potential confounders?
7. Did the study perform appropriate statistical analyses on potential confounders?

Appendix G. Overall Strength of Evidence

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)*	Strength of Evidence (High, Moderate, Low, or Insufficient)
1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?							
<i>Treatment Strategies: Support</i>							
Experimental surface: Air-fluidized beds greater than other surfaces	4 randomized trials, 1 observational	908	Fair	High	Direct	Low/Unclear	Moderate
Alternating pressure: (Different brand or form factors of AP beds) Type A equal to type B	4 randomized trials	327	Fair	High	Direct	Low	Moderate
AP beds vs. other surfaces	2 randomized trials, 1 trial, allocation unclear	239	Fair	Moderate	Direct	Low/Unclear	Low
AP cushions vs. other cushions	2 randomized trials	69	Fair	Low	Direct	Unclear	Insufficient
LAL beds equal to other surfaces	4 randomized trials	344	Poor	Moderate	Direct	Unclear	Moderate
Other (non powered innovation) vs. standard care	4 randomized trials	361	Poor	-	-	-	Unable to summarize (5 different interventions)
<i>Treatment Strategies Key Outcomes: Nutrition</i>							
Mixed nutritional supplementation vs. standard nutritional care or placebo	3 randomized trials, 2 observational	230		High	Direct	Low	Low

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)*	Strength of Evidence (High, Moderate, Low, or Insufficient)
Protein or amino acid supplementation vs. standard nutritional care	5 randomized trials, 3 observational	454	Fair	Moderate	Direct	Low	Low
Specific nutrient supplementation vs. high or low dose or placebo	1 randomized trial, 1 observational	147	Fair	-	-	-	Insufficient
<i>Treatment Strategies Key Outcomes: Local Wound Care</i>							
Hydrocolloid superior to standard care	10 randomized trials	560	Poor	Moderate	Direct	Low	Low
Hydrogel vs. standard care	4 randomized trials	156	Poor	Low	Direct	Low	Insufficient
Foam vs. standard care	3 randomized trials	118	Poor	Low	Direct	Low	Insufficient
Transparent film vs. standard care	3 randomized trials	106	Poor	Low	Direct	Low	Insufficient
Hydrocolloid vs. hydrogel	3 randomized trials	167	Poor	Low	Direct	Low	Insufficient
Hydrocolloid equivalent to foam	7 randomized trials	508	Fair	Moderate	Direct	Moderate	Moderate
Radiant heat superior to other dressings	4 randomized trials	160	Good	Moderate	Direct	Moderate	Moderate
Collagenase superior to hydrocolloid/standard care	4 randomized trials	218	Fair	Moderate	Direct	Low	Low
Phenytoin vs. hydrocolloid/standard care	3 randomized trials	154	Fair	Low	Direct	Low	Insufficient
Dextranomer inferior to hydrogel/alginate dressings	2 randomized trials	227	Fair	Moderate	Direct	Low	Low
Collagen equivalent to hydrocolloid/standard care	3 randomized trials	169	Fair	Low	Direct	Low	Low
Platelet-derived growth factor superior to placebo	3 randomized trials	196	Fair	Moderate	Direct	Low	Low
Fibroblast growth factor vs. placebo	2 randomized trials	60	Poor	Low	Direct	Low	Insufficient

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)*	Strength of Evidence (High, Moderate, Low, or Insufficient)
Nerve growth factor vs. placebo	1 randomized trial	36	Good	NA	Direct	Low	Insufficient
Macrophage suspension	1 randomized trial 1 cohort	299	Fair	Low	Direct	Low	Insufficient
Radiant heat superior to other dressings	4 randomized trials	160	Good	Moderate	Direct	Moderate	Moderate
Treatment Strategies Key Outcomes: Surgery							
Recurrence Rate							
Sacral < Ischial vs trochanteric fasciocutaneous/myocutaneous closure	4 observational	560	Fair	Moderate	Indirect	Low	Low
Treatment Strategies Key Outcomes: Adjunctive							
Wound Healing							
Electrical stimulation superior to sham	9 randomized trials	397	Fair	Moderate	Direct	Moderate	Moderate
Electromagnetic therapy equivalent to sham	3 randomized trials	72	Fair	High	Direct	Moderate	Low
Ultrasound equivalent to sham or standard care	3 randomized trials	148	Fair	High	Direct	Moderate	Low
NPWT equivalent to standard care or topical gel	2 randomized trials 1 observational	52 86	Fair	High	Direct	Moderate	Low
Light Therapy equivalent to sham or standard care	5 randomized trials	489	Fair	Low	Direct	Moderate	Low
Laser Therapy equivalent to sham or standard care	4 randomized trials	157	Fair	High	Direct	Moderate	Low
1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?*							
Key Outcomes: Surgery							
Recurrence Rate: Sacral<Ischial vs trochanteric fasciocutaneous/myocutaneous flaps	4 observational	560	Fair	Moderate	Indirect	Low	Low

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)*	Strength of Evidence (High, Moderate, Low, or Insufficient)
Key Outcomes: Adjunctive							
Electrical stimulation vs. sham - Stage II vs III, vs IV pressure ulcers	5 randomized trials	197	Fair	Moderate	Direct	Moderate	Insufficient
Electromagnetic therapy vs. sham	1 randomized trial	30	Fair	~	Direct	Low	Insufficient
1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age; race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? *							
Key Outcomes: Surgery							
Recurrence Rate: Spinal cord injured > other	2 observational	185	Fair to poor	Moderate	Indirect	Low	Low
Key Outcomes: Adjunctive							
Electrical stimulation vs. sham: spinal cord injured patients	4 randomized trials	138	Fair	High	Direct	Low	Low
Electromagnetic therapy vs. sham	2 randomized trials	60	Fair	High	Direct	Low	Insufficient
1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training? *							
Key Outcomes: Surgery							
Sacral vs Ischial vs Trochanteric and Cutaneous vs. fasciocutaneous vs. myocutaneous flaps	5 observational	560	Fair	Low	Indirect	Low	Insufficient
Key Outcomes: Adjunctive							

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)*	Strength of Evidence (High, Moderate, Low, or Insufficient)
Electrical stimulation vs. sham	9 randomized trials	397	Fair	Moderate	Direct	Low	Low
Electromagnetic therapy vs. sham	3 randomized trials	72	Fair	High	Direct	Low	Insufficient
2. What are the harms of treatments for pressure ulcers? *							
<i>Treatment Harms: Surgery</i>							
Complication rates: ischial > sacral and trochanteric surgical repairs	2 observational	3	Fair	Moderate	Indirect	Low	Low
<i>Treatment Harms: Adjunctive</i>							
Electrical stimulation vs. sham	3 randomized trials	146	Fair	Low	Direct	Unclear	Low
Electromagnetic therapy vs. sham	1 randomized trial	30	Fair	NA	Direct	NA	Insufficient
Ultrasound vs. sham	3 randomized trials	101	Fair	Low	Direct	Low	Low
Negative pressure wound therapy	2 observational	77	Fair	Low	Indirect	Unclear	Insufficient
Light therapy vs. sham – no significant harm	4 randomized trials	327	Fair	Moderate	Direct	Low	Low
Laser therapy vs. sham or standard care – no significant harm	4 randomized trials	137	Fair	Moderate	Direct	Moderate	Low
2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline? *							
Complication rates: ischial > sacral and trochanteric surgical repairs	2 observational	376	Fair	Low	Indirect	Low	Low
<i>Adjunctive</i>							
Electrical stimulation vs. sham	3 randomized trials	146	Fair	Low	Direct	Unclear	Insufficient

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)*	Strength of Evidence (High, Moderate, Low, or Insufficient)
2b. Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? *							
Electrical stimulation vs. sham: Overall withdrawal and withdrawal due to adverse events: Frail elderly > younger mostly spinal cord injured patients	3 randomized trials	146	Fair	Moderate	Direct	Low	Low
2c. Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training? *	No studies						

Abbreviations: NA, not applicable.

*Overall strength of evidence ratings are only displayed for statements in intervention categories where there was sufficient evidence from each body of evidence to provide an assessment. Domains were adapted from Owens et al.

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Appendix H

Appendix H. Evidence Tables and Overall Quality Ratings

Evidence Table 1: Support

Evidence Table 1a: Support Trials

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type
Allman, 1987 ¹ US Good	> 18 years old; presence of a pressure sore on sacrum, buttocks, trochanters, or back; activity expected to be limited to bed or chair in hospital for at least one week; patient expected to live at least one week; consent obtained from patient or family after attending MD agreed patient could participate	Previous inclusion in trial; skin graft or flap planned for pressure sore within one week	Number screened NR 140 eligible 72 consented and enrolled 7 (9.7%) withdrew--6 died, 1 withdrew due to nausea and dislike of bed 65 analyzed (31 to air-fluidized bed; 34 to conventional treatment)	Age(Mean): 65.5 vs. 67.6 years Female: 64.5% vs. 52.9% Race: Black: 54.8% vs.67.6%	Air-Fluidized Bed (AF)
Branom, 2001 ² US Poor	Admitted as inpatient to one of the two test sites; Stage III or IV PUs on trunk or pelvis; Bedridden	NR	Screened and eligible: NR Enrolled/analyzed: 20 (10 to air/foam mattress; 10 to low-air-loss mattress); (later 2 patients were switched by physician to study mattress)	Age (Mean), range Air/foam: 72.8 vs. 70.5 vs. 71.5 years Female: NR Race: NR	Air/Foam vs. Low-Air-Loss
Caley, 1994 ³ US Poor	Existing Pressure Ulcer; LAL recommended for treatment by MD or enterostomal therapy nurse.	NR	93 enrolled and randomized; 55 completed (3 weeks in hospital on assigned surface). 106 PUs. Results presented by PUs, not patients	Age(Mean):76 years Female: 60% Race: Caucasian: 87% African American: 13%	Low air loss bed vs. LAL overlay
Clark, 1997 ⁴ UK Fair	Over 65 years old; established PU over the sacrum or ischial tuberosities and perceived by nursing staff to be at moderate to high risk of developing further sores; Stage II, III, or IV with surface area greater than 2 cm ² ; able to sit out of bed for at least 2 hours; serum albumin level of greater than 2.5 mg/dl; expected to remain in study for more than 7 days, able to consent.	PU greater than 15 cm ²	33 eligible and enrolled; 25 analyzed	Age(Mean):84. vs. 80.0 years Female: 72% Race: NR	An AP to a static air-filled cushion.
Day, 1993 ⁵ US Poor	Hospitalized, 18 or older with a stage II, III or IV PU; Life expectancy of at least one week; Activity limited to bed or chair during hospitalization; Informed consent signed; Permission of attending MD	Previous study enrollment; Expected hospitalization less than 7 days; Skin grafting or flap within 7 days of enrollment.	118 screened/83 eligible 83 enrolled (44 to air-suspension, 39 to foam overlay)	Age(Mean):75 vs. 77.1 years Female: 61.4% vs. 53.8% Race: NR	Air suspension vs. foam overlay

Evidence Table 1a. Support Trials, continued					
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type
Devine, 1995 ⁶ Scotland Fair	Patients admitted to Geriatric Unit with or developed PU of Stage II or above (on a five grade scale) and who agreed to participate (or family agreed)	NR	Screened and eligible: NR 41 enrolled (22 to Nimbus 1 and 19 to Pegasus) 30 analyzed (16 Nimbus, 14 Pegasus) 9 died and 2 moved to other hospitals	Age(Mean):81 vs. 84 years Female: 54%/26% Race: NR	Alternating pressure air beds
Evans, 2000 ⁷ Land, 2000 ⁸ UK Good	65 years or older with a Stage III PU or 65 years or older with a Stage II PU and one or more of: difficulty repositioning in bed and unable to tolerate at 30 degree tilt; unable to move in bed; in bed for more than 20h in 24h; Weight greater than 108kg and bed bound; or undergone spinal anesthetic	Spinal metastases; exudating wounds that may lead to hygiene or infection control problems; weight greater than 250 kg.	Screened and eligible: NR Enrolled: 12 in hospital (7 to experimental and 5 to comparator). 20 in nursing home (10 to each group). All enrolled analyzed.	Age (Mean):68 vs. 78 vs. 84.5 vs. 88.5 years Female: 42.9% vs. 60% vs. 100% vs. 90% Race: NR	Alternating pressure mattress overlay
Ferrell, 1993 ⁹ US Good	PU (stage 2 or higher on Shea scale) on truck, buttocks or trochanters; informed consent; approval of primary care MD.	Expected survival of less than one month; previous participation in study; previous or planned surgical excision of PU.	Screened and eligible: NR Enrolled: 84, 43 assigned to low-air loss bed and 41 to foam mattress Analyzed: 84 All followed until healing or departure from study due to death, transfer, discontinuation at subject request or deviation from protocol.	Age(Mean):85 vs. 84 years Female: 49% vs. 51% Race: NR	Low-Air Loss Bed vs. Foam
Groen, 1999 ¹⁰ Holland Fair	Patient in one of three nursing homes; 60 years old or older; PU on truck classified as stage III or IV (article used Grade PU criteria)	Severe or terminal illness	NR/NR/120/101 completed, however if patient was in trial for 14 days, they were included. How many of the 19 who did not complete the full 4 weeks that were included in analysis is not specified.	Age(Mean): 81.9 vs. 83.5 years Female: NR Race: NR	Foam and Water Mattresses
Izutsu, 1998 ¹¹ Japan Poor	Bedridden patients with de cubitus admitted to Miki Long-Term Care Hospital in Japan	Immunocompromised and patients with mycobacterial infections	NR/NR/31/31	Age(Mean): 78 years Female: 58% Race: NR	Automatic rolling air cushioned bed vs. conventional bed with turning

Evidence Table 1a. Support Trials, continued					
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type
Jackson, 1988 ¹² US Poor	(1) 18 years of age or older; (2) had at least one pressure ulcer, stage III, IV, or V; (3) required some form of pressure-relieving device; (4) required at least 14 days of hospitalization from the time they were inducted into the study (this is a strict inclusion criterion was waived and is discussed later); (5) consent to participate could be obtained.	(1) renal disease; (2) fluid restriction, (3) dehydration, (4) congestive heart failure/pulmonary edema (5) urinary incontinence (in which indwelling catheters were contraindicated) and severe diarrhea, (6) daily treatments that required getting the patient into and out of the air-fluidized bed, (7) patient inability to get into an out of the bed without assistance (8) sensory deprivation, and (9) poor ventilatory excursion.	NR/NR/35/35	Age(Mean):77.3 vs. 76.8 years Female: 60% vs. 66.7% Race: NR	Air-Fluidized Bed (AF) vs. non air-fluidized devices
Keogh, 2001 ¹³ UK Poor	Patient over 18 years old; patients had to give consent; likely to stay in bed for at least 12 hours a day; tissue damage no greater than stage I ulcer	Patient with terminal illness; weighing more than 120kg, patients posing a manual handling risk who required an electric bed.	NR/100/100/70 analyzed for a larger study of both prevention and treatment. 14 had PU on admission and were analyzed for treatment.	Age(mean: 71.3 vs. 68.7 years Female: 60% vs. 30% Race: NR	Profiling bed compared to conventional bed
Makhsous, 2009 ¹⁴ US Fair	Wheelchair user with SCI (Paraplegia or tetraplegia) with existing Stage II or III PUs in sacral and/or ischial area; Able to independently use manual or powered wheelchair; Sitting tolerance of at least 4 hours per day	Degenerative disorders of the spine; history of injury or surgery of the pelvis, hip joint and the thigh; hip contractures; severe pain, spasm, and psychological concerns preventing proper cooperation.	NR/NR/44/44	Age(Mean):42.4 vs. 44.5 years Female: 4.5% vs. 9.1% Race: NR	Cyclic pressure relief seating vs. regular wheel chair cushions
Malbrain, 2010 ¹⁵ Belgium Fair	Patients admitted to ICU with high pressure ulcer risk (Norton Score < or = to 8 or a pressure ulcer on admission who were going to require mechanical ventilation for an estimated duration of at least 5 days.	If consent was not obtained from closest relative or at least one of each of the two mattresses studied were not available when the patient was admitted.	NR/NR/16/16	Age(Mean): 56.9 vs.71.5 years Female: 62.5% vs. 37.5% Race: NR	Reactive Air and Active Alternating Pressure
Mulder, 1994 ¹⁶ US Poor	PU Stage III or IV (Int'l Assoc. of Enterostomal Therapies); Size between 1.5 cm x 1.5 cm and 10.0 cm x 20.0 cm	Carcinomatosis; osteomyelitis affecting the target ulcer; uncontrolled target ulcer infection; immune deficiency disorders, and inadequate nutritional status.	NR/NR/49/39	Age(Mean): NR Female: NR Race: NR	Low air loss v. foam
Munro, 1989 ¹⁷ US Fair	Stage II or III ulcers and expected to remain in hospital at least 15 days.	Stage IV ulcers; weight over 250 pounds. Extremely malnourished-<70% of ideal body weight or with serum albumin <2.1g/100 ml	NR/NR/40/40	67.2	AF Bend (Clinitron) vs. Standard

Evidence Table 1a. Support Trials, continued					
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type
Nixon, 2006 ¹⁸ UK Good	Sub group of large study of PU prevention and treatment Common criteria: 55 years old or older; Admitted to participating vascular, orthopaedic, medical or geriatric ward in previous 24 hours; Expected length of stay 7 or more days; Consented to participate Full trial criteria: included restricted mobility or Stage II Ulcer. For sub group analysis of treatment, only patients with Stage II included	Stage III or higher existing PU; Prior participation in trial; Elective surgery patients with planned post op in ICU or admitted more than 4 days pre surgery; Slept in chair at night; Weight more than 140 kg or less than 45 kg	6155/1972/1972/1971	Age (Mean):ITT – 75.4 vs75.0 years Per Protocol - 75.2 vs. 74.5 years Female: ITT – 63.1% vs. 64.8% Per Protocol- 62.1% vs. 63.4% Race: NR	Alternating pressure overlay and mattresses
Rosenthal, 2003 ¹⁹ US Poor	All subjects were alert, had been able to sit in the 6 months before the study, and could still sit up with assistance. Patients with a stage III or IV ulcer were studied.	Patients excluded if (1) they were previously in a trial to treat their current pressure ulcer; (2) they were already on low air loss, or transfer to low air loss was planned (3) skin grafting was planned within 1 week (4) they had an active sinus tract or fistula (5) nutrition was poor, as indicated by albumin levels below 3.0g/dL (6) antibiotics were required to treat methicillin-resistant Staphylococcus aureus, vancomycin-resistant enterococci, or active skin infection; (7) osteomyelitis was diagnosed by radiography or be one scan performed whenever it was suspected by clinical indicators (8) body weight was below 60kg, because such subjects were too small to fit the seating frame and (9) patients were unable to flex both hip and knee past 90 degrees, because such patients tend to slide out of the seat. Further, persons with sacral pressure ulcers were excluded from the study because the sacral area is suspended above the generic total contact seat and hence is not in contact with the seat.	NR/NR/NR/NR	Study 1 Generic Total Contact Seat (GTCS) vs. Low Air Loss (LAL) Bed vs. Bed Overlay: Age(Mean): 70.4 vs. 69.0 vs. 68.6 years Female: NR Race: NR Study 2 Generic Total Contact Seat (GTCS) vs. Low Air Loss (LAL) Bed: Age (Mean):68.0 years vs. 68.7 years Female: NR Race: NR	GTCS vs. LAL vs. overlay
Russell, 2000(a) ²⁰ Russell(b), 2000 ²¹ UK Fair	Presence of Ulcer, Stage II or higher on Torrance Grading scale	Unwilling to participate; randomized equipment not available; previous inclusion in trial and readmitted; weighed more than 25 stone.		Age(Mean):83.9 vs. 84.6 years Female: NR Race: N	Two brands of AP mattresses

Evidence Table 1a. Support Trials, continued					
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type
Russell, 2003 ²² UK Fair	Admitted between April 2001 and April 2002; PU stage I or above on European Pressure Ulcer Advisory Panel scale.	Unwilling to participate; previously in trial; obese	NR/NR/199/153	Age(Mean):80.4 vs. 79.8 years Female: 53.0% vs. 56% Race: NR	Nimbus 3 vs. RIK (fluid overlay)
Strauss, 1991 ²³ US Fair	Had at least one stage 3 or 4 PU; patients whom the medical provider believed patient would probably require future hospitalization for PU related care; severely limited mobility; adequate social support to use home AF therapy; likely to comply; likely to like at least one year; at least 16 years old; out of hospital at least 3 weeks; medical provider willing to closely manage care in home.	Febrile or septic or otherwise required immediate hospitalization; PU on radiated skin.	NR/112/97/69	Age (mean): 65 vs. 63 years Female: 50% vs. 48% Race: NR	AF bed vs. other

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Allman, 1987 ¹ US Good	Characteristic: AF(n=31), Conventional (n=34) Multiple Sores: 26, 24 Stage Superficial-Epidermis: 4, 4 Superficial- Dermis: 12, 16 Deep-Subcutis: 9, 11 Deep-Bone/Muscle: 2, 1 Deep-Eschar: 4, 2 Sore size < 7.8 cm ² : 15, 17	Air-fluidized bed with positioning ever 4 hours from 0700 hours to 2300 hours.	Conventional Therapy: Alternating air mattress covered by a foam pad with repositioning every 2 hours and elbow or heel pads as needed.	NA	Patients with one or more healed sores during study AF: 20 of 31 Conventional: 15 of 34 p=0.10	Change in total surface area, cm ² Median/Range AF -1.2/ -38.0 to +15.5 Conventional: +0.5 / -55.1 to +94.7 p=0.01 50% reduction in total surface area AF: 9 Conventional: 8 p=0.64	NR	Change in pain intensity from baseline AF (n=13) vs. Conventional (n=14) Decreased: 8 vs. 4 No change: 5 vs. 7 Increased: 0 vs. 3; p=0.01 Change in comfort from baseline AF (n=13) vs. Conventional (n=14) Increased: 8 vs. 3 No change: 4 vs. 4 Decreased: 1 vs. 6; p=0.04
Branom, 2001 ² US Poor	Average cm ³ at start Air/Foam: 32.5 LAL: 50.44 Stage III n (%) Air/Foam: 3 (30%) LAL: 2 (25%) Stage IV Air/Foam: 7 (70%) LAL: 6 (75%) Switched 3 (on 2 patients)	Non powered air mattress with foam overlay (brand: PressureGuard Constant Force Technology by Span-American Medical Systems)	Low-air-loss mattress	NA	NR	Mean wound size, amount closed cm ³ , rate of closure per week, % closed, % closed per week At 3 weeks Air/Foam: 15.5, 17.0, 5.7, 43.0%, 14.4% LAL: 34.57, 17.1, 5.7, 21.8%, 7.2% At 8 weeks Air/Foam: 25.8, 3.5, 60%, 9.0% LAL: 22.2, 2.8, 39.6%, 5.0%	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Caley, 1994 ³ US Poor	Severity NR. 106 ulcers total. Authors report that "the number of large (>7.8 cm ²) and small (<7.8cm ²) were comparable for both study groups.	LAL Bed (Monarch, Support Systems International) n=50	LAL overlay (SPR PRLUS, Gaymar Industries, Inc.) n=56	NA	NR	No significant difference Change in Surface Area Median/Mean/Range Overlay: 3.9/10.2/-39.86 to +74.35 Bed: 1.9/3.8/ -28.40 to +51.36 p=0.06 (for mean) Perimeter average of initial and final, cm Median/Mean/Range Overlay: 20.7/23/7/1.57 to 80.25 Bed: 17.8/20.0/ 4.78 to 69.58 p=0.06 (for mean) Healing Progress over time (Change in Surface area/perimeter average) Mean (SD) Overlay: .3872 (.577) Bed: .2219 (.449) p=0.101 DF 102.13 CI (-0.036, +0.363)	NR	NR
Clark, 1997 ⁴ UK Fair	AP Cushion (Group A)/Air Cushion (Group B) # of subjects Stage II= 7/7 Stage III = 2/1 Stage IV= 5/3	AP cushion with 4 cells (Pro-Active 2, Pegasus Airwave) n=14	Static air filled cushion (ROHO Quadro) n=11	NA	No statically significant difference (per author, no test given) AP cushion: 3/14 Static cushion: 5/11	No statically significant difference (per author, no test given) AP/Static for Stage II, change in area absolute change: mean (SEM) 0.13 (0.10)/0.27 (0.17) % change in area per day 2.56(2.10)/ 5.71 (1.68) for Stage III and IV, volume absolute change: mean (SEM) 0.56 (0.23)/0.49(0.26) % change in volume per day 1.00 (0.49)/ 0.68 (0.26)	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Day, 1993 ⁵ US Poor	Air/Foam--number of patients Stage of PU II 25/23 III 6/8 IV 11/4 Unable to Stage 2/4 Modified Norton Scale Scores Air: 8.84 SD 2.84 Foam: 9.03 SD 3.19 not significantly different p=0.6204	Air-suspension bed (brand: TheraPulse, Kinetic Concepts) with 23 Gore-Tex fabric cushions that alternately inflate and deflate	Foam overlay (Geo Matt, Span America) with a geometric design and contour cut into individual foam units.	NA	NR	Initial/ Ending Mean (SD) in cm ² by stage Stage II Air: 12.7 (3.2) /7.3 (2.4) Foam: 10.0 (3.9)/5.3 (2.1) Stage III and IV Air: 51.8 (11.9)/37.1 (8.1) Foam: 13.7 (2.9)/12.4 (3.5) ANCOVA including initial size as covariate for all ulcers found no significant difference (F (1, 78)=0.35, p>0.05)	NR	NR
Devine, 1995 ⁶ Scotland Fair	Initial Sore size (cm ²), range Nimbus: 13.5, 1-110 Pegasus: 12, 3-272 Median Initial Stage, range Nimbus: 3 (2-5) Pegasus: 3 (2-5) Douglas score: Median, range Nimbus: 13 (10-19) Pegasus: 14 (5-15) Norton score: Median, range Nimbus: 10 (7-14) Pegasus: 10 (6-14) Authors report these are not statistically significantly different	Nimbus 1 (rows of figure 8 shaped cells that inflate and deflate over a 10 minute cycle and adjusts to position of patient)	Pegasus Airwave (double layer with a 3 cell alternating cycle of 7.5 minutes).	NA	Wound healing Nimbus: 10 of 16 Pegasus: 5 of 14 not statistically significant	Median reduction per day cm ² Nimbus: 0.089 Pegasus: 0.107 Difference in medians: 0.0 95% CO 0.179 - 0.144 p=0.92	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Evans, 2000 ⁷ Land, 2000 ⁸ UK Good	Waterlow score: high risk=15+, very high risk=20+/Stage Hospital: Expt, 0 high, 7 very high Hospital: Comparator, 2 high, 3 very high Stage II: 3,2 Stage III: 4,3 NH: Expt, 1 high, 8 very high, 1 missing NH: Comparator: 0 high, 9 very high, 1 missing Stage II: 1,2 Stage III: 7,4 Stage IV: 2,4	Alternating pressure mattress: Nimbus 3 (differs from prior models in that it has five heel- guard cells that power down during deflation--no other information provided)	Other brands of alternating pressure mattresses (Pegasus Airwave, Pegasus Biowave and Alpha Xcell, and Pegasus Cairwave).	NA	NR	Median absolute reduction per day (range) Hospital, Nimbus 3: 0.12 cm ² (0-0.21cm ²) Hospital, Other: 0.08cm ² (0.04- 0.33cm ²) not significant NH, Nimbus 3: 0.11 cm ² (0.04- 0.41cm ²) NH, Other: 0.05cm ² (0- 0.48cm ²) not significant Median relative reduction (range) Hospital, Nimbus 3: 2.44% (0- 7.14%) Hospital, Other: 1.34% (1.11- 2.88%) not significant NH, Nimbus 3: 1.57% (0.45- 5.00%) NH, Other: 0.99% (0-2.54%) not significant	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Ferrell, 1993 ⁹ US Good	Shea scale N (%) Superficial ulcers: Stage 2 Low-Air Loss Bed: 25 (58) Foam: 27 (66) p=0.47 Deep ulcers: Stage 3 or 4 Low-Air Loss Bed: 18 (42) Foam: 14 (34) p=0.47	Low-Air Loss Bed (Kinair bed) available for 10+ years at time of study, it consists of multiple inflatable pillows attached to a modified bed frame.	Foam convoluted mattress (10 cm) overlying a hospital mattress. Conventional pressure reduction in the settings at the time.	NA	# (%) Low-Air Loss: 26 (60) Foam: 19 (46) p=0.19 not significant	Decrease in size, mm ² per day Median (25th, 75th percentile) Low Air Loss significantly better All PUs Low-Air Loss: 9.0 (4.0, 19.8) p=0.0002 Foam: 2.5 (0.5, 6.5) p=0.0002 Superficial Low-Air Loss: 9.0 (3.7, 13.1) Foam: 3.2 (0.3, 6.7) p=0.004 Deep Low-Air Loss: 9.9 (4.4, 34.7) Foam: 0.7 (-2.5, 11.5) p=0.02	NR	NR
Groen, 1999 ¹⁰ Holland Fair	Stage III or IV was an inclusion criteria Scoring system used for severity including diameter, depth and wound bed characteristics. Assessment at first screening, number of pressure ulcers: foam mattress group: 4.8 water mattress group: 5.50 not significantly different	High Quality Foam Replacement Mattress (TheraRest): 14cm thick, weighs 9kg, consist of three layers of polyurethane foam of differing thicknesses, comfort layer, load-distributing layer and support layer. Can be arranged at an angle to allow patient to sit up	Water Mattress (Sucutex): consists of three PVC sections, each hold approximately 26 liters held in place by foam frame. Filled mattress weighs approximately 80kg and contains heating element. Cannot be arranged at an angle	NA	Percent completely healed at four weeks A. Foam: 45% B. Water: 48% not significantly different	NR	NR	Reported as complicating factor: see harms
Izutsu, 1998 ¹¹ Japan Poor	Treatment: stage II 39cm ² Comparison: Stage III 21cm ² (article used grade criteria)	Rolling air cushion bed made by Morten company (type RACB-1, Hiroshima), which turned patients to a 15-degree inclined lateral position by an inflating ripple mattress, a longitudinally aligned air inflatable tube.	Conventional bed with their positions being changed every 2 hours between right and left laterals and to supine position by caregivers.	NA	NR	Treatment group saw 52% decrease in wound surface area (19cm ²) Comparison group saw 2% decrease in wound surface area (18cm ²)	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Jackson, 1988 ¹² US Poor	<p>–Air-Fluidized group: 26.7% with stage III 26.7% with stage IV 26.7% with stage V</p> <p>Non-air-fluidized group: 20% with stage III 20% with stage IV 20% with stage V</p>	An Air-Fluidized mattress consisting of millions of silicone-coated soda lime glass beads that lie in a 12-inch layer in the bed. The patient penetrates 4 inches of the 4 layer. Warm, pressurized air lifts the microspheres to the undersurface of the patient, creating a dry fluid environment on which the patient can float. Air flow and temperature can be controlled	A variety of non air-fluidized devices were used, including a non alternating air mattress	NA	NR	9/15 (60%) experienced decreases in primary pressure ulcer area as compared with 9/20 in the comparator group (45%).	NR	NR
Keogh, 2001 ¹³ UK Poor	<p>Experimental group: 11.4% had stage I</p> <p>Comparator group: 28.5% had stage I pressure ulcers</p>	Profiling Bed: electrically operated, four-sectioned and pressure-relieving/reducing mattress	Conventional Bed: standard hospital bed and pressure-relieving/reducing mattress	NA	4 of 4 patients on profiling bed healed; 2 of 10 on the conventional bed.	NR	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Makhous, 2009 ¹⁴ US Fair	<p>Number of stage II, number of stage III Treatment: 12, 10 Comparator: 9, 13; p>0.05; not significant</p> <p>Wound area entering trial (mm²) Mean (SD) Treatment: 1745.8 (1324.9) Comparator: 1672.4 (1938.0); p>0.05; not significant</p> <p>Wound PUSH score Mean (SD) Treatment: 12.9 (2.0) Comparator: 12.8 (2.3); p>0.05; not significant</p>	Wheelchairs with a cyclic pressure-relief seating system that alternates 10 minutes of normal sitting with 10 minutes of off-load sitting.	Regular wheelchairs	NA	1 patient achieved complete wound healing (2.3%)	<p>Percentage reduction in wound area Mean (SD) Treatment: 45.0 (21.) Comparator: 10.2 (34.9) p<0.001</p>	<p>Median time and cumulative probability to 30% wound reduction Median time in days Treatment: 25 Comparator >30 p=0.007</p> <p>Probability to achieve wound closure at 30 days: Treatment: 0.727 Comparator: 0.364 p=0.007</p>	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Malbrain, 2010 ¹⁵ Belgium Fair	PU on admission 9 of 16 patients; 13 ulcers total; 2 deep pressure damage stage III or IV	Nimbus 3 mattress, a fully automatic active alternating pressure mattress replacement with 20 individual cells that inflate and deflate over a 10 minute cycle.	ROHO Dry Floatation mattress overlay, a manually inflatable reactive low- pressure mattress that overlays a normal hospital bed	NA	NR directly. Reported percent of all wounds (present on admission or new during hospital stay) that improved or were unchanged or deteriorated. Improved: Nimbus 82% ROHO 0% p=0.002 Unchanged: Nimbus 18% ROHO 67% NS Deteriorated: Nimbus 0% ROHO 67% p=0.006	Nimbus 3/ROHO p value Change in surface area (cm ²), SD -2.1±2.3/25.8±46.1 0.05	NR	NR
Mulder, 1994 ¹⁶ US Poor	Stage III or IV (International Association of Enterostomal Therapists) N Treatment, Comparator Stage III: 24, 13 Stage IV: 7, 5	Low-Air Loss Bed (Therapulse)	Foam Overlay (Geo Matt)	NA	5 in LAL group, 3 on foam. No statistical test reported.	Decrease in ulcer area. Significantly greater in LAL group. ANCOVA p=0.042 Adjusted for initial stage, percentage change 77% higher for LAL. Decrease in ulcer volume. Not significantly different. ANCOVA p=0.174	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Munro, 1989 ¹⁷ US Fair	Stage II: N=21 (52.2%) Stage III: N=19 (47.5%)	Air fluidized bed (Clinitron)	Standard hospital bed	NA	NR	Mean size of ulcers shrank in the Clinitron bed and expanded over time in the standard bed group. (F=2.6, p=0.05)	NR	Pain scores fell over time in both groups. The Clinitron group demonstrated the greatest change, but the difference was not significantly different (F=0.87, p=0.359)
Nixon, 2006 ¹⁸ UK Good	All had Stage II PU at baseline per inclusion criteria Baseline cm ² Mean (SD), median, range, # missing Overlay: 2.3 (4.4), 0.7, (0.1- 29.2), 5 Replacement: 3.9 (7.9), 1.2, (0.1-48.9), 2	Alternating Pressure Mattress Overlay	Alternation Pressure Mattress Replacement	NA	Overall Complete healing of all PUs: 39 (34.5%) Overlay: 20 (33.9%) Replacement: 19 (35.2%)	Absolute change Mean (SD), median, range, # missing Overlay: 1.0 (2.3), 0.4, (-3.7 to 9.2), 26 Replacement: 2.0 (6.1), 0.3, (- 6.0 to 30.5), 18 Percentage change Mean (SD), median, range, # missing Overlay: -35 (605.5), 100, - 3400 to 100, 26 Replacement 34.4 (108.6), 91.8, (-405 to 100), 18	Median time to healing : 20 days for both groups (p=0.86)	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Rosenthal, 2003 ¹⁹ US Poor	Stage III or IV	Generic Total Contact Seat	Low Air Loss Bed	Bed Overlay	NR	NR	Using the Kaplan- Meier estimation, the median healing time to total healing differed between the groups: GTCS was 3.33 +/- 0.12 months (95% CI: 3.09- 3.58), LAL 4.38+/-0.14 (95% CI: 4.1- 4.65) and bed overlay was 4.55 +/- 0.22 months (95% CI: 4.19- 4.98)	NR
Russell 2000(a) ²⁰ Russell 2000(b) ²¹ UK Fair	Average severity of all ulcers Nimbus 3: 2.46 +/- 0.49 Pegasus: 2.57 +/- 0.48 not significant Highest severity ulcer Nimbus 3: 3.14 0.98 Pegasus: 3.17 0.81 not significant	Nimbus 3 and Aura Cushion	Pegasus Cairewave and Proactive Seating cushion	NA	NR	Used linear growth rate of wound edge (Area change/ circumference/ time increment). Negative values indicate healing. Unit is mm/24hours Mean Pegasus/Nimbus Stage IIa 0.17/1.50 Stage IIb -0.84/0.04 Stage III +: excluded due to insufficient data Median Pegasus/Nimbus Stage IIa -0.16/-0.29 Stage IIb -0.02/0.015 Not statistically significantly different	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain
Russell, 2003 ²² UK Fair	Nimbus/RIK Admission Waterlow score mean (SD) 21.84 (4.59)/21.30 (4.15) Admission Burton score 14.57 (3.33)/14.16 (3.60) neither statistically significantly different	Nimbus 3, Alternating Pressure mattress	RIK Mattress, Fluid overlay system, constant pressure reduction.	NA	NR	NR	NR	NR
Strauss, 1991 ²³ US Fair	Stage 3 and 4 PU	Air-Fluidized Bed (Clinitron Therapy)	Conventional or Standard Included AP beds, air, water and high density foam.	NA	29/47 healed to Stage 2 and were removed from AF bed. Number healed NR for comparator.	NR	Reported for AF group only Mean: 93 days, (SD 42 days)	NR

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	Outcomes: Infection Rate	Outcomes: Osteomyelitis	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting
Allman, 1987 ¹ US Good	See harms	NR	NR	Patients improved (masked assessment by 2 raters) AF: 22 Conventional: 16 p=0.05 Odds of improvement on AF verse Conventional: 5.6 (95% CI: 1.4 to 21.7)	Weekly from enrollment until death or discharge from hospital Median: 13 days Range: 4 to 77 days	Hospital
Branom, 2001 ² US Poor	NR	NR	NR	Goals for treatment vs. results (at admission goal was classified as progressive closure, prepare for flap or maintenance) Air/Foam vs. LAL Achieved: 7 (70%) vs. 4 (50%) Exceeded: 3 (30%) vs. 1 (13%) Not achieved: 0 vs. 3 (37%)	Eight weeks from admission with data collection at 3 and 8 weeks	Other - Acute care with specialty in ventilator and sub-acute center
Caley, 1994 ³ US Poor	NR	NR	NR		One month or until hospital discharge.	Hospital
Clark, 1997 ⁴ UK Fair	NR	NR	NR	NR	Mean days of followup(SEM) AP: 58.64 (15.82) Static: 43.73 (11.32) not significantly different	Other - Hospital and Nursing Homes
Day, 1993 ⁵ US Poor	NR	NR	NR	Mean (SD) of weekly patient assessments of comfort Air (20 patients) 4.1 (1.3) Foam (19 patients) 3.7 (1.3) not significantly different. p>0.05 Note: most patients unable to provide comfort rating due to patient status and difficulty with the measure.	Assessed weekly until discharge.	Hospital

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	Outcomes: Infection Rate	Outcomes: Osteomyelitis	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting
Devine, 1995 ⁶ Scotland Fair	NR	NR	NR	<p>Patient responses on a 10 point scale</p> <p>Median, range</p> <p>How comfortable was the mattress? Nimbus: 8 (5-10) Pegasus: 8 (3-10)</p> <p>How well did you sleep? Nimbus: 8 (4-10) Pegasus: 8(7-10)</p> <p>Nimbus group 9 of 22 were able to report Pegasus group 11 of 19 were able to report</p>	Followed for 4 weeks after enrollment.	Nursing home/LTC
Evans, 2000 ⁷ Land, 2000 ⁸ UK Good	NR	NR	NR	<p>Median weekly comfort rating (1-5 scale, 5 most comfortable)</p> <p>Hospital, Nimbus 3: 5 Hospital, Other: 4 p=0.006</p> <p>NH: Nimbus 3: 5 NH Other: 4 p=0.002</p>	<p>Varied by patient. In hospital until discharged, healed or died.</p> <p>In NH until died, hospitalized, healed, or 'completed' study period.</p> <p>Number of days NR.</p>	Other - Hospital and Nursing Home

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	Outcomes: Infection Rate	Outcomes: Osteomyelitis	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting
Ferrell, 1993 ⁹ US Good	NR	NR	NR	<p>Improvement</p> <p>Change in Stages Median (25th , 75th percentile)</p> <p>Shea scale Low-Air Loss: 2.0 (0, 2) Foam: 1.0 (0,2) p<0.05</p> <p>Sessing scale Median (25th , 75th percentile) Low-Air Loss: 3.0 (1,3) Foam: 1.0 (0,3) p<0.01</p> <p>Cure Probability ratio= Cox hazard ratio (probability of cure with Low-Air Loss divided by the probability of cure with foam for subjects under each condition for the same period of time. Ratio (95% confidence level) p value All PU 2.66 (1.34-5.17) p=0.004 Superficial 2.60 (1.24-5.41) p=0.01 Deep 2.97 (0.61-14.5 p=0.18</p>	<p>Followed until healed, death, transfer, pt. withdrawal or protocol deviation</p> <p>Number followup days Median (25th , 75th percentile) Low Air-Loss: 33 (15, 60) Foam: 40 (21.5, 90.5) p=0.56</p>	Nursing home/LTC
Groen, 1999 ¹⁰ Holland Fair	NR	NR	NR	<p>Change in Severity/Improvement from screening to week 4 [Values NR for week 4, represented in figure]. A Foam from 4.8 to 1.2 (read from graph) B Water from 5.5 to 1.6 (read from graph) Authors report that healing progressed equally, but provided no statistical test of the comparison.</p>	Four weeks from initial assessment and assignment	Nursing home/LTC

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	Outcomes: Infection Rate	Outcomes: Osteomyelitis	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting
Izutsu, 1998 ¹¹ Japan Poor	NR	NR	NR	Improvement in Stage Treatment Group: Decubitus Stage improved from 2.8 to 2.0 (SE 0.3 p<0.01) after three months vs. conventional bed: Decubitus Stage changed from 3.0 to 3.2 (SE 0.2 p>0.5) after three months. Initially, 5 patients experienced sea sickness but were soon acquainted	3 months	Nursing home/LTC
Jackson, 1988 ¹² US Poor	NR	NR	0/15 in treatment group developed new pressure ulcers while 2/20 developed new pressure ulcers.	The differences between the groups with regard to nursing time required for dressing changes and repositioning the patient were not statistically significant. The observed mean times for the treatment group were slightly less compared to the comparator group.	Until discharge (no level of detail reported). Median stay in hospital: 20 days vs. 37.5 days	Hospital
Keogh, 2001 ¹³ UK Poor	NR	NR	NR	No other outcomes reported just for the patients with PUs on admission	5 to 10 days.	Hospital
Makhsous, 2009 ¹⁴ US Fair	NR	NR	NR	Percentage improvement in PUSH score mean (SD) Treatment: 21.9 (24.6) Comparator: 5.8 (9.2) p=0.003	30 days	Community
Malbrain, 2010 ¹⁵ Belgium Fair	NR	NR	NR	Nimbus 3/ROHO p value Change in PUSH score - 1±1.6/3.4±4.8 0.01; change in category (EPUAP) 0±0.6/0.8±1 0.03	Followed until discharge. Mean was 11±5 days	Hospital
Mulder, 1994 ¹⁶ US Poor	NR	NR	NR	NR	12 weeks or ulcer healed, whichever came first.	Nursing home/LTC

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	Outcomes: Infection Rate	Outcomes: Osteomyelitis	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting
Munro, 1989 ¹⁷ US Fair	NR	NR	NR	Nursing time on day 8: Not significantly different Cost of supplies on day 8 AF \$6.70 Comparator: \$17.85 t=3.12, p=0.004	15 days	Hospital
Nixon, 2006 ¹⁸ UK Good	NR	NR	NR	NR	Until healing (skin assessment of Stage 0 1a or 1b), Hospital discharge, or end of trial.	Hospital
Rosenthal, 2003 ¹⁹ US Poor	NR	NR	NR	NR	6 months	Nursing home/LTC
Russell, 2000 ²⁰ Russell, 2000 ²¹ UK Fair	NR	NR	NR	Improvement factor (not defined) No significant difference for all ulcers and sacral ulcers. For heel ulcers, trial was extended because results were near significance, but after 6 additional months of study the difference was still not significant.	To discharge or healed	Hospital
Russell, 2003 ²² UK Fair	NR	NR	NR	Nimbus/RIK # (%) Overall ulcer progress Improved: 60 (71.3)/56 (74.7) No change: 1 (1.2)/ 3 (4.0) Worse: 22 (26.5)/16 (21.3) p=0.67 Worst ulcer progress Improved: 63 (75.9)/63 (84.0) No change: 1 (1.2)/ 4 (5.3) Worse: 19 (22.9)/8 (10.7) p=0.053	Until discharge Average Length of stay Nimbus: 22.17 days RIK: 20.05 days. p=0.23	Hospital

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	Outcomes: Infection Rate	Outcomes: Osteomyelitis	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting
Strauss, 1991 ²³ US Fair	NR	NR	5/47 returned to AF bed after recurrence of stage 3 or 4 PU	Higher proportion of AF assessed as improved by 2 blinded nurse reviewers (not significant, test NR). Improved Reviewer 1 # (%) / Reviewer 2 # (%) AF: 20 (91)/18 (22) Comparator: 8 (62)/10 (77) AF had 55% fewer hospital days and used fewer inpatient resources.	36 weeks	Other

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Harms: Pain	Harms: Dermatologic Complication	Harms: Bleeding	Harms: Infection	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Allman, 1987 ¹ US Good	See outcomes	New skin breakdown AF: 9 of 31 Conventional: 15 of 34 p=0.24	1 serious episode of epistaxis in AF requiring transfusion (AF decreases humidity and could be cause of drying)	No significant difference in pneumonia, urinary tract infections, sepsis or fever	No difference in heart failure	4 withdrew due to difficulty in transferring from AF beds, 2 returned by MD, 1 MD decided was improved enough, 1 transferred to ICU	1 of 31, see bleeding	Support Systems International, Inc. American Pharmaceutical Company (provided supplies), Henry J. Kaiser Family Foundation, Burroughs- Wellcome Scholar in Pharmacoepidemiology.
Branom, 2001 ² US Poor	NR	NR	NR	NR	NR	NR	NR	Mattress supplied by Span-America Medical System
Caley, 1994 ³ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Clark, 1997 ⁴ UK Fair	NR	Authors report no subjects developed new PUs	NR	NR	NR	2 (1 from each group) withdrew due to malfunction of the cushion	NR	Raymor Ltd. supplied Quadtro cushions. Funding by Pegasus Airwave Ltd.
Day, 1993 ⁵ US Poor	NR	NR	NR	NR	NR	NR; all withdrawal reported as due to death or discharge prior to 7 days	NR	Supported in part by funding from KCI
Devine, 1995 ⁶ Scotland Fair	NR	NR	NR	NR	NR	NR	NR	Supported by HNE healthcare grant for a part time research nurse and provision of 3 Nimbus 1 mattresses
Evans, 2000 ⁷ Land, 2000 ⁸ UK Good	NR	NR	NR	NR	NR	NR	NR	Huntleigh Healthcare
Ferrell, 1993 ⁹ US Good	NR	NR	NR	NR	NR	9 subjects in the foam mattress group were deviated from the protocol because their ulcers became substantially worse or failed to heal.	NR	Jewish Home for the Aged of Greater Los Angeles Sepulveda VA Geriatric Research and Education Clinical Center West Los Angeles VA Geriatric Research and Education Clinical Center; Kinetic Concepts International

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Harms: Pain	Harms: Dermatologic Complication	Harms: Bleeding	Harms: Infection	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Groen, 1999 ¹⁰ Holland Fair	% of Patients Pain Week: Foam, Water 0: 40.0, 20.0 1: 26.7, 16.7 2: 21.7, 11.9 3: 9.6, 5.3 4: 4.1, 3.8	% of patients Eczema Week: Foam, Water 0: 10.0, 1.7 1: 0, 0 2: 1.7, 0 3: 3.8, 0 4: 0, 0 Maceration 0: 16.7, 13.3 1: 15.0, 8.3 2: 6.7, 1.7 3: 5.8, 3.5 4: 4.1, 3.8 Authors report the differences between groups were not significant (test or p value not provided)	NR	NR	NR	NR	NR	NR
Izutsu, 1998 ¹¹ Japan Poor	NR	NR	NR	NR	NR	None	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Harms: Pain	Harms: Dermatologic Complication	Harms: Bleeding	Harms: Infection	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Jackson, 1988 ¹² US Poor	NR	NR	Among the 15 patients in the treatment group, all had some granulation or bleeding at both entry and endpoint. Among 17 patients in the comparator group with evolutions at both entry and endpoint, 14 continued to have granulation or bleeding. In one subject, granulation or bleeding ceased; in two subjects, granulation or bleeding developed. These findings were not statistically significant.	NR	NR	NR	NR	Support Systems International
Keogh, 2001 ¹³ UK Poor	NR	NR	NR	NR	NR	NR	NR	Huntleigh Healthcare Ltd
Makhsous, 2009 ¹⁴ US Fair	NR	NR	NR	NR	NR	NR	NR	National Institutes of Health and Falk Medical Research Trust
Malbrain, 2010 ¹⁵ Belgium Fair	NR	NR	NR	NR	None reported	None	NR	Beds, but no other support provided by manufacturers. No other funding source reported.
Mulder, 1994 ¹⁶ US Poor	NR	NR	NR	NR	NR	NR	Author state "There were no major adverse affects which could be attributed to the study devices." No specifics provided	Kinetic Concepts, Inc.

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	Harms: Pain	Harms: Dermatologic Complication	Harms: Bleeding	Harms: Infection	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Munro, 1989 ¹⁷ US Fair	NR	NR	NR	NR	NR	NR	authors report "None of the patients developed any of the problems sometimes associated with Clinitron beds.	Support Systems International
Nixon, 2006 ¹⁸ UK Good	NR	NR	NR	NR	NR	NR	Nine reported for the full trial, but not separated for the cohort with existing PU. These included 4 falls, 3 cot-side incidents, one contact dermatitis and one patient who caught back on bed rail when mattress deflated during transfer.	National Health Service, Health Technology Assessment
Rosenthal, 2003 ¹⁹ US. Poor	NR	NR	NR	NR	NR	NR	NR	Equipment loaned to hospital by manufacturers.
Russell, 2000 ²⁰ Russell, 2000 ²¹ US Fair	No statistically significant difference in the amount of pain reported.	NR	NR	NR	NR	NR	NR	Equipment loaned to hospital by manufacturers
Russell, 2003 ²² UK Fair	NR	NR	NR	NR	NR	NR	NR	KCI Medical
Strauss, 1991 ²³ US Fair	NR	"several" had dry skin and one mild dehydration	NR	NR	NR	NR	NR	Support Systems International

Evidence Table 1b: Support Observational Studies

Author, year Country Overall Quality Rating	Population: Eligibility Criteria	Population: Exclusion Criteria	Population Data: Number Screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention: Type	Intervention: Type comment	Support - subcategories	Intervention Ulcer Type/Severity at Baseline (Intervention Onset)
Ochs, 2005 ²⁴ US Fair	Enrolled in National Pressure Ulcer Long-Term Care Study (NPULS)--18 years old or older and with length of stay of 14 days or longer during study period; Have at least one PU documented in medical record; Been treated on one of the three groups of support surfaces.	Treated on support surface for less than 5 days	2,486 / 664// 664/664	Age (Mean): 79.3 vs. 77.4 vs. 67.6 years Female: 65.9% vs. 63.9% vs. 45.1% Race: Race data only available for 182 (27.4%) out of 664; Caucasian: 66.5% African American: 28.6% Other: 4.9%	Support Surface	Comparison of air fluidized to two other types	Largest ulcer per patient Initial surface area cm ² mean (SD) range Group 1: 11.3 (24.7) 0.04-384 Group 2: 22.2 (34.2) 0.12-224 Group 3: 56.5 (94.6) 0.5-540 Stages Group 1 # (%), Group 2 # (%), Group 3 # (%) Not staged: 10 (2.2), 3 (2.5), 0 (0) Stage I: 47 (10.2), 9 (7.6), 3 (3.7) Stage II: 288 (62.2), 45 (37.8), 15 (18.3) Stage III: 59 (12.7), 23 (19.3), 14 (17.1) Stage IV: 32 (6.9), 29 (24.4), 44 (53.7) Eschar: 27 (5.8), 10, 8.4), 6 (7.3)	Air fluidized therapy (Group 3)

Evidence Table 1b: Support Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Pain	Outcomes: Infection Rate	Outcomes: Osteomyelitis
Ochs, 2005 ²⁴ US Fair	Non powered overlays, powered low-air-loss overlays and mattresses, powered low-air-loss reducing beds, and alternating pressure surfaces (Group 2)	Overlay and replacement mattresses such as dry pressure mattresses, gel pressure pads, and air and water pressure overlays (Group 1)	Air fluidized beds	<p>Mean change in cm²/per week</p> <p>Mean (SD) range All ulcers Group 1: 1.5 (7.5) -24.0 to 112.0 Group 2: 1.8 (7.9) -45.5 to 43 Group 3: 5.2 (18.9) -26.6 to 151.7 ANOVA p=0.0071</p> <p>Stage I/II: Group 1: 1.6 (8.5) -24.0 to 112 Group 2: 2.4 (6.3) -9.6 to 29.1 Group 3 8.8 (35.9) -9.8 to 151.7 ANOVA p=0.0229</p> <p>Stage III/IV/eschar: Group 1: 1.1 (3.6) -7.0 to 20.2 Group 2: 1.4 (9.0) -45.5 to 42 Group 3: 4.1 (4.1) 26.6-48.6 ANOVA p=0.0259</p> <p>Group 3 statistically significantly better</p> <p>Subset stage III/IV with baseline size 20-75 cm² Group 1: 2.5 (9.4) -30. to 29.6 Group 2: -2.1 (23.1) -117.0 to 41.4 Group 3: 2.3 (12.1) -99.0-35.0</p> <p>Groups 1 and 3 significantly better than 2 (p=0.0399)</p>	NR	NR	NR	NR	NR

**Evidence Table 1b:
Support
Observational
Studies, continued**

Author, year Country Overall Quality Rating	Outcomes: Recurrence Rate	Other: Please Specify	Timing: Duration of Followup	Setting	Setting Comment	Harms: Pain	Harms: Dermatologic Complication	Harms: Bleeding	Harms: Infection	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate	Funding Source
Ochs, 2005 ²⁴ US Fair	Hospitalizations and ER visits Number (%) of patients with 1 or more Group 1: 47 (10.2%) Group 2: 23 (19.0%) Group 3: 6 (7.3%) Probability of difference 1 vs. 2 p=0.0080 2 vs. 3 p=0.0195 1 vs. 3 p=0.4184		Three months	Hospital - Nursing home/LTC	NR	NR	NR	NR	NR	NR	NR	Analyses were done on person level and episode level, where episode is each ulcer for a 7-10 day period. As conclusion are the same, person level is included here.	Hill-Rom

Evidence Table 2: Support Quality Rating

Evidence Table 2a: Support Trials Quality Rating

Author, Year Country	(1) Appropriate Randomization Technique	(2) Allocation concealment adequate?	(3) Groups (intervention and comparator) similar at baseline?	(4) Eligibility criteria specified?	(5) Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	(7) Dropout rate percent	(8) Intention- to-treat analysis	(9) Appropriate Statistical Analyses	Overall Quality Rating	Funding Source
Allman,1987 ¹ US	Yes	Yes	Yes	Yes	Yes	a)Yes b)No c)Yes d)Yes	Yes	Yes	Yes	Good	Support Systems International, Inc. American Pharmaceutical Company (provided supplies), Henry J. Kaiser Family Foundation, Burroughs- Wellcome Scholar in Pharmacoepidemiology.
Branom, 2001 ² US	No	No	Yes	Yes	No	a) NA b)No c)No d)Yes	Yes	No	No	Poor	Mattress supplied by Span-America Medical System
Caley, 1994 ³ US	Unclear	No	Yes	Yes	No	a)Yes b)No c)No d)No	No	Unclear	Yes	Poor	NR
Clark, 1997 ⁴ UK	Yes	Yes	Yes	Yes	No	a)Yes b)No c)No d)No	Yes	No	Unclear	Fair	Raymor Ltd. supplied Quadro cushions. Funding by Pegasus Airwave Ltd.
Day, 1993 ⁵ US	Yes	Yes	No	Yes	No	a)No b)No c)No d)No	Unclear	Unclear	Yes	Poor	Kinetic Concepts, Inc.
Devine, 1995 ⁶ Scotland	Yes	Yes	Yes	Yes	No	a)Yes b)No c)Yes d)No	Yes	Yes	Yes	Fair	HNE Healthcare
Evans, 2000 ⁷ Land, 2000 ⁸ UK	Yes	Yes	Yes	Yes	Yes	a)Yes b)No c)No d)No	Yes	Yes	Yes	Good	Huntleigh Healthcare

**Evidence Table
2a: Support Trial
Studies Quality
Rating, continued**

Author, Year Country	(1) Appropriate Randomization Technique	(2) Allocation concealment adequate?	(3) Groups (intervention and comparator) similar at baseline?	(4) Eligibility criteria specified?	(5) Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	(7) Dropout rate percent	(8) Intention-to- treat analysis	(9) Appropriate Statistical Analyses	Overall Quality Rating	Funding Source
Ferrell, 1993 ⁹ US	Unclear	Yes	Yes	Yes	No	a)Yes b)Yes c)Yes d)Yes	No	Yes	Yes	Good	Jewish Home for the Aged of Greater Los Angeles Sepulveda VA Geriatric Research and Education Clinical Center West Los Angeles VA Geriatric Research and Education Clinical Center; Kinetic Concepts International
Groen, 1999 ¹⁰ Holland	Yes	Yes	Yes	Yes	No	a)Yes b)No c)Yes d)No	Yes	Unclear	Unclear	Fair	NR
Izutsu, 1998 ¹¹ Japan	No	No	Yes	Yes	No	a)Yes b)No c)No d)No	Yes	Unclear	Yes	Poor	NR
Jackson, 1988 ¹² US	Unclear	No	Yes	Yes	No	a)No b)No c)No d)No	Yes	No	Yes	Poor	Support Systems International
Keogh, 2001 ¹³ UK	Yes	Yes	Yes	Yes	Unclear	a)Yes b)No c)No d)No	No	No	Unclear	Poor	Huntleigh Healthcare Ltd
Makhsous, 2009 ¹⁴ US	Unclear	Unclear	Yes	Yes	No	a)Yes b)No c)Yes d)No	Yes	Yes	Yes	Fair	National Institutes of Health and Falk Medical Research Trust
Malbrain, 2010 ¹⁵ Belgium	Yes	Yes	Yes	Yes	No	a)No b)No c)No d)No	Yes	Unclear	Yes	Fair	Beds, but No other support provided by manufacturers. No other funding source reported.
Mulder, 1994 ¹⁶ US	No	No	Yes	Yes	No	a)Yes b)No c)No d)No	No	Yes	Yes	Poor	Kinetic Concepts, Inc.

Evidence Table 2a: Support Trial Studies Quality Rating, continued												
Author, Year Country	(1) Appropriate Randomization Technique	(2) Allocation concealment adequate?	(3) Groups (intervention and comparator) similar at baseline?	(4) Eligibility criteria specified?	(5) Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	(7) Dropout rate percent	(8) Intention-to- treat analysis	(9) Appropriate Statistical Analyses	Overall Quality Rating	Funding Source	
Munro, 1989 ¹⁷ US	Unclear	Unclear	Yes	Yes	Unclear	a)Yes b)No c)No d)No	No	No	Yes	Fair	Support Systems International	
Nixon, 2006 ¹⁸ UK	Yes	Yes	Yes	Yes	No	a)Yes b)No c)Yes d)Yes	No	Yes	Yes	Good	National Health Service, Health Technology Assessment	
Rosenthal, 2003 ¹⁹ US	No	Yes	Yes	Yes	No	a)Yes b)No c)Yes d)No	Yes	No	Yes	Poor	General statement that author has No financial interest in the results	
Russell, 2000 ²⁰ UK	No	No	Yes	Yes	Yes	a)Yes b)No c)No d)No	No	No	Yes	Fair	Equipment loaned to hospital by manufacturers.	
Russell, 2000 ²¹ UK	Unclear	Unclear	Yes	Yes	Yes	a)Yes b)No c)No d)No	No	No	Yes	Fair	Equipment loaned to hospital by manufacturers	
Russell, 2003 ²² UK	Yes	Yes	Yes	Yes	No	a)Yes b)No c)No d)Yes	Yes	No	Yes	Fair	NR	
Strauss, 1991 ²³ US	Yes	Unclear	Yes	Yes	Yes	a)Yes b)No c)No d)No	No	Yes	Unclear	Fair	Support Systems International	

Evidence Table 2b: Support Observational Studies Quality Rating

Author, year Country	Study Type	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	Overall Quality Rating	Funding Source
Ochs, 2005 ²⁴ US	Cohort	Yes	No	No	Yes	No	Yes	Yes	No	Fair	Hill-Rom

Evidence Table 3: Nutrition

Evidence Table 3a: Nutrition Trials

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type: Specify	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Cereda, 2009 ²⁵ Italy Good	Residents of long-term care, age 65+ with recent stage II, III and IV PU (NPUAP)	Presence of acute illness or chronic disease possibly affecting the nutritional intervention and healing process.	371/39/30/28	Treatment: mean age 82.1 69% female p=0.71 race NR Comparator mean age 81.4 60% female race NR	Nutrition; 30kcal/kg per day plus 400mL oral supplement vs. 30kcal/kg per day plus standard nutrition	Intervention PU n=13 15% stage II 31% stage III 54% stage IV mean area 2151mm ² Comparator PU n=15 20% stage II 27% stage III 53% stage IV mean area 2,069mm ²	30kcal/kg per day plus 400mL oral supplement with 20% of calories from protein	30kcal/kg per day plus standard nutrition with 16% of calories from protein	NA	12 weeks	4 long-term care facilities

Evidence Table 3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type: Specify	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Desneves, 2005 ²⁶ Australia Poor	Bedridden elderly patients with stage II, III and IV PU. Comparator groups did not have PU, half were at high risk for developing PU and the other half were not bedridden nor were they at high risk for developing PU.	Clinical suspicion or diagnosis of osteomyelitis; patients with diabetes mellitus; receiving enteral or parenteral nutrition support; individuals prescribed hydroxyurea or greater than 10mg of steroids/day.	NR/NR/16/16	Diet A: mean age 63.0 33% female race NR Diet B: mean age 75.6 40% female race NR Diet C: mean age 83.2 40% female race NR	Nutrition; protein, arginine, vitamin C, zinc.	75% with stage II PU 19% with stage III PU 6% with stage IV PU (Stages according to Australian Wound Management Association Clinical Practice Guidelines which are compatible with NPUAP)	Diet A: Standard hospital diet	Diet B: standard hospital diet plus two TetraPaks of a high-protein, high-energy supplement providing an additional 500 kcal: 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc (brand name Resource Fruit Beverage)	Diet C: standard hospital diet plus two TetraPaks of a defined arginine-containing supplement supplying an additional 500 kcal: 21g protein, 0g fat, 500mg vitamin C, 30mg zinc and 9g arginine (brand name Resource Arginaid Extra)	3 weeks	Hospital
Lee 2006 ²⁷ US Poor	Residents of long-term care facilities with stage II, III or IV PU	Terminal diagnosis; hospice care; protein-restricted diet due to renal insufficiency; active metabolic or gastrointestinal diseases; food allergies; use of corticosteroids or antibiotics for wound infection; failure to provide informed consent	295/89/89/71	NR	Nutrition: collagen protein hydrolysate supplement vs. placebo	Treatment PU n=75 65% stage II 17.8% stage III 17.2% stage IV (NPUAP) Comparator PU n= 33 51% stage II 26.2% stage III 22.8% stage IV	Standard care plus concentrated, fortified, collagen protein hydrolysate supplement (Pro-Stat) 15g in a 45mL dose	Standard care plus placebo: noncaloric liquid indistinguishable from study product	NA	8 weeks	Long-term care facilities

Evidence Table 3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type: Specify	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Meaume 2009 ²⁸ Bulgaria France Germany Italy Romania Spain Fair	Over 60 years; written informed consent to participate; heel PU stage II or III in process of recovery with early signs of granulation tissue, after accidental immobilization. (NPUAP)	Confined to bed 24 hours a day before the development of PU; PU entirely covered by necrosis or fibrin, infected ulcer; poorly controlled type I or II diabetes; dialyses patient; active neoplastic disease; parenteral nutrition serum albumin <22g/l advanced peripheral arterial occlusive disease	194/165/165/ 160	Intervention: mean age 81 p=0.760 65.9% female p=0.017 race NR Comparator mean age 80.5 47.4% female race NR	Nutrition: ornithine alpha- ketoglutarate vs. placebo	Treatment 38.8% stage II 47.1% stage II or III p=0.656 14.1% stage III mean ulcer area 8.7cm ² Comparator 32.0% stage II 53.3% stage II or III 14.7% stage III mean ulcer area 8.2cm ²	10g of ornithine alpha- ketoglutarate per day with 200ml of water or with food at lunch	Placebo of similar aspect and taste administered in the same way	NA	6 weeks	Hospital
Myers 1990 ²⁹ US Poor	Patients with non- surgically debrided PU, admitted to medical center over 2 year period	NR	80/80/80/80	Mean age 70 43% female Race NR	Nutrition: oral supplements vs. wound care	7.5% stage I 41.2% stage II 20% stage III 31.2% stage IV mean ulcer size 0.92mm (stage criteria on p19 but not specified whether it is NPUAP or otherwise) (Stage criteria is compatible with NPUAP but is specific to this study)	Treatment A: wound care Treatment B: Prescribed nutritional support including oral supplements, tube feedings, parenteral nutrition, vitamins and trace elements Treatment C: wound care and nutritional support	Standard hospital care	NA	7 days	Hospital

Evidence Table 3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type: Specify	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Ohura 2011 ³⁰ Japan Poor	Tube-fed patients; NPUAP stage III-IV PU in the sacral, coccygeal, trochanteric, or calcaneal region; Albumin (Alb) 2.5-3.5 g/dL, Braden scale 9-17.	Current condition or history of serious liver or renal disorder; severe diabetes mellitus; arteriosclerosis obliterans; or a malignant tumor (within the past 5 years); Unmanageable severe general condition; unevaluable pressure ulcer wounds.	NR/NR/60/50	Intervention age: 81.4 p=0.738 sex: 71.4% female p=0.658 race: NR Comparator age: 80.6 sex: 65.5% female race: NR	Nutrition: calorie supplementation	Intervention Wound size 30cm ² comparator Wound size 40cm ²	Intervention group administered calories accordingly. Standard tube-feeding formula (Brand name Racol) at mean of 1384kcal/day.	Standard tube-feeding formula (Brand name Racol) at mean of 1092kcal/day	NA	12 weeks	Hospital
ter Riet 1995 ³¹ The Netherlands Good	Residence in a nursing home or hospital; at least 1 existing pressure ulcer. Patients with stage II ulcers could only participate if de-epithelization had persisted for at least 7 days without interruption.	Difficulties swallowing; frequent vomiting; osteomyelitis in the ulcer area; idiopathic hemochromatosis; thalassemia major; sideroblastic anemia; Cushing's syndrome or disease; pregnancy; radiotherapy in the ulcer area; use of antineoplastic agents or systemic glucocorticosteroids and a high probability to drop out and already taking vitamin C supplements in excess of 50mg/day.	NR/NR/88/79	NR	Nutrition: vitamin C supplementation	Intervention stages II and III: 86.0% comparator stages II and III: 77.8 % (Study uses grade criteria to categorize PU)	Intervention Ascorbic acid, 500mg twice daily	Comparator Ascorbic acid, 20mg daily	NA	12 weeks	Nursing home and Hospital

Evidence Table 3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type: Specify	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
van Anholt 2010 ³² Czech Republic, Belgium, The Netherlands, Curacao Fair	Age 18 to 90 years; at least one stage III to IV PU; receiving standard care and standard diet without nutritional supplements for at least 2 weeks before the study.	Malnourished; severe medical conditions; non-pressure-related ulcers; life expectancy shorter than 6 months; receiving palliative care; use of corticosteroids; dietary restrictions.	NR/NR/47/43	Oral nutritional supplements (ONS) mean age 76.2 63.6% female race: NR Comparator mean age 73.0 47.6% female race: NR	Nutrition: calorie and vitamin/mineral supplementation.	ONS stage III: 77% stage IV: 23% Size cm ² : 10.5 comparator stage III: 67% stage IV: 33% Size cm ² : 11.5 (PU stages are in accordance with EPUAP, which are compatible with NPUAP)	Nutritional Supplement 750 kcal/day 85.2g carbohydrate 60g protein (includes 9g arginine) 21g fat, several vitamins and minerals	Non-caloric flavored placebo.	NA	8 weeks	Health care centers Hospitals Long- term care facilities

Evidence Table 3a: Nutrition Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Cereda, 2009 ²⁵ Italy Good	7.6% complete wound healing (1 patient)	NR	Pressure Ulcers decreased from 2,151mm ² at baseline to 701mm ² at 12 weeks. 68% improvement in wound surface area	Pressure Ulcers decreased from 2,069mm ² at baseline to 1228mm ² at 12 weeks 41% improvement in wound surface area	Area was reduced 40% at 6 weeks and 70% at 12 weeks	Area was reduced 30% at 6 weeks and 40% at 12 weeks	3 subjects
Desneves, 2005 ²⁶ Australia Poor	NR	NR	NR	NR	Estimate Diet B: 14.8 weeks to completely heal. Diet C: 5 weeks too completely heal.	Estimate Diet A: 15.6 weeks to completely heal.	NR
Lee 2006 ²⁷ US Poor	NR	NR	NR 60% decrease in PUSH score p<0.05	NR 48% decrease in PUSH score	Treatment group showed about twice the rate of healing compared with comparator group	Treatment group showed about twice the rate of healing compared with comparator group	NR
Meaume 2009 ²⁸ Bulgaria France Germany Italy Romania Spain Fair	N=2	N=3	Mean decrease in area for PU (equal or less than) 8cm ² was 2.3cm ²	Mean decrease in area for PU (equal or less than) 8cm ² was 1.7cm ²	Mean closure rate for PU (equal or less than) 8cm ² was 0.07 cm ² /day	Mean closure rate for PU (equal or less than) 8cm ² was 0.04cm ² /day p=0.007	NR

Evidence Table 3a: Nutrition Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Myers 1990 ²⁹ US Poor	NR	NR	Treatment A Mean change in ulcer size was 2.76mm Treatment B Mean change in ulcer size was 2.60mm Treatment C Mean change in ulcer size was 2.34mm Treatment A: 70% improvement Treatment B: 70% improvement Treatment C: 65% improvement	Mean change in ulcer size was 2.70mm 50% improvement	NR	NR	NR
Ohura 2011 ³⁰ Japan Poor	24% at 12 weeks	19% at 12 weeks	Mean wound size decreased from 30cm ² to 0.5cm ² Wound surface improved 83%	Mean wound size decreased from 40cm ² to 7cm ² Wound surface improved 82%	Mean wound size decreased to 2cm ² at 6 weeks and 0.5cm ² at 12 weeks	Mean wound size decreased to 9cm ² at 6 weeks and 7cm ² at 12 weeks	NR
ter Riet 1995 ³¹ The Netherlands Good	40% healed at 11 weeks	55% healed at 12 weeks	Mean surface reduction: 0.21cm ² /week 13.88%/week	Mean surface reduction: 0.27cm ² /week 22.85%/week	30% of ulcers healed at 6 weeks and 40% at 11 weeks	30% of ulcers healed at 6 weeks and 55% at 12 weeks	NR
van Anholt 2010 ³² Czech Republic, Belgium, The Netherlands, Curacao. Fair	27% at 8 weeks	24% at 8 weeks	Mean ulcer size decreased from 10.5 to 2cm ² Wound area improved 81%	Mean ulcer size decreased from 11.5 to 3cm ² Wound area improved 74%	9% of ulcers healed at 4 weeks and 27% at 8 weeks	No ulcers healed at 4 weeks, and 24% at 8 weeks.	NR

Evidence Table 3a: Nutrition Trials, continued

Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Cereda, 2009 ²⁵ Italy Good	9 subjects experienced infection (p=0.07, Fisher exact test)	NR	NR	NR	NR	NR	NR	NR
Desneves, 2005 ²⁶ Australia Poor	NR	NR	NR	NR	NR	NR	NR	NR
Lee 2006 ²⁷ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Meaume 2009 ²⁸ Bulgaria France Germany Italy Romania Spain Fair	NR	NR	NR	NR	NR	NR	NR	NR
Myers 1990 ²⁹ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Ohura 2011 ³⁰ Japan Poor	NR	NR	NR	NR	NR	NR	NR	NR
ter Riet 1995 ³¹ The Netherlands Good	NR	NR	NR	NR	NR	NR	NR	NR
van Anholt 2010 ³² Czech Republic, Belgium, The Netherlands, Curacao. Fair	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 3a: Nutrition Trials, continued											
Author, Year Country Overall Quality Rating	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Cereda, 2009 ²⁵ Italy Good	NR	NR	NR	NR	NR	NR	NR	NR	2 deaths	7%	Nutricia
Desneves, 2005 ²⁶ Australia Poor	NR	NR	NR	NR	NR	NR	NR	NR	3 (2 deaths, 1 discharge)	19%	Windermere Foundation Ltd.
Lee, 2006 ²⁷ US Poor	NR	NR	NR	NR	NR	NR	Nausea or distention (n=4)	NR	2 deaths	12%	Medical Nutrition, US, Inc
Meaume, 2009 ²⁸ Bulgaria France Germany Italy Romania Spain Fair	NR	NR	NR	NR	NR	NR	NR	30 of 347 adverse events considered serious but none related to studied medication	8 fatalities	18%	CHIESI France and Italy
Myers, 1990 ²⁹ US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Ross Laboratories
Ohura, 2011 ³⁰ Japan Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	27.6% in intervention group; 16.7% in comparator group	Health and Labor Sciences Research Grants (Comprehen- sive Research on Aging and Health)
ter Riet, 1995 ³¹ The Netherlands Good	NR	NR	NR	NR	NR	NR	NR	NR	8 deaths, 3 withdrawals.	12% overall	The Netherlands Organization for Scientific Research.
van Anholt, 2010 ³² Czech Republic, Belgium, The Netherlands, Curacao. Fair	NR	NR	NR	NR	NR	NR	Higher rate of gastrointestinal symptoms in nutritional support group.	NR	Two subjects in nutrition support group withdrew due to gastrointestinal symptoms. One death and one stroke in comparator group.	10% in each group	Nutricia

Evidence Table 3b: Nutrition Observational Studies

Author year Country Overall Quality Rating	Study Type	Confounders assessed in analysis	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Barnes, 2007 ³³ US Poor	Observational	Hypertension Cardiovascular disease Paraplegia/ quadriplegia organic brain syndrome	Stage III-IV PU; chronically malnourished patients.	Extremity decubital	NR/28/28/28	Age (Mean): NR Female: NR Race: NR	Stages III and IV	Prealbumin levels of 18.0 to 45.0 mg/dL.	NA	NA	≥30 days	Hospital
Breslow, 1993 ³⁴ US Good	Observational: non-randomized trial	Malnourished; dementia; cerebrovascular accident; anozic encephalopathy; spinal cord injury; Parkinson's disease.	NPUAP Stage III-IV PU; malnourished; nutritional risk (Article reports Shea stage II-IV PU criteria)	Insulin dependent diabetes, renal failure, liver dysfunction, hematocrit <25%, chronic use of steroids; cancer; significant gastrointestinal dysfunction	NR/48/48/28	Age (Mean): 72 vs. 72 years Female: 62% vs. 53% Race: NR	Total PU n=33 Treatment A mean surface area 14.9 cm ² 38% stage III 62% stage IV Treatment B mean surface area 28.6cm ² 47% stage III 53% stage IV	14% of total calories as protein (brand name Ensure, 1000 calories and 37 g protein/L) tube fed or as meal supplements	24% of total calories as protein (brand name Sustacal, 1060 calories and 61g protein/L) tube fed or as meal supplements	NA	8 weeks	Nursing home/long- term care facility
Brewer, 2010 ³⁵ Australia Fair	Observational: prospective	Spinal cord injury Paraplegic Quadriplegic	Spinal cord injury, 18+ years of age, residing in Melbourne metropolitan area and category II, III or IV PU.	Phenylketonuria, Sepsis, Chronic renal failure, metabolic disease, diabetic foot ulcers and clinical suspicion of osteomyelitis, receiving hydroxyurea or greater than 10 mg prednisolone or 1.5 mg dexamethasone/ day.	68/35/35/35	Age (Mean): 52.2 vs. 49.9, p=0.648 Female: 6% vs. 0%,p=1.00 0 Race: NR	Treatment PU n=30 mean area 4.5cm ² p=0.406 Comparator PU n=26 mean area 6.7 cm ²	Two sachets of commercially available argine- containing powder per day until full wound healing had been confirmed	Participants were compared to a historical comparator group.	NA	10 months	Community

Evidence Table 3b: Nutrition Observational Studies, continued												
Author year Country Overall Quality Rating	Study Type	Confounders assessed in analysis	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Houston, 2001 ³⁶ US Fair	Observational	Older population	Older, institutionalized and under current PU treatment	NR	NR/NR/70/68	Age (Mean): NR Female: NR Race: NR	Treatment 84% stage II 16% stage III-IV Comparator 91% stage II 9% stage III-IV	Zinc sulfate (440mg/d, similar to 100mg elemental zinc/day)	Similar care, no oral supplements	NA	30 days	Nursing home/long-term-care facility
Frias Soriano, 2004 ³⁷ Spain Fair	Observational Open prospective multicentre intervention	Primary diagnosis: 26% Dementia/Alzheimer 13% Paralysis 15% Pressure ulcer 3% Fracture 3% Diabetes 15% Infection/pneumonia 26% Other	18+ years with stage III and IV PU. (Article used grade PU criteria)	Renal or hepatic insufficiency.	NR/63/63/39	Age (Mean):74.7 vs. 49.9 years Females: 54% vs. 0% Race: NR	Mean wound area: 23.6cm ² stage III: 36% stage IV: 62% Location: sacrum (26), heel (5), back (1)	1 to 3 packets each day of 200 ml package containing: energy (250 kcal), protein	NA	NA	3 weeks	10 hospitals
Spungen, 2001 ³⁸ US Poor	Observational	Spinal cord injury Paraplegic Tetraplegic	Nonhealing PU existing for longer than two months; full-thickness PU that extended through fascia into muscle, tendon, or bone.	NR	9/9/9/9	Age (Mean): 49.9 years Female: 0% Race: NR	Mean ulcer size 26.42 cm ² 11% stage III 89% stage IV	20 mg daily of oxandrolone 20 g daily of glutamine.	NA	NA	Up to 12 months	VA hospital
Yamamoto, 2009 ³⁹ Japan Poor	Observational: retrospective	Malignant neoplasm Cerebral disease Orthopedic disease Cardiovascular disease Gastrointestinal disease Renal disease Respiratory disease	Medical Center patients with either improved or worsened PU wounds.	Discharged prior to PU healing or died within 1 month	NR/40/40/40	Age (Mean): 67.4 vs. 71.7 years Female: NR Race: NR	Improved group 38% stage I 62% stage II Unimproved group 26% stage I 74% stage II	More than 30kcal/kg per day	Less than 20 kcal/kg per day	NA	6 weeks	Hospital

Evidence Table 3b: Nutrition Observational Studies, continued

Author, year Country Overall Quality Rating	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate	Recurrence Rate	Pain	Other: Specify
Barnes, 2007 ³³ US Poor	NR	Mean improvement of 0.82 cc reduction of wound volume per day.	NR	NR	NR	NR	NR	NR
Breslow, 1993 ³⁴ US Good	NR	Treatment A 12.7cm ² p<0.02 15% improvement Treatment B 24.4cm ² p<0.05 15% improvement	Treatment A PU decreased by 2.1cm ² in 8 weeks Treatment B PU decreased by 4.2 cm ² in 8 weeks	NR	NR	NR	NR	NR
Brewer, 2010 ³⁵ Australia Fair	100% complete wound healing 30 PU healed in the intervention group and 26 PU healed in the historical comparator group	NR	The mean time to healing for the intervention group was 10.5 weeks, mean time to healing for the historical comparator group was 21.1 weeks p=0.006	NR	NR	NR	NR	NR
Houston, 2001 ³⁶ US Fair	NR	Improvement in volume of PU stages III or IV of intervention patients but not in stage II PU	NR	NR	NR	NR	NR	NR
Frias Soriano, 2004 ³⁷ Spain Fair	NR	Mean area reduced by 19% to 19.2cm ² p<0.05	0.34cm ² /day.	Incidence of exudate decreased by 53% Incidence of malodor decreased by 67% Incidence of inflamed edges decreased by 36% p<0.05	NR	NR	Incidence of pain decreased by 13%	NR
Spungen, 2001 ³⁸ US Poor	88.9% complete wound healing	Wound surface area closed completely in 88.9% of the study population	33.3% healed after 3 months, 22.2% healed after 4 months, 11.1% healed after 6 months, 22.2% healed after 12 months of treatment	NR	NR	NR	NR	NR

Evidence Table 3b: Nutrition Observational Studies, continued								
Author, year Country Overall Quality Rating	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate	Recurrence Rate	Pain	Other: Specify
Yamamoto, 2009 ³⁹ Japan Poor	52% of patients healed or improved	NR	52% of patients healed or improved in 6 weeks	NR	NR	NR	NR	NR

Evidence Table 3b: Nutrition Observational Studies, continued									
Author, year Country Overall Quality Rating	Pain	Dermatologic Complications	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Barnes, 2007 ³³ US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Breslow, 1993 ³⁴ US Good	NR	NR	NR	NR	NR	NR	NR	NR	NR
Brewer, 2010 ³⁵ Australia Fair	NR	NR	NR	NR	NR	NR	NR	NR	NR
Houston, 2001 ³⁶ US Fair	NR	NR	NR	28% had infection requiring antibiotics 5% had infection requiring antibiotics	NR	20% of intervention group experienced nausea/vomiting 2% experienced nausea/vomiting	2 withdrawals	3%	NR
Frias Soriano, 2004 ³⁷ Spain Fair	NR	NR	NR	NR	NR	NR	NR	NR	NR
Spungen, 2001 ³⁸ US Poor	NR	NR	NR	NR	NR	NR	0	NR	NR
Yamamoto, 2009 ³⁹ Japan Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 4: Nutrition Quality Rating

Evidence Table 4a: Nutrition Trial Quality Rating

Author Year Country	Appropriate randomization technique?	Allocation concealment adequate?	Groups (intervention and comparator) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout rate <20 percent?	Intention- to-treat analysis?	Appropriate statistical analyses?	Overall Quality Rating	Funding Source
Cereda, 2009 ²⁵ Italy	Yes	No	Yes	Yes	Yes	a)Yes b)No c)Yes d)Yes	Yes	Yes	Yes	Good	Nutricia
Desneves, 2005 ²⁶ Australia	No	No	No; quite big age differences (20 year difference between A and C)	Yes	Yes	a)No b)No c)Yes d)No	Unclear	Yes	Yes	Poor	Windermere Foundation Ltd.
Lee 2006 ²⁷ US	No	No	Yes	Yes	Yes	a)Yes b)No c)No d)No	Yes	Yes	Yes	Poor	Medical Nutrition, US, Inc
Meaume 2009 ²⁸ Bulgaria France Germany Italy Romania Spain	Yes	No	Yes	Yes	Yes	a)Yes b)No c)No d)No	No	Yes	Yes	Fair	CHIESI France and Italy
Myers 1990 ²⁹ US	No	No	Yes	Yes	Yes	a)Yes b)No c)No d)No	Yes	Yes	Yes	Poor	Ross Laboratories
Ohura 2011 ³⁰ Japan	Yes	Yes	Yes	Yes	No	a)Yes b)No c)Yes d)No	Yes	No	Yes	Poor	Health and Labor Sciences Research Grants (Comprehensive Research on Aging and Health)

Evidence Table 4a: Nutrition Trial Quality Rating, continued											
Author Year Country	Appropriate randomization technique?	Allocation concealment adequate?	Groups (intervention and comparator) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout rate <20 percent?	Intention- to-treat analysis?	Appropriate statistical analyses?	Overall Quality Rating	Funding Source
ter Riet 1995 ³¹ The Netherlands	Yes	No	Yes	Yes	Yes	a)Yes b)No c)Yes d)No	Yes	Yes	Yes	Good	The Netherlands Organization for Scientific Research.
Van Anholt 2010 ³² Czech Republic Belgium The Netherlands Curacao	No	No	Yes	Yes	Unclear	a)Yes b)No c)Yes d)No	No	Yes	Yes	Fair	Nutricia

Evidence Table 4b: Nutrition Cohort Study Quality Rating

Author, Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	(9) Were outcomes pre specified and defined, and ascertained using accurate methods?	Overall Quality Rating	Funding Source
Barnes 2007 ³³ US	Yes	Unclear	Unclear	Yes	No	No	Yes	Unclear	Yes	Poor	NR
Breslow, 1993 ³⁴ US	Yes	Yes	Yes	Yes	Unclear	No	Yes	Unclear	Yes	Good	Mean Johnson Nutritional Group, Francis Scott Key Medical Center General Clinical Research Center, Johns Hopkins Academic Teaching Home Award
Brewer 2010 ³⁵ Australia	Yes	Yes	Yes	Yes	Unclear	No	Yes	No	Yes	Fair	NR
Frias Soriano 2004 ³⁷ Spain	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Fair	NR
Houston 2001 ³⁶ US	Yes	Unclear	Unclear	Yes	No	No	Yes	Unclear	Yes	Fair	NR
Spungen 2001 ³⁸ US	No	No	Yes	Unclear	Unclear	Yes	Yes	No	Yes	Poor	NR
Yamamoto 2009 ³⁹ Japan	Unclear	No	No	Yes	Unclear	No	Yes	Unclear	Yes	Poor	NR

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

Evidence Table 5a: Dressings Trials

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Alm, 1989 ⁴⁰ Sweden Fair	Long-term ward patients with pressure ulcers whose condition was evaluated with the Norton scale less than or equal to 9 and greater than or equal to 7.	Pressure ulcers evaluated at less than 7 on the Norton scale at screening	NR/NR/50/50 PU N=56	Age (Mean): 83.5 Female: 75% Race: NR	Dressing: Hydrocolloid vs. Wet saline gauze	Hydrocolloid Dressing vs. Wet Saline Gauze Dressing N=31 vs. 25 PUs Mean Norton Score: 12 (+/- 2) vs. 13 (+/- 3) Median area: 2.02 vs., 2.44 cm Median granulated area: 0.32 vs., 0.25 cm Ulcer 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, 1998 ⁴¹ UK Poor	If in the judgment of the investigator, treatment with either dressing was deemed appropriate; leg ulcers of any etiology except those with venous ulceration that was able to tolerate high compression therapy; stage II or III or other granulating wounds with moderate to high levels of exudates.	Pregnant and lactating women, Patients with stage I or IV PU, wounds that were too large to be covered by one dressing, Wounds expected to heal within one week, Wounds with sloughy or necrotic tissue or grossly infected wounds	NR/100/100/96 N=32 PUs	Age(Mean): 76 years Female: 76% vs.78% Race: NR	Dressing: Hydrocolloid vs. Hydrocellular	Hydrocellular vs. Hydrocolloid: Stage II: N=11 (65%) vs. N=6 (40%) Stage III: N=6 (35%) vs. N=9 (60%) Note: Mean area at baseline available for aggregate data only which includes venous leg ulcers and PU

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Banks, 1994a ⁴² UK Fair	Written, informed consent; older than 16 years of age, both sexes included; with shallow, moist pressure sores, stage II and III; pressure sores that could be covered adequately by a single 10 x 10 cm dressing; subjects who could be managed to prevent further lesions developing	Subjects with lesions which involved tissues other than skin and subcutaneous fat; subjects with stage I, IV and V pressure ulcers; dry or necrotic lesions; subjects taking systemic corticosteroids; subjects whose pressure ulcers had been dressed with either of the study dressings in the preceding two weeks; subjects with a sensitivity reaction to either dressing; infected pressure sores; subjects who were incapable to giving their opinion of the dressing; incontinent of urine or feces with pressure sores on the sacrum or any other site likely to be soiled repeatedly	NR/NR/40/40	Age(Mean):71 vs. 73 years Female: 55% vs. 40% Race: NR	Dressing: polyurethane (Spyrosorb) vs. hydrocolloid (Granuflex E)	Polyurethane vs. Hydrocolloid Wound area (cm ²) mean 1.47 vs. 1.51 Location: Buttock 50% vs. 45% Sacrum 20% vs. 5% Other 30% vs. 50% Stages II and III: 100% vs. 100%
Banks, 1994b ⁴³ UK (Wales) Fair	Had given written, informed consent; over 16 years old; shallow, moist pressure sores stage II or III; could be managed to prevent further lesions developing	Lesions which involved tissues other than skin or subcutaneous fat; stage I, IV or V PU; dry or necrotic lesions (could be included after debriding); taking systematic corticosteroids; PU that had been dressed with either of the study dressings in preceding two weeks; previously shown sensitivity reaction 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): 73 vs. 74 Female: 69% vs. 56% Race: NR	Dressing: Semi-Permeable polyurethane vs. Hydrocolloid	Polyurethane vs. Hydrocolloid Wound area (cm ²): mean 1.4 vs. 2.4 Ulcer location: Buttock: 62% vs. 56% Sacrum: 31% vs. 38% Other: 7% vs. 6%

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Belmin, 2002 ⁴⁴ France Fair	Location on the sacrum, elsewhere on the pelvic girdle, or on the heel; surface area of less than 50 cm ² , as measured by planimetry; granulation tissue area not covering more than 50% of the ulcer surface, as visually estimated by the investigator; and no clinical evidence of active local infection.	Serum albumin concentration was below 25 g/L; if they were being treated with radiotherapy, cytotoxic drugs, or corticosteroids; or if surgical or palliative care was needed.	NR/NR/110/ 110	Age(Mean):84.8 vs. 82.2 years Female: 74% vs. 68% Race: NR	Dressing: alginate + hydrocolloid	Treatment vs. comparator: Ulcer stage III: 40 (71.4%) vs. 43 (82.7%). Ulcer stage IV: 16 (28.6%) vs. 9 (17.3%) Mean surface area: 14.7cm ² vs. 12.6cm ²
Brod, 1990 ⁴⁵ US Poor	Patients were to have an estimated life expectancy of at least 6 months and normal marrow, hepatic, and renal function; elderly with stage II or III pressure ulcer	NR	NR/NR/43/43	Age(Mean): 86 vs. 82 years Female: NR Race: NR	Poly-hema vs. Hydrocolloid	Poly-hema group: Median area 2.5cm ² Hydrocolloid: median area 1.9cm ²

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Brown-Etris, 2008 ⁴⁶ US Fair	Patients with at least 1 stage II or shallow stage III, minimally to moderately draining pressure ulcer or any anatomical location that, in the investigator's opinion, could have been treated with a hydrocolloid dressing	<p>Patients with skin disease or abnormal conditions on or near the product application site.</p> <p>Patients with insulin-dependent diabetes that, in the investigator's opinion, had inadequately controlled blood sugar. Patients receiving steroid, immunosuppressive therapy, or radiation to the area where the pressure ulcer was located.</p> <p>Patients participating in another clinical research study.</p> <p>Exclusion criteria for specific wounds: Wounds with more than 50% necrotic tissue, or in the opinion of the investigator, should have undergone debridement before application of an occlusive or semiocclusive dressing.</p> <p>Wounds with greater than 1cm undermining or tunneling.</p> <p>Wounds that required use of a filling or packing material.</p> <p>Wounds that required the dressing to be cut to a smaller size or to a specialty shape. Wounds that exhibited clinical infection as evidenced by purulent, malodorous, or recent increase in drainage and/or periwound erythema, or elevated temperature, or required treatment with a concomitant medication or product.</p>	NR/NR/72/72	Age(Mean): 78.3 vs. 72.7 years , p=0.157 Female: 62.9% vs. 48.6%, p=0.225 Race: NR	Dressing: Transparent Absorbent Acrylic Dressing (TAAD)	<p>Wound area (cm²): TAAD (1.5cm²) vs. HD (2.5cm²). p=0.752</p> <p>Stage II: 65.7% vs. 59.5% Stage III: 34.3% vs. 40.5%</p> <p>Ulcer location: sacrum, buttock, ischium, heel, other</p>

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Chang, 1998 ⁴⁷ Malaysia Poor	Presenting stage II or III PU; at least 18 years of age; provide written informed consent (in the case of unconscious patients, consent was provided by a close relative)	Immunocompromised; infected PU; known sensitivity to study dressings	NR/NR/34/34	Age(Mean): 57.6 years Female: NR Race: NR	Dressing: Saline soaked gauze vs. DuoDERM CGF hydrocolloid dressing	Hydrocolloid vs. Gauze: N=17 vs. 17 stage II N=11 vs. 7 stage III N=6 vs. 7 Note: 3 cases are missing from the gauze group, N is reported at 17, however only 14 PU are reported Localization (both groups): Sacral: N=30 Iliac: N=3 Greater Trochanter: N=1
Colin, 1996 ⁴⁸ Multinational Poor	NR	NR	NR/NR/135/135	Age(Mean): 79 vs. 81 years Female: 58% vs. 50% Race: NR	1. Hydrogel (IntraSite) 2. Dextranomer paste (Debrisan)	Hydrogel vs. Dextranomer Paste: N=67 vs. 68 Stage: I: 0% vs. 1.4% II: 23.8% vs. 14.7% III: 56.7% vs. 66.1% IV: 19.4% vs. 17.6% Area: <4cm ² : 22.3% vs. 26.4% 4-13cm ² : 37.3% vs. 36.7% >13cm ² : 40.2% vs. 36.7%
Colwell, 1993 ⁴⁹ US Poor	Clinically non-infected stage II or III pressure ulcers	Any factors that could adversely influence wound healing such as uncontrolled diabetes mellitus or radiation therapy; clinical signs and symptoms indicating the pressure ulcer was clinically infected; stage I or IV pressure ulcer; a pressure ulcer that could not be accurately staged. Patients were also excluded if they did not remain in the study for a minimum of 8 days or were receiving any other kind of treatment that could confound the results of the assigned pressure ulcer treatment	NR/NR/94/70 PU N=97	Age(Mean): 68 vs. 68 years Female: 45% vs. 49% female Race: NR	Hydrocolloid (DuoDerm) vs. Saline gauze	Hydrocolloid (DuoDerm) vs. Saline gauze: Pressure ulcer n= 48 vs. 49 Ulcer Stage(Mean): II: 69% vs. 44% III: 31% vs. 56% Ulcer Location: Sacrum/coccyx: 60% vs. 55% Other: 40% vs. 45%

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Darkovich, 1990 ⁵⁰ US Poor	Stage I and II PU, 2-30 cm ² ; located on sacrum, trochanters, lower extremities, buttocks, scapula, and heel; blood sugar levels less than 180mg/dl; improved nutritional status	Known infection, sinus tracts, or fistulae in the wound; radiation therapy	NR/NR/90/90 PU N=129	Age(Mean): 75 years Female:61% female Race: NR	Dressing: Hydrogel (Biofilm) vs. Hydrocolloid	Hydrogel (BioFilm) vs. Hydrocolloid: N= 62 vs. 67 PUs Mean wound size: 11.0cm ² vs. 9.2cm ² Stage I: 43.5% vs. 46.2% Stage II: 56.4% vs. 53.7% (Article used Enis and Sarmienti pressure ulcer grade)
Day, 1995 ⁵¹ US, UK, Canada Fair	Of legal consenting age; stage II or III PU in the sacral area which required treatment	Clinical signs and symptoms of wound infection; treatment with systemic steroid medication; had a condition known to impair healing; patients receiving concomitant topical or local treatment of their PU which could not be interrupted; chronic skin disorders, hypersensitivity to skin adhesives; participation in a similar study within one month of treatment	NR/NR/103/96 PU N=96	Age(Mean): 72 vs. 78 years Female: 42.5% vs. 55.1% Race: Caucasian 95.7% vs. 91.8% Black, Hispanic, American Indian, Asian 4.2% vs. 8.1%	Dressing: Hydrocolloid triangle vs. Hydrocolloid oval	Hydrocolloid triangle vs. Hydrocolloid oval: N= 52 vs. 51 Stage II: 81% vs. 84% Stage III: 19% vs. 16% Ulcer location: Sacrum
Gorse, 1987 ⁵² US Fair	Stage II and III PU Stage IV PU that only extended into muscle	Adjacent osteomyelitis or extension of PU into fascia, bone, and or joint space Venous stasis and ischemic ulcers of the extremities Rapidly fatal underlying disease Planned hospital discharge within 7 days of treatment initiation	NR/NR/52/52 PU N=128	Age(Mean): 72 vs. 68 years Female: 0% Race: NR	Hydrocolloid (DuoDerm) vs. Saline gauze + chramine-T (Dakin's solution)	Hydrocolloid (DuoDerm) vs. Saline gauze + chramine-T (Dakin's solution): N= 76 vs. 52 Stage: II: 86.8% 78.8% III: NR IV:NR Ulcer location: Femoral trochanteric: 19.7% vs. 26.9% Sacral/Coccygeal: 47.45% vs. 38.5% Ischiatic: 15.8% vs. 19.2% Other: 17.1% vs. 15.4% Article used Shea scale for stages

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Honde, 1994 ⁵³ France Fair	Hospitalized patients; aged >65 years; stage II to IV pressure (Shea) at any site and less than 10 cm in diameter.	Signs and symptoms of clinical infection (which should be treated before entry); necrotic pressure sores with black crust (to be removed before entry); pressure sores on irradiated skin; sores requiring surgery; deep ulcers extending to bone with risk of osteitis complications; patients on air-fluidized beds	NR/NR/168/ 167	Age(Mean):80.4 vs. 83.5 years, p<0.05 Female: 67.5% vs. 76.1% Race: NR	Dressing: amino acid copolymer vs. hydrocolloid dressing	Treatment vs. comparator: Mean surface area 8.99 cm ² vs. 6.85 cm ² Stage II: 63.7% vs. 54.0% Stage III: 30.0% vs. 40.2% Stage IV: 6.2% vs. 5.7%. These differences were not significant. 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, 2005 ⁵⁴ Turkey Good	Not reported. Only stated hospitalized patients with spinal cord injury and with pressure ulcers	NR	NR/NR/27/27	Age(Mean): 35.3 vs. 29.7 years, p=0.32 Female: 11.1% Race: NR	Dressing: hydrogel-type dressing (Elastogel) vs. gauze	Treatment vs. comparator: Stage I: 24% vs. 25% Stage II: 68% vs. 70.8% Stage III 8% vs. 4.2% Ulcer size: 4.13cm ² vs. 6.45cm ²
Kerihuel, 2010 ⁵⁵ France Poor	PU's with an area ranging from 5 to 100 cm ² . PU's of less than three month's duration. PU's stage II or IV. PU's considered by investigators to have abundant necrotic tissue and slough	Inability to give written consent to participate; severe illness; pressure ulcers totally covered with necrotic tissue or requiring surgical debridement; infected ulcers requiring systemic antibiotics; known allergy to study dressing; previous use of Actisorb.	NR/NR/60/59	Age(Mean):83.2 vs.78.5 years Female: 83% vs. 70% Race: NR	Dressing: Actisorb vs. DuoDerm	Treatment vs. comparator: Wound area (cm ²): 25.3 vs. 22.6 Location: Heel 75.9% vs. 66.7% Sacrum 3.8% vs. 20% Other 10.3% vs. 13.3%
Kim, 1996 ⁵⁶ Korea Poor	Patients admitted to the Department of Rehabilitation Medicine presenting stage I or II decubitus ulcers	Patients presenting stage III or IV ulcers, with systemic infections, with endocrinologic disorders, difficulty keeping pressure relieving positions, or with aggravated general conditions due to other factors	NR/NR/44/44	Age(Mean): 50.5 vs. 46.9 years Female: 11.5% vs. 27.7% Race: NR	Dressing: Hydrocolloid occlusive dressing (DuoDERM) vs. wet-to-dry gauze dressing	Hydrocolloid vs. gauze: N=26 vs. 18 NPAUP Stage Stage I: 23% vs. 33.3% Stage II: 76.9% vs. 66.6% Localization: Sacral ulcer: 26.9% vs. 22.2% Other pelvic girdle ulcer: 26.9% vs. 38.8% Other regions: 46.1% vs. 38.8 Mean Ulcer size mm ² : 172 vs. 192

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Kloth, 2002 ⁵⁷ US Poor	NR	Poorly controlled diabetes; terminally ill; undermining greater than 1cm; >50% of wound bed covered with necrotic tissue after debridement; an allergy to adhesives	NR/56/43/40	Age (Mean): 77.9 vs. 78.1 years Female: 68% vs. 57% Race: NR	Dressing: Normothermic Noncontact Wound Therapy vs. Standard care	Treatment vs. comparator: Mean wound surface area: 5.4cm ² vs. 4.1cm ² .
Kraft, 1993 ⁵⁸ US Good	Stage II and III ulcers. Specific eligibility criteria not reported.	Stage I and IV pressure ulcers. Clinically infected ulcers. Patients on special beds. Unstable insulin-dependent diabetes. Serum albumin < 2gm. Hemoglobin < 12 gm. Class IV congestive heart failure. Chronic renal insufficiency. Documented severe peripheral vascular disease. Documented severe COPD.	NR/NR/NR/38	Age (Mean): 56 years Female: NR Race: 36.8% African-American -63.2% Caucasian -	Dressing: Epi-Lock vs. saline gauze	Stage II: 57.8% Stage III: 42.1%
Kurzuk-Howard, 1985 ⁵⁹ US Poor	All patients who were admitted with decubitus ulcers	NR	NR/NR/43/43	Age(Mean): 76.8 years Female: 69.7% Race: NR	Dressing: moist wound healing (Op-Site) vs. dry wound healing (Alternative Treatment)	Stage I: 16.2% Stage II: 41.8% Stage III: 32.5% Stage IV: 9.3% Treatment vs. comparator mean wound size: 8.5 vs. 6.39
Matzen, 1999 ⁶⁰ Denmark Good	Patients with stage III or IV non-infected pressure sores located in the sacral (65.6%) or trochanteric (34.3%) areas.	Patients with diseases or taking drugs known to impair healing were excluded	NR/NR/32/32	Age(Mean):82 years vs. 84 years Female: 88.2% vs. 80% Race: NR	Dressing: hydrogel vs. saline gauze	All patients had stage III and IV wounds

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Meaume, 2005 ⁶¹ France Good	Hospitalized adult patients who could be seen every day 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 clear signs of infection requiring the use of systematic antibiotics or lymphangitis and or fever; however, at least two of the following criteria had to be present: continuous pain; erythema; edema; heat; moderate to high levels of serous exudate. At least 50% of the wound covered with yellow slough, discolored, or friable granulation tissue, pocketing or undermining at the base of the wound, or foul odor	Patients who had received systemic antibiotics during the previous five days for any reason; patients with a very poor life expectancy or with a clinical condition that might interfere with wound healing such as active carcinoma, vasculitis, use of systemic corticosteroids, immunosuppressive agents, radiation therapy or chemotherapy within the past 30 days; patients who had received a topical chemical debriding agent within the previous seven days	NR/NR/101/99	Age(Mean): 74.9 vs. 77.6 years Female: 58.8% vs. 68.8% Race: NR	Dressing: silver-releasing hydroalginate dressing (Silvercel) vs. calcium alginate dressing (Algosteril)	Silvercel vs. Algosteril: Area cm ² : 22.5 vs. 22.4
Meaume, 2003 ⁶² Finland Poor	Aged 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	Presence of underlying disease that according to investigator, might possibly interfere with the treatment of the pressure ulcer; food and/or intake score of 2 or below on the Modified Norton Scale; allergic/hypersensitivity problem with any material in the two dressings; wound larger than 11 cm x 11 cm; or a wound with black necrotic tissue or clinical signs of local infection at baseline.	NR/NR/38/38	Age NR Female: NR Race: 100% Caucasian	Dressing: silicone, vs. hydropolymer	Stage II ulcer Mostly located on heels and the sacral area

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Motta, 1999 ⁶³ US Poor	Stage II or III PU No underlying medical condition such as long term steroid use or uncontrolled diabetes Understood and executed informed consent agreement	NR	NR/NR/10/10	Age(Mean):60 years Female: 50% Race: NR	Dressing: polymer hydrogel (AcryDerm Sheet Wound Dressing) vs. traditional hydrocolloid (DuoDERM)	Stage II: 30% Stage III: 70% Wound size, mean: treatment vs. comparator 7.51cm ² vs. 0.55cm ² Localization: Foot/Ankle: 20%; coccyx: 40%; buttock: 10%; sacrum: 10%; elbow: 20%
Mulder, 1993 ⁶⁴ US Poor	All patients enrolled into the study had either a stage II or III pressure ulcer no smaller than 10 cm x 10 cm. All patients were at least 18 years of age, signed an informed consent, and had a life expectancy of at least 2 months.	Stage IV wounds or those with tendon, bone capsule, of fascia exposure; pregnant women, patients receiving chemotherapy, patients with documented wound infection, patients with extensive undermining (>1.0 cm)of the ulcer, patients testing positive for human immunodeficiency virus, or patients receiving more than 10 mg of corticosteroids per day.	NR/NR/67/53	Age(Mean):56.7 vs. 63.1 vs. 57.2 years Female: 21.7% vs. 15.0% vs. 9.5% Race: White - 7.3% vs. 80% vs. 70%; Black - 18.2% vs. 15% vs. 30% Hispanic - 4.5% vs. 5% vs. 0%	Dressing: hydrogel (Clearsite) vs. hydrocolloid (DuoDERM) vs. standard wet-to-moist gauze	Clearsite vs. DuoDERM vs. standard Stage II: 8 vs. 9 vs. 5 Stage III: 14 vs. 13 vs. 18
Neill, 1989 ⁶⁵ US Poor	18 years or older Written consent obtained Stage II or III PU	Patient: Inability to give written consent Insulin dependent diabetes Skin problems Radiation treatment of PU area Medical condition that would interfere with study PU: Stage I or IV 1.5cm in depth, undermining, or 5.6cm x10cm in area Skin disease around PU PU infected Peripheral vascular ulcers Scare, contusions, abrasions, or open skin in immediate PU area	NR/NR/100/65 PU N=87 Subject N=65	Age(Mean):NR ["no difference in the mean age of subjects"] Female: NR Race: NR	Dressing: Hydrocolloid (Tegasorb) vs. Saline gauze (WTD)	Hydrocolloid vs. gauze Mean size: 8.3cm ² vs. 7.6cm ² Stage II: 59.5% vs. 75.5% Stage III: 40.4% vs. 24.4%

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Oleske, 1986 ⁶⁶ US Poor	<p>Patient Characteristics: 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. If the patient is unable, due to disease process, must have next of kin who is capable of communicating in English</p> <p>PU Characteristics: Involves a skin break caused by pressure Skin break is a minimum, but does not extend into muscle (stage I or II only) Is not contained in an area that is currently being irradiated Has no evidence of infection (absence of redness, swelling, purulence, and/or malodor with or without drainage)</p>	NR	59/22/16/15	Age(Mean):69 years Female: NR Race: NR	Dressings: Polyurethane vs. normal saline	<p>Polyurethane vs. saline: Total surface area mean 3.5cm² vs. 7.9cm²</p> <p>Stage: I: 22.2% vs. 50% II: 77.7% vs. 50%</p> <p>Localization: Gluteal or coccyx</p>
Payne, 2009 ⁶⁷ US Good	At least 18 years of age; either gender; not pregnant or (if of appropriate age) using contraception; and have a Stage II pressure ulcer with slight to moderate levels of exudate. If a patient had more than one eligible wound, the largest wound was selected to receive the study treatment.	Known history of poor compliance; presence of clinical infection in the wound; presence of Stage I, Stage III, or Stage IV pressure ulcers; and previous participation in the evaluation were excluded.	NR/NR/36/36	Age(Mean):72.5 vs. 7.3.years Female:35% vs. 43.8% Race: NR	Dressing: Self adhesive polyurethane foam vs. saline-soaked gauze	<p>Treatment vs. comparator</p> <p>Mean ulcer size 5.6cm² vs. 6.2cm²</p> <p>Localization: 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%</p> <p>All PU were NPUAP Stage II</p>

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Price, 2000 ⁶⁸ UK Good	Adults with stage III and IV non infected PU	Existing dermatitis, a history of sensitivity to adhesive products, taking oral corticosteroids	NR/NR/50/50 PU N=21	Age(Mean):69.7 vs. 75.7 years Female: 6% vs. 68% Race: NR	Radiant heat dressing vs. standard care (alginate absorbent dressings)	Radiant heat vs. standard care: Mean surface area: 7.3cm ² vs. 9.8cm ² Ulcer stage: III: 80% vs. 92% IV:20% vs. 8%
Sebern, 1986 ⁶⁹ Sebern, 1989 ⁷⁰ US Fair	Stage II or III PU Receiving VNA (Visiting Nursing Association) service	Stage I or IV PU; ulcer containing eschar; terminal patient; white count below 4,000;	NR/NR/100/48 PU N=77	Age(Mean):76.3 vs. 72.4 years Female: NR Race: NR	Transparent Moisture vapor permeable dressing (MVP) vs. Saline gauze	MVP vs. saline gauze: N= 37 vs. 40 Ulcer Stage: II:59.4% vs. 30% III: 40.5% vs. 70% Median size of stage II ulcers: 1.9cm ² vs. 3.4cm ² Median size of stage III ulcers: 6.1cm ² vs. 4.5cm ² Ulcer Location: NR Ulcer Location: NR (Article used Shea ulcer stages: II, III)

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Seeley, 1999 ¹ US Fair	Either sex >18 years one or more stage II or III (AHCPR system)	Ulcer smaller than 1cm ² or larger than 50cm ² Clinically infected ulcer Uncontrolled diabetes Known history of poor compliance with medical treatment	NR/NR/40/39 PU N=40	Age(Mean):75.7 vs. 76.7 years Female: 54% Race: NR	Hydrocellular dressing vs. Hydrocolloid dressing	Hydrocellular: N=20 Ulcer Stage: II: N=3 (15%) III: N=17 (85%) Ulcer Location: Sacrum or Coccyx: N=4 Heel: N=7 Foot: N=3 Trochanter: N=1 Ischium: N=1 Thigh: N=2 Buttocks: N=1 Other: N=1 Mean area of PU: 6.84 cm ² Hydrocolloid: N=19 Ulcer Stage: II: N=2 (11%) III: N=17 (89%) Ulcer Location: Sacrum or coccyx: N=5 Heel: N=3 Foot: N=4 Trochanter: N=1 Ischium: N=1 Thigh: N=1 Buttocks: N=2 Other: N=2 Mean area of PU: 4.61 cm ²

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Small, 2002 ⁷² South Africa Good	<p>Patients in the Bloemfontein community 18 years or older with a clinically uninfected stage 2,3, or 4 PU (Stirling scale)</p> <p>Patients with their guardians, who gave informed consent</p> <p>Patients who were willing and able to comply</p>	NR	60/58/58/58	Age(Mean):76.5 vs. 78 years Female: 75% female vs. 47% female Race: NR	<p>Dressing: Advanced wound care: Hydrogel dressing Foam dressing Transparent film dressing vs. Standard wound care: Cotton, alginates, gauze, hydrocolloids</p>	<p>Advanced wound care: Localization: Sacrum: N=11 Trochanter: N=6 Malleolus: N=3 Iliac crest: N=2 Ischium: N=2 Heel: N=2 Wrist: N=1 Lat. Side of foot: N=1</p> <p>Standard Wound Care: Localization: Sacrum: N=15 Trochanter: N=6 Malleolus: N=0 Iliac crest: N=2 Ischium: N=1 Heel: N=3 Wrist: N=0 Lat. Side of foot: N=0 Elbow: N=2 Scapula: N=1</p>

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Thomas, 1997 ⁷³ UK Poor	Stage II or III PU Any wound less than 10mm deep and maximum diameter of 8cm	Under 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):80.1 vs. 78.6 years Female: 70% vs. 67.3% Race: NR	Dressing: Hydropolymer dressing vs. Hydrocolloid dressing	Hydrocolloid: PU Stage: II: N=30 III: N=19 Location: Heel: N=25 Buttock: N=2 Sacrum: N=6 Hip: N=4 Other: N=12 Hydropolymer: PU Stage: II: N=27 III: N=23 Location: Heel: N=23 Buttock: N=6 Sacrum: N=10 Hip: N=2 Other: N=9
Thomas, 1998 ⁷⁴ US Poor	>18 years old Stage II, III, IV PU area >/= to 1.0cm ²	Ulcers resulting from venous or arterial insufficiency or other nonpressure etiology Wounds with sinus tracts and or undermining greater than 1cm Infected wounds Concomitant use of other topical medications Severe generalized medical conditions and estimated survival of less than 6 mo HIV positive, currently abusing drugs, pregnant, breast feeding, non on acceptable means of contraception, cancer diagnosis or chemotherapy	NR/NR/41/30 PU N=30	Age(Mean):77 years Female: 54% Race: 53% Caucasian (Analyzed)	Topical hydrogel dressing vs. Saline gauze	Hydrogel: N=16 Ulcer Stage: II: N=8 (50%) III: 6 (38%) IV: 2 (13%) Wound area (cm ²): 8.9 Saline: N=14 Ulcer stage: II: N=6 (43%) III: 7 (50%) IV: 1 (7%) Wound area (cm ²): 5.9

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Thomas, 2005 ⁷⁵ US Good	male or female subjects, > 18 years old with a diagnosis of a non-infected stage 3 or stage 4 pressure ulcer with an area greater than or equal to 1.0 cm ²	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 acceptable means of contraception in premenopausal women, current diagnosis of cancer (subjects whose cancer is in remission and who are not receiving concomitant chemotherapy may be included in the study), severe generalized medical condition with estimated survival of less than 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 PU N=41	Age(Mean):75.5 years Female: 32% Race: 51% Caucasian	Radiant heat dressing vs. Hydrocolloid	Radiant heat dressing: N= 21 Stage III: N=11 Stage IV: N=10 Size cm ² : 11 Hydrocolloid: N=20 Stage III: N=11 Stage IV: N=9 Size cm ² : 12.1
Viamontes, 2003 ⁷⁶ US Poor	"All patients in the database who had a pressure ulcer, venous ulcer, diabetic ulcer, or traumatic wound that was treated with either the hydrocellular or soft-silicone dressing or both dressings on at least one occasion were included."	NR	NR/NR/NR/1,891 4,200 wounds	Age(Mean):82.5 years Female: NR Race: NR	Dressing: Hydrocellular vs. soft silicone	Hydrocellular: mean area 7.53 cm ² SD 13.66 Soft silicone: 5.50cm ² SD 8.74 Of 4,200 wounds included in the study 3,969 were PU (94%)

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Whitney, 2001 ⁷⁷ US Fair	Male or female 18 years or older Stage III or IV PU (NPAUP) English speaking	Documented wound infection Dermatitis Recurrent ulcer Sensitivity to adhesives Corticosteroid medication End-stage disease with <3 mo life expectancy	NR/NR/40/29 PU N=30	Age(Mean):53 years vs. 63 years Female: 38% Race: 79% Caucasian	Noncontact normothermic wound therapy (heated dressing) vs. Standard care (moisture retentive dressings including alginates with saline gauze, foam, hydrocolloids, or hydrogels)	Heated dressing vs. Standard care: N=15 vs.14 Ulcer Stage: III: N=7 vs. 11 IV: N=8 vs. 3 Ulcer locations: Ischium: 5 vs. 3 Sacrum: 3 vs. 3 Coccyx: 2 vs. 1 Heel: 1 vs. 4 Malleolus: 2 vs. 2 Plantar: 0 vs. 1 Trochanter: 1 vs. 0 Thoracic: 1 vs. 0 Mean wound area (cm ²): 10 vs. 7
Winter, 1990 ⁷⁸ UK Poor	Patients with chronic leg ulcers or PU	Terminally ill or their wounds were <1cm ²	NR/NR/114/51	Age(Mean):74 years (median) Range: 25-93 years Female: 67% Race: NR	Hydrocolloid vs. Paraffin gauze	Ulcer Stage: NR ("ordinary vs. difficult" ulcers) Ulcer locations: "Chronic leg ulcers and pressure ulcers"
Xakellis, 1992 ⁷⁹ US Fair	Patients who developed a PU with a break in the skin	Stage I and IV PU Anticipated discharge within 1 week Ulcers caused by their causes	NR/NR/NR/39 PU N=39	Age(Mean):77 years vs. 84 years Female: 92% Race: NR	Hydrocolloid vs. Saline gauze	Hydrocolloid vs. saline gauze: N=18 vs. 21 Ulcer Stage: II: N=18 vs. 19 III: N=0 vs. 2 Ulcer Location: Sacrum: N=6 vs. 8 Pelvic girdle: N=8 vs. 6 Other: N=4 vs. 7 Median total surface area (cm ²): 0.66 vs. 0.38 (Article used Shea Ulcer rating: II and III)
Yapucu Gune, 2007 ⁸⁰ Turkey Fair	Stage II or III PU 18 years or older	Diabetes mellitus Terminal illness	NR/36/27/26	Age(Mean):65.8 years vs. 66.6 years Female:40% vs. 38% Race: NR	Honey dressing vs. Exthoxy- diaminoacridine + nitrofurazone dressing	Honey group: mean stage of PU, 2.96 Comparator group: mean stage of PU, 2.96

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Yastrub 2004 ⁸¹ US Poor	"Inclusion criteria were based on the patient's age (> 65 years), diagnosis, location of the pressure ulcer, limitations in activities of daily living (ADLs), and the Agency for Health Care Policy and Research (AHCPR, 1994) definition of a stage II pressure ulcer."	NR	NR/NR/50/44	Age(Mean):NR Female: NR Race: NR	Polymer membrane dressing vs. Dry clean dressing (gauze + antibiotic ointment)	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study Setting	Funding Source
Alm, 1989 ⁴⁰ Sweden Fair	Hydrocolloid Dressing (Comfeel Ulcus dressing system: Comfeel Ulcus sheet, Comfeel paste, Comfeel powder) Changed when necessary	Wet Saline Gauze Changed 2x daily	NA	6 Weeks	Hospitals	NR
Bale, 1998 ⁴¹ UK Poor	Hydrocellular dressing (Allevyn): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N pressure ulcers= 17	Hydrocolloid dressing (Granuflex): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N pressure ulcers=15	NA	8 weeks	Community	Smith and Nephew Ltd
Banks, 1994a ⁴² UK Fair	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.	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.	NA	6 weeks	Community	C.V. Laboratories Ltd and Calgon Vestal Laboratories
Banks, 1994b ⁴³ UK (Wales) 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.	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.	NA	6 weeks	Hospital	C.V. Laboratories Ltd and Calgon Vestal Laboratories

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study Setting	Funding Source
Belmin, 2002 ⁴⁴ France Fair	Alginate for 4 weeks and hydrocolloid for 4 weeks. Calcium alginate dressings were removed every other day or more often if they were saturated, especially when exudates appeared through the secondary dressing. Hydrocolloid dressings were removed every third day or more often if the area discolored by exudates was less than 1cm from the edge of the dressing or if a leakage was apparent.	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.	NA	8 weeks	Hospital	Laboratories Uργο
Brod, 1990 ⁴⁵ US Poor	Poly-hema paste changed twice weekly N=27	Hydrocolloid dressing changed twice weekly N=16	NA	16 weeks	Long-term care	Acme/Chaston Division, National Patent Development Corp.
Brown-Etris, 2008 ⁴⁶ US Fair	Transparent absorbent acrylic dressing (TAAD)	Hydrocolloid dressing (HD)	NA	56 days	Community	3M Company
Chang, 1998 ⁴⁷ Malaysia Poor	Gauze dressings soaked in normal sterile saline changed daily or when secondary dressing was soaked through N=17	DuoDERM CGF Hydrocolloid dressing changed every seven days or when leakage occurred N=17	NA	8 weeks	University Hospital, Kuala Lumpur	ConvaTec (Bristol-Myers Squibb)
Colin, 1996 ⁴⁸ Multinational Poor	Hydrogel (IntraSite) N=67	Dextranomer paste (Debrisan), N=68	NA	3 weeks	"Multicenter investigation"	NR
Colwell, 1993 ⁴⁹ US Poor	Hydrocolloid (DuoDerm), changed every 4 days or as needed	Saline gauze, changed every 6 hours or as needed.	NA	14 months	Long-term care	ConvaTec
Darkovich, 1990 ⁵⁰ US Poor	Hydrogel (BioFilm), changed every three or four days N=41	Hydrocolloid, changed every three or four days N=49	NA	8.6 weeks (60 days)	Acute and long-term care	NR
Day, 1995 ⁵¹ US, UK, Canada Fair	Hydrocolloid triangle N=52	Hydrocolloid oval N=51	NA	10 treatment days (mean)	Hospital (acute care)	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study Setting	Funding Source
Gorse, 1987 ⁵² US Fair	Hydrocolloid (DuoDerm), changed every four days or more frequently N=76	Saline gauze + chramine-T (Dakin's solution), changed every 8 hours N=52	NA	6-39 days	Hospital	NR
Honde, 1994 ⁵³ France Fair	Amino acid copolymer (Inerpan)	Hydrocolloid dressing (Comfeel)	NA	8 weeks	Hospital	Synthélabo Recherche
Kaya, 2005 ⁵⁴ Turkey Good	Hydrogel-type dressing (Elasto- gel), changed every four days, or more frequently if the membrane became contaminated or non- occlusive.	Povidone-iodine-soaked gauze, changed daily to prevent contamination	NA	NR	Hospital	NR
Kerihuel, 2010 ⁵⁵ France Poor	Actisorb, changed two to three times per week or more frequently in cases of abundant exudation	Hydrocolloid dressing (DuoDerm), changed two to three times per week or more frequently in cases of abundant exudation	NA	4 weeks in study period.	Hospital	Systagenix Wound Management
Kim, 1996 ⁵⁶ Korea Poor	Hydrocolloid occlusive dressing: dressing change every 4 to 5 days or more if leakage occurred	Wet-to-dry gauze dressing: povidone soaked wet gauze and then covered with a layer of dry gauze changed three times per day	NA	NR	Hospital	NR
Kloth, 2002 ⁵⁷ US Poor	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 LTC	Augustine Medical Inc
Kraft, 1993 ⁵⁸ US Good	Epi-Lock: can be left on for up to 7 days or until there is leakage of exudate	Saline Dressings: changed once every 8 hours	NA	24 weeks.	Hospital	Calgon Vestal Laboratories
Kurzik-Howard, 1985 ⁵⁹ US Poor	Moist Wound Healing (Op Site treatment): applied to dry, clean wound area and removed after healing or it may slough off naturally.	Dry Wound Healing (Alternative treatment); depending on ulcer stage this can vary from egg crate mattresses and turning the patient every two hours to cleaning and dressing the ulcer followed by a heat lamp for 15- 20 minutes.	NA	1 year	Hospital	Partially funded by Acme United Corporation, Bridgeport, Connecticut

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study Setting	Funding Source
Matzen, 1999 ⁶⁰ Denmark Good	Hydrogel: wounds were changed and dressing changed daily	Saline gauze compress: wounds were changed and dressing changed daily	NA	12 weeks	Hospital	NR
Meaume, 2005 ⁶¹ France Good	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, 2003 ⁶² Finland Poor	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.	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.	NA	8 weeks	Nursing home/LTC	NR
Motta, 1999 ⁶³ US Poor	Polymer hydrogel dressing (AcryDerm Sheet Wound Dressing) changed as needed, at least once a week. N=5	Hydrocolloid dressing (DuoDERM), changed as needed, at least once a week N=5	NA	8 weeks	Home healthcare	AcryMed, Portland, OR
Mulder, 1993 ⁶⁴ US Poor	Clearsite: changed twice a week by the patient or caregiver	DuoDERM: changed twice a week by the patient or caregiver	Standard wet-to-moist saline gauze dressing: changed three times a day by the patient or caregiver	8 weeks	Hospital	NR
Neill, 1989 ⁶⁵ US Poor	Hydrocolloid (Tegasorb): changed every 3 – 7 days	Saline gauze (WTD): changed every 8 hours	NA	15 months	Tertiary care facility and nursing home	3M Company, Medical-Surgical Division

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study Setting	Funding Source
Oleske, 1986 ⁶⁶ US Poor	Saline: Normal saline dressings custom cut to the size of the ulcer and covered with a plastic pad. Changed every 4 hours	Polyurethane dressing that was self adhesive. Changed only if it dislodged from the ulcer site, usually remained in place for 2 days	NA	10 days	Hospital	Department of Medical Neurnign, Rush-Presbyterian-St. Luke's Medical Center and the Chicago Community Trust
Payne, 2009 ⁶⁷ US Good	Self adhesive polyurethane foam: dressing change frequency determined at the discretion of the clinical investigator N=20	Saline-soaked gauze dressings: dressing change frequency determined at the discretion of the clinical investigator N=16	NA	4 weeks	Hospital inpatient wards, outpatient clinics, long-term residential center, and a community based wound clinic	NR
Price, 2000 ⁶⁸ UK Good	Radiant heat dressing: warming element inserted into dressing pocket for 1 hour, twice daily (morning and evening)	Standard care (alginate absorbent dressings): cleaned as clinically indicated	NA	6 weeks	Multiple: Hospital, long-term care, community	NR
Sebern 1986 ⁶⁹ Sebern 1989 ⁷⁰ US Fair	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, 1999 ⁷¹ US Fair	Hydrocellular dressing N=20	Hydrocolloid dressing N=19	NA	8 weeks	Long term care facilities and Outpatient wound clinic	NR
Small, 2002 ⁷² South Africa Good	Advanced wound care: Hydrogel dressing Foam dressing Transparent film dressing, n=28	Standard wound care: Cotton, alginates, gauze, hydrocolloids, N=30	NA	6 weeks	Community	NR
Thomas, 1997 ⁷³ UK Poor	Hydrocolloid dressing N= 49	Hydropolymer dressing N = 50	NA	6 weeks	community	NR
Thomas, 1998 ⁷⁴ US Poor	Topical hydrogel dressing N=16	Saline gauze n=14	NA	10 weeks	Skilled nursing facilities and Community	Carrington Laboratories
Thomas, 2005 ⁷⁵ US Good	Radiant heat dressing, N=21	Hydrocolloid, N=20	NA	12 weeks	Outpatient clinics, Long-term care, and rehabilitation center	NR
Viamontes, 2003 ⁷⁶ US Poor	Hydrocellular dressing N (wounds)= 3,795	Soft silicone dressing N (wounds)=352	Both dressings N (wounds)=53	Data was gathered retroactively for a 5 year period	Nursing home	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study Setting	Funding Source
Whitney, 2001 ⁷⁷ US Fair	Noncontact normothermic wound therapy (heated dressing) N=15	Standard care (moisture retentive dressings including alginates with saline gauze, foam, hydrocolloids, or hydrogels) N=14	NA	8 Weeks	Multiple: Acute care, community, and long-term care	Augustine Medical Inc and Small Business Innovation Grant No. NIH
Winter, 1990 ⁷⁸ UK Poor	Hydrocolloid	Paraffin Gauze	NA	12 Weeks	Hospital and community	Coloplast Ltd
Xakellis, 1992 ⁷⁹ US Fair	Hydrocolloid N=18	Saline gauze N=21	NA	6 Months	Long-term care	Family Health Foundation of America and ConvaTec
Yapucu Gune, 2007 ⁸⁰ Turkey Fair	Honey dressing, N=15	Exthoxy-diaminoacridine + nitrofurazone dressing, N=11	NA	5 weeks	Hospital	NR
Yastrub 2004 ⁸¹ US Poor	Polymer membrane dressing, N=21	Dry clean dressing (gauze and antibiotic ointment), N=23	NA	4 weeks	LTC	Partially funded by NPUAP

Evidence Table 5a: Dressings Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Alm, 1989 ⁴⁰ Sweden Fair	Hydrocolloid: 50-60% had healed	Saline Gauze: 10-20% had healed	Hydrocolloid dressing: At 6 weeks median value: 0%	Wet saline gauze: At 6 weeks median value: 31%	" Healing was faster in ulcers dressed with the hydrocolloid dressing	NR	NR
Bale, 1998 ⁴¹ UK Fair	Hydrocellular: N=10 (59%)	Hydrocolloid: N=4 (27%)	NR	NR	NR	NR	NR
Banks, 1994a ⁴² UK Fair	60% complete wound healing	50% complete wound healing	30% showed improvement.	0% showed improvement	NR	NR	NR
Banks, 1994b ^{43b} UK (Wales) Fair	77% complete wound healing	62.5% complete wound healing	No data	6.1% greatly improved	13.36 days	12.69 days	NR
Belmin, 2002 ⁴⁴ France Fair	5.1% complete wound healing	15.1% complete wound healing	Wound surface area mean: 5.0cm ² , 66% improvement	Wound surface area mean: 7.4cm ² , 42% improvement	NR	NR	NR
Brod, 1990 ⁴⁵ US Poor	Poly-hema: 52%	Hydrocolloid: 62% (p=0.54)	NR	NR	Poly-hema: 0.18cm ² /week Median time to complete healing: 32 days	Hydrocolloid: 0.10cm ² /week Median time to complete healing: 42 days	NR
Brown-Etris, 2008 ⁴⁶ US Fair	TAAD: 21, 60%	HD: 22, 59.5%, p=0.963	TAAD: 1.1 cm ²	HD: 1.6 cm ² p=0.598	Linear healing rate, mean: 0.10cm ²	Linear healing rate, mean: 0.12cm ² p=0.6520	NR
Chang, 1998 ⁴⁷ Malaysia Poor	NR	NR	CGF Hydrocolloid: mean reduction of 34% from baseline surface area	Gauze: mean 9% increase to baseline surface area	NR	NR	NR
Colin, 1996 ⁴⁸ Multinational Poor	NR	NR	Hydrogel – 35%	Dextranomer – 7%	NR	NR	NR
Colwell, 1993 ⁴⁹ US Poor	Hydrocolloid (DuoDerm): 22%	Saline gauze: 2%	Hydrocolloid (DuoDerm): 0.73 cm reduction	Saline gauze: 0.67 cm increase	NR	NR	NR
Darkovich, 1990 ⁵⁰ US Poor	Hydrogel (BioFilm): 43%	Hydrocolloid: 24%	Hydrogel (BioFilm): 7.5cm ² wound area reduction	Hydrocolloid: 3.7cm ² wound area reduction	Hydrogel (BioFilm): 8.1% wound area/day	Hydrocolloid: 3.1% wound area/day	NR
Day, 1995 ⁵¹ US, UK, Canada Fair	Hydrocolloid triangle: 36%	Hydrocolloid oval: 22%	Mean width reduction: 32% Mean length reduction: 28%	Mean width reduction: 17% (p=0.034) Mean length reduction: 24% (NS)	Hydrocolloid triangle: 13.5 days	Hydrocolloid oval: 11.0 days	NR

Evidence Table 5a: Dressings Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Gorse, 1987 ⁵² US Fair	71% healed	50% healed	15.7% healing	19.2% healing	0.72cm ² /day Mean healing days: 10	0.55cm ² /day Mean healing days: 8.7	NR
Honde, 1994 ⁵³ France Fair	38.7% achieved healing (chi-square test; p=0.089)	26.1% achieved healing (chi-square test; p=0.089)	At each visit, progress of healing was calculated as the percentage, with respect to baseline, of ulcer healed. This progress tended to be higher with the amino acid copolymer membrane (p=0.090).	At each visit, progress of healing was calculated as the percentage, with respect to baseline, of ulcer healed. This progress tended to be higher with the amino acid copolymer membrane (p=0.090).	32 days	38 days	NR
Kaya, 2005 ⁵⁴ Turkey Good	84% of wounds became epithelialized	54.2% of wounds became epithelialized	NR	NR	0.12cm ² /days Healing time was 48 days	0.08cm ² /days Healing time was 45.23 days	NR
Kerihuel, 2010 ⁵⁵ France Poor	NR	NR	26.9% wound reduction	18.5% wound reduction	NR	NR	NR
Kim, 1996 ⁵⁶ Korea Poor	80% complete wound healing	77.8% complete wound healing	NR	NR	9.1mm ² /day	7.9mm ² /day	NR
Kloth, 2002 ⁵⁷ US Poor	48% wound closure	36% wound closure	69% decrease in mean surface area	50% decrease in mean surface area	0.52cm ² per week	0.23cm ² per week (p=0.02)	NR
Kraft, 1993 ⁵⁸ US Good	42% healed	21% healed	NR	NR	NR	NR	NR
Kurzik-Howard, 1985 ⁵⁹ US Poor	32.5% total healing (both groups combined)	32.5% total healing (both groups combined)	No significant difference between the two treatment groups was found in the average rate of improvement in the size (p<0.66)	NA	The rate of improvement over time was greater for the Op-Site group than for the alternative group.	NA	1 patient in the Op-Site group experienced an infection
Matzen, 1999 ⁶⁰ Denmark Good	29.4% complete wound healing	0% complete wound healing	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Meaume, 2005 ⁶¹ France Good	NR	NR	Absolute decrease: 7.2cm ² wound reduction: 31.6%	Absolute decrease: 0.8cm ² wound reduction: 13.9%	0.26cm ² /day	0.03cm ² /day	NR
Meaume, 2003 ⁶² Finland Poor	44.4% healed	50% healed	38.8% showed improvement	NR	NR	NR	NR
Motta, 1999 ⁶³ US Poor	40% healed	40% healed	79.2% wound improvement	88.6% wound improvement	0.15cm/day	0.35cm/day	NR
Mulder, 1993 ⁶⁴ US Poor	NR	NR	NR	NR	Clearsite vs. DuoDERM Mean reduction/week 8% vs. 3.3%	Mean reduction/week 5.1%	1 case of inflammation related to ClearSite.
Neill, 1989 ⁶⁵ US Poor	31% healed	22% healed	50% or more reduction in size: 50%	50% or more reduction in size: 46%	NR	NR	No infection occurred
Oleske, 1986 ⁶⁶ US Poor	1 ulcer healed	0 healed	Mean 7.7 cm ² SD (pre and post change not significant)	Mean 2.0 cm ² (pre and post change significant at p=0.01)	NR	NR	Saline group: One patient developed an infection in the treated ulcer and died the next day from pulmonary embolism and sepsis. It is not clear what (the underlying disease, or the dressing) contributed to the infection
Payne, 2009 ⁶⁷ US Good	55.5% healed	37.5% healed	NR	NR	NR	NR	5.56% showed signs of infection
Price, 2000 ⁶⁸ UK Good	12% complete wound healing	8% complete wound healing	Reduction of initial wound area: 75%	Reduction of initial wound area: 40%	66.7cm ² /week	63.3cm ² /week	NR
Sebern 1986 ⁶⁹ Sebern 1989 ⁷⁰ US Fair	MVP: 64%	Saline Gauze: 0%	MVP median improvement: 100%	Saline gauze median improvement: 52% (p<0.05)	NR	NR	No sepsis reported

Evidence Table 5a: Dressings Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Seeley 1999 ⁷¹ US Fair	64% of stage II ulcers healed	0% of stage III ulcers healed	Stage II median improvement: 100% Stage III median improvement: 67%	Stage II median improvement: 52% (p<0.01) Stage III median improvement: 44%	NR	NR	NR
Small, 2002 ⁷² South Africa Good	Advanced wound care - 53.6%	Standard care - 30%	NR	NR	NR	NR	Advanced Wound Care: 1 infection
Thomas, 1997 ⁷³ UK Poor	Hydropolymer -33%	Hydrocolloid dressing-20%	Hydropolymer - 47%	Hydrocolloid dressing-10%	NR	NR	NR
Thomas, 1998 ⁷⁴ US Poor	Topical hydrogel dressing: 63%	Saline gauze: 64%	NR	NR	Topical hydrogel dressing: 5.3 weeks	Saline gauze: 5.2 weeks (p=0.87)	NR
Thomas, 2005 ⁷⁵ US Good	Radiant heat dressing: 57%	Hydrocolloid: 44% (p=0.46)	NR	NR	NR	NR	NR
Viamontes, 2003 ⁷⁶ US Poor	Hydrocellular: 1,996 of 3,792 (53%) wound closed completely. Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	Soft silicone: 152 out of 351 (43%) wounds closed completely. Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	NR	NR	Average treatment time (for all groups) 71.3 days (range 5-1386 days)	"	Hydrocellular: 76 out of 2,616 (3%) experienced an infection Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)
Whitney, 2001 ⁷⁷ US Fair	Normothermic wound therapy: 53%	Standard care: 43%	NR	NR	Mean linear rate of healing: Normothermic wound therapy: 0.012cm ² per day	Mean linear rate of healing: Standard care: 0.004 cm ² per day	NR
Winter, 1990 ⁷⁸ UK Poor	Hydrocolloid: 63% (12 out of 19)	Paraffin Gauze: 19% (3 out of 16)	NR	NR	NR	NR	NR
Xakellis, 1992 ⁷⁹ US Fair	Hydrocolloid: 89%	Saline gauze: 86%	NR	NR	Hydrocolloid median time to healing: 9 days	Saline gauze median time to healing: 11 days (p=0.12)	NR

Evidence Table 5a: Dressings Trials, continued							
Author, year Country Overall Quality Rating	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Yapucu Gune, 2007 ⁸⁰ Turkey Fair	Honey dressing – 20%	Exthoxy-diaminoacridine + nitrofurazone dressing – 0% (p<0.05)	Decrease in ulcer size: (mean) Honey dressing – 56% reduction	Mean decrease in ulcer size: Exthoxy-diaminoacridine + nitrofurazone dressing – 13% (p<0.001)	Nr	NR	NR
Yastrub 2004 ⁸¹ US Poor	NR	NR	Polymer membrane: improvement in wound healing 87%	Dry clean dressing: improvement in wound healing 65.2%	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Alm, 1989 ⁴⁰ Sweden Fair	NR	NR	NR	NR	NR	Neither the patients nor the staff was of the opinion that the dressing change was painful at any stage.	NR	NR
Bale, 1998 ⁴¹ UK Fair	NR	NR	NR	NR	NR	NR	NR	NR
Banks, 1994a ⁴² UK Fair	NR	NR	NR	NR	NR	NR	Two patients in the hydrocolloid were withdrawn at their own request because of the discomfort they experienced in using the dressing.	Two patients were withdrawn because of deterioration. The two patients withdrawn from the study in addition to the two who requested withdrawal due to discomfort were considered treatment failures.
Banks, 1994b ^{43b} UK Fair	NR	NR	NR	NR	NR	NR	20.9% of dressings were changed due to patient discomfort	33.8% of dressings were changed due to patient discomfort
Belmin, 2002 ⁴⁴ France Fair	NR	NR	NR	NR	NR	NR	NR	NR
Brod, 1990 ⁴⁵ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Brown-Etris, 2008 ⁴⁶ US Fair	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Chang, 1998 ⁴⁷ Malaysia Poor	Gauze: One subject developed infection	NR	NR	NR	NR	CGF Hydrocolloid: Overall comfort, 0% uncomfortable p<0.01	Gauze dressing: Overall comfort, 50% uncomfortable p<0.01	exudate handling good/excellent: CGF Hydrocolloid, 69% Gauze, 44% p<0.019
Colin, 1996 ⁴⁸ Multinational Poor	NR	NR	NR	NR	NR	NR	NR	NR
Colwell, 1993 ⁴⁹ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Darkovich, 1990 ⁵⁰ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Day, 1995 ⁵¹ US, UK, Canada Fair	NR	NR	NR	NR	NR	Hydrocolloid triangle (baseline vs. final): 47% vs. 18%	Hydrocolloid oval (baseline vs. final): 29% vs. 32% Pain higher at final assessment in oval group (p=0.04)	NR
Gorse, 1987 ⁵² US Fair	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Honde, 1994 ⁵³ France Fair	NR	NR	NR	NR	NR	NR	NR	The Shea grade distributions in each group were compared, showing that on Day 14, there were more patients healed or nearing healing (Grade I) in the amino-acid copolymer group than hydrocolloid dressing (25.8% vs. 8.3%, p=0.029)
Kaya, 2005 ⁵⁴ Turkey Good	NR	NR	NR	NR	NR	NR	NR	NR
Kerihuel, 2010 ⁵⁵ France Poor	NR	NR	NR	NR	NR	NR	NR	NR
Kim, 1996 ⁵⁶ Korea Poor	NR	NR	NR	NR	NR	NR	NR	Healing speed (mm ² /day): Hydrocolloid 9.1 +/-5.4 Gauze 7.9 +/-4.7
Kloth, 2002 ⁵⁷ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Kraft, 1993 ⁵⁸ US Good	NR	NR	NR	NR	NR	NR	NR	The average total weekly cost per type of dressing was obtained by adding the weekly cost of dressing and the weekly cost of nursing time: For example: Epi-lock dressing (total \$20.48) vs. Saline dressing (total \$74.97)

Evidence Table 5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Kurzuk-Howard, 1985 ⁵⁹ US Poor	NR	NR	NR	NR	NR	Many patients reported being more comfortable after an application of Op-Site to the ulcers.	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, 1999 ⁶⁰ Denmark Good	40% developed necrotic tissue with infection	NR	NR	NR	NR	Median of 2 patients reported pain	Median of 2 patients reported pain	NR
Meaume, 2005 ⁶¹ France Good	NR	NR	NR	NR	NR	NR	Pain during dressing and erythema, pain reported	NR
Meaume, 2003 ⁶² Finland Poor	NR	NR	NR	0%	10% developed new ulcers	NR		NR
Motta, 1999 ⁶³ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Mulder, 1993 ⁶⁴ US Poor	NR	NR	NR	NR	NR	Minor irritation in one patient with DuoDerm dressing, minor sensitivity to DuoDerm dressing and one patient.	NR	NR
Neill, 1989 ⁶⁵ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Oleske, 1986 ⁶⁶ US Poor	NR	NR	NR	NR	NR	NR	NR	In one instance a patient in the saline group with two ulcers within 1 cm of one another, the two ulcers merged into a single ulcer with greater depth.
Payne, 2009 ⁶⁷ US Good	No infections reported in the saline gauze group	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Price, 2000 ⁶⁸ UK Good	NR	NR	NR	NR	NR	No difference in pain scores from baseline to end of study	.No difference in pain scores from baseline to end of study. Mean=17.5; SD=19.72	NR
Sebern 1986 ⁶⁹ Sebern 1989 ⁷⁰ US Fair	No sepsis reported	NR	NR	NR	NR	NR	NR	NR
Secley 1999 ⁷¹ US Fair	NR	NR	NR	NR	NR	Hydrocellular: Mean wound pain 0.15	Hydrocolloid: mean wound pain 0.47	NR
Small, 2002 ⁷² South Africa Good	Standard wound care: 1 infection	NR	NR	NR	NR	NR	NR	NR
Thomas, 1997 ⁷³ UK Poor	NR	NR	NR	NR	NR	NR	NR	NR
Thomas, 1998 ⁷⁴ US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Thomas, 2005 ⁷⁵ US Good	NR	NR	NR	NR	NR	NR	NR	NR
Viamontes, 2003 ⁷⁶ US Poor	Soft silicone: 23 out of 265 (9%) experienced an infection Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	NR	NR	NR	NR	NR	NR	NR
Whitney, 2001 ⁷⁷ US Fair	NR	NR	NR	NR	NR	NR	NR	NR
Winter, 1990 ⁷⁸ UK Poor	NR	NR	NR	NR	NR	NR	NR	NR
Xakellis, 1992 ⁷⁹ US Fair	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Pain	Pain (Comparator)	Other: Specify
Yapucu Gune, 2007 ⁸⁰ Turkey Fair	NR	NR	NR	NR	NR	NR	NR	Improved PUSH tool scores: Honey dressing – 6.55 +/- 2.14 Exthoxy-diaminoacridine + nitrofurazone dressing – 12.62 +/- 2.15 (p<0.001)
Yastrub 2004 ⁸¹ US Poor	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Pain	Pain (Comparator)	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)
Alm, 1989 ⁴⁰ Sweden Fair	Hydrocolloid dressing: No pain reported on dressing removal Although, it later says one patient withdrew due to pain.	Wet saline gauze: No pain reported on dressing removal	NR	NR	NR	NR
Bale, 1998 ⁴¹ UK Poor	Patients who found the dressing "uncomfortable" are reported, but only in aggregate with the other types of wounds	NR	NR	NR	NR	NR
Banks, 1994a ⁴² UK Fair	NR	Two patients in the hydrocolloid were withdrawn at their own request because of the discomfort they experienced in using the dressing.	Two patients were withdrawn because of deterioration.	NR	NR	NR
Banks, 1994b ⁴³ UK (Wales) Fair	NR	NR	NR	NR	NR	NR
Belmin, 2002 ⁴⁴ France Fair	31.3% reported pain during the removal of the dressings.	35.6% reported pain during the removal of the dressings.	Erythema of surrounding skin 3.5%, Maceration 1.8%	Erythema of surrounding skin 0%, Maceration 0%	Sequential treatment group: N=1	Comparator group: N=0

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Pain	Pain (Comparator)	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)
Brod, 1990 ⁴⁵ US Poor	NR	NR	NR	NR	NR	NR
Brown-Etris, 2008 ⁴⁶ US Fair	NR	NR	NR	NR	NR	NR
Chang, 1998 ⁴⁷ Malaysia Poor	CGF Hydrocolloid: Pain during dressing removal moderate/severe 0% p<0.01	Gauze: Pain during dressing removal moderate/severe, 44% p<0.01	CGF Hydrocolloid: Adherence to surrounding skin, non-adherent 44% p<0.01	Gauze: Adherence to surrounding skin non adherent, 94% p<0.01	NR	NR
Colin, 1996 ⁴⁸ Multinational Poor	Hydrogel: No pain reported	Dextranomer Paste: One patient reported pain when dressing was removed	NR	NR	NR	NR
Colwell, 1993 ⁴⁹ US Poor	NR	NR	NR	NR	NR	NR
Darkovich, 1990 ⁵⁰ US Poor	NR	NR	NR	NR	NR	NR
Day, 1995 ⁵¹ US, UK, Canada Fair	Hydrocolloid triangle: Mean pain score at dressing change 3.8 (range 1-10)	Hydrocolloid oval dressing group: Mean pain score at dressing changes 4.3 (range 2-9)	Hydrocolloid triangle (Wound Deterioration): 4%	Hydrocolloid oval (Wound Deterioration): 31%	NR	Minor bleeding reported
Gorse, 1987 ⁵² US Fair	NR	NR	NR	NR	NR	NR
Honde, 1994 ⁵³ France Fair	NR	NR	Ten withdrew from the study for emergent reasons (4 amino acid copolymer and 6 hydrocolloid dressing) because of local complication (mainly necrosis)	Ten withdrew from the study for emergent reasons (4 amino acid copolymer and 6 hydrocolloid dressing) because of local complication (mainly necrosis)	NR	NR
Kaya, 2005 ⁵⁴ Turkey Good	NR	NR	NR	NR	NR	NR
Kerihuel, 2010 ⁵⁵ France Poor	None	NR	None	NR	None	NR
Kim, 1996 ⁵⁶ Korea Poor	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Pain	Pain (Comparator)	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)
Kloth, 2002 ⁵⁷ US Poor	NR	NR	NR	NR	NR	NR
Kraft, 1993 ⁵⁸ US Good	NR	NR	NR	NR	NR	NR
Kurzik-Howard, 1985 ⁵⁹ US Poor	NR	NR	NR	NR	NR	NR
Matzen, 1999 ⁶⁰ Denmark Good	NR	NR	NR	NR	NR	NR
Meaume, 2005 ⁶¹ France Good	NR	NR	NR	NR	NR	NR
Meaume, 2003 ⁶² Finland Poor	NR	NR	In most patients, the sign/symptom reported as damage to the surrounding skin was redness. Two patients in the hydropolymer group developed blisters on the surrounding skin. This was not observed in the soft silicone group.	In most patients, the sign/symptom reported as damage to the surrounding skin was redness. Two patients in the hydropolymer group developed blisters on the surrounding skin. This was not observed in the soft silicone group.	NR	NR
Motta, 1999 ⁶³ US Poor	NR	NR	NR	NR	NR	NR
Mulder, 1993 ⁶⁴ US Poor	NR	NR	NR	NR	NR	NR
Neill, 1989 ⁶⁵ US Poor	Nr	NR	Hydrocolloid group: mild skin irritation, perilesional erythema, and eczema reported	NR	NR	NR
Oleske, 1986 ⁶⁶ US Poor	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Pain	Pain (Comparator)	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)
Payne, 2009 ⁶⁷ US Good	NR	NR	NR	NR	NR	NR
Price, 2000 ⁶⁸ UK Good	No pain reported due to dressing	No pain reported due to treatment	NR	Nr	NR	NR
Sebern 1986 ⁶⁹ Sebern 1989 ⁷⁰ US Fair	NR	NR	Wound deterioration: 14% Stage II skin maceration: 50% Stage III skin maceration: 40%	Wound deterioration: 58% Stage II skin maceration: 25% Stage III skin maceration: 25%	NR	NR
Seeley 1999 ⁷¹ US Fair	Hydrocellular: mean wound pain .15	Hydrocolloid: mean wound pain .47	Hydrocellular: Blisters beneath adhesive border 5% (1)	Hydrocolloid: Maceration of ulcer 5% (1); Rash beneath dressing 5% (1)	NR	NR
Small, 2002 ⁷² South Africa Good	NR	NR	NR	NR	NR	NR
Thomas, 1997 ⁷³ UK Poor	NR	NR	NR	NR	NR	NR
Thomas, 1998 ⁷⁴ US Poor	NR	NR	NR	NR	NR	NR
Thomas, 2005 ⁷⁵ US Good	NR	NR	NR	NR	NR	NR
Viamontes, 2003 ⁷⁶ US Poor	NR	NR	Hydrocellular: 12 PU experienced skin stripping	Soft silicone: 4 PU experienced skin stripping	NR	NR
Whitney, 2001 ⁷⁷ US Fair	NR	NR	Heated dressing group: 1 patient had maceration of wound due to treatment	NR	NR	NR
Winter, 1990 ⁷⁸ UK Poor	NR	NR	Hydrocolloid: Rash, inflammation, or allergic reaction to dressing 1	Paraffin Gauze: Rash, inflammation, allergic reaction to dressing, 1	NR	NR
Xakellis, 1992 ⁷⁹ US Fair	NR	NR	NR	NR	NR	NR
Yapucu Gune, 2007 ⁸⁰ Turkey Fair	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Pain	Pain (Comparator)	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)
Yastrub 2004 ⁸¹ US Poor	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate
Alm, 1989 ⁴⁰ Sweden Fair	NR	NR	NR	NR	1 patient withdrawn from hydrocolloid due to pain from changing the dressings	Hydrocolloid dressing: N=1 Wet saline gauze: N=0
Bale, 1998 ⁴¹ UK Poor	NR	NR	NR	NR	NR	NR
Banks, 1994a ⁴² UK Fair 275	NR	NR	NR	NR	NR	NR
Banks, 1994b ⁴³ UK (Wales) Fair	NR	NR	1 withdrawal due to being discharged from the hospital (Spyrosorb group)	Wound deterioration Wound/dressing-related problems	2 from the Spyrosorb group and 4 from the Granuflex E group.	20.6%
Belmin, 2002 ⁴⁴ France Fair	Sequential Treatment group: N=1	Comparator group: N=0	Hypergranulation: STG, N=1, Comparator group, N=5	NR	1 in STG group and 3 in comparator group	6 local adverse events in STG group and 5 in comparator group
Brod, 1990 ⁴⁵ US Poor	NR	NR	NR	NR	1 withdrawal due to adverse event	2.3%
Brown-Etris, 2008 ⁴⁶ US Fair	NR	NR	NR	NR	NR	NR
Chang, 1998 ⁴⁷ Malaysia Poor	CGF Hydrocolloid: No infection reported	Gauze: 1 infection reported	Adherence to wound bed: CGF Hydrocolloid: 100% Gauze: 44% p<0.01	NR	1 subject in gauze group developed wound infection	NR
Colin, 1996 ⁴⁸ Multinational Poor	NR	NR	NR	NR	Only dressing related adverse event was pain upon application of dressing, one subject in the dextranomer paste group	NR
Colwell, 1993 ⁴⁹ US Poor	NR	NR	NR	NR	NR	NR
Darkovich, 1990 ⁵⁰ US Poor	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate
Day, 1995 ⁵¹ US, UK, Canada Fair	NR	NR	Erythema, severe pain, increase in necrotic tissue, wound size, and depth: Hydrocolloid triangle: 4% Hydrocolloid oval: 31%	Deteriorating wound appearance, inflammation of surrounding skin, severe pain upon dressing removal/redness of the surrounding skin, minor bleeding at the wound site in the hydrocolloid oval group	8 patients	8.3%
Gorse, 1987 ⁵² US Fair	Rate of wound increase: 2.89cm ² /day	Rate of wound increase: 0.75cm ² /day	NR	NR	NR	NR
Honde, 1994 ⁵³ France Fair	NR	NR	NR	Local complications (mainly necrosis)	10	5.9%
Kaya, 2005 ⁵⁴ Turkey Good	NR	NR	NR	NR	NR	NR
Kerihuel, 2010 ⁵⁵ France Poor	1 patient	2 patients	NR	Maceration/high exudation; wound infection; wound aggravation; overgranulation; eczema; pruritus	1 from hydrocolloid group	16.9%
Kim, 1996 ⁵⁶ Korea Poor	NR	NR	NR	NR	NR	NR
Kloth, 2002 ⁵⁷ US Poor	NR	NR	NR	NR	NR	NR
Kraft, 1993 ⁵⁸ US Good	NR	NR	NR	NR	NR	NR
Kurzuk-Howard, 1985 ⁵⁹ US Poor	1 patient experienced an infection using the Op-Site treatment	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate
Matzen, 1999 ⁶⁰ Denmark Good 8477	NR	NR	9 patients in the hydrogel group withdrew because of illness (n = 5), death (n=2), missing schedule (n=1), and a wish to cease participating in the trial (n = 1)	NR	9	28.1%
Meaume, 2005 ⁶¹ France Good	NR	NR	Poor local acceptability and/or tolerability was noted in 1 PU case in the test group	Dry wound; pain; peri-wound eczema	19 withdrawals: 10 vs. 9	19.2%
Meaume, 2003 ⁶² Finland Poor	NR	NR	NR	3 adverse events in soft silicone group not related to study dressing (death, hip fracture, PU deteriorated to stage IV).	None	NR
Motta, 1999 ⁶³ US Poor	NR	NR	NR	NR	NR	NR
Mulder, 1993 ⁶⁴ US Poor	NR	NR	NR	NR	NR	NR
Neill, 1989 ⁶⁵ US Poor	NR	NR	In the WTD group one sore enlarged by 216%	NR	Hydrocolloid group: 9 WTD group: 1	18% vs. 2%
Oleske, 1986 ⁶⁶ US Poor	One patient developed an infection in the treated ulcer and died the next day from pulmonary embolism and sepsis. It is not clear what (the underlying disease, or the dressing) contributed to the infection	NR	In one instance a patient in the saline group with two ulcers within 1 cm of one another, the two ulcers merged into a single ulcer with greater depth.	NR	NR	NR
Payne, 2009 ⁶⁷ US Good	One patient (5%) in the foam group showed clinical signs of infection in the reference wound and was withdrawn from the study.	No infection was reported in the saline group	NR	NR	0 (9 patients withdrew from the study, none as a result of treatment)	NR
Price, 2000 ⁶⁸ UK Good	NR	NR	Undermining, no difference reported in the occurrence of undermining	NR	NR	NR
Sebern 1986 ⁶⁹ Sebern 1989 ⁷⁰ US Fair	0	0	11 ulcers developed necrosis and eschar after being randomly assigned treatment	0	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate
Seeley 1999 ⁷¹ US Fair	NR	NR	Adverse incidents (blisters, rash or maceration) Hydro cellular: 5% Hydrocolloid: 10%	NR	1 patients from the hydrocellular and 2 patients from the hydrocolloid group	8% (3 out of 39)
Small, 2002 ⁷² South Africa Good	NR	NR	NR	NR	NR	NR
Thomas, 1997 ⁷³ UK Poor	NR	NR	Seven patients in the Hydrocolloid group and 10 in the hydropolymer group reported adverse events including minor trauma or erythema removal during dressing change, maceration, bleeding, and wound dehydration. Note: leg ulcer group and PU group data combined.	Five patients died during the study for reasons unrelated to the treatments	NR	
Thomas, 1998 ⁷⁴ US Poor	NR	NR	Worsening of Ulcer: (1 patient in each group) Topical Hydrogel: 6% Saline gauze: 7%	NR	2	7% (2 out of 30)
Thomas, 2005 ⁷⁵ US Good	NR	NR	NR	NR	NR	NR
Viamontes, 2003 ⁷⁶ US Poor	Hydrocellular: 76 out of 2,616 (3%) experienced an infection Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	Soft silicone: 23 out of 265 (9%) experienced an infection Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	Skin stripping: Hydrocellular <1% (13 out of 2,773 wounds) Soft silicone: 2% (4 out of 227 wounds)	NR	NA	3% (116 out of 4200 wounds)
Whitney, 2001 ⁷⁷ US Fair	NR	NR	NNWT: 7% (1 out of 15) due to periwound maceration related to treatment	NR	1 patient withdrawn from heated dressing group due to periwound maceration related to treatment	3% (1 out of 30)
Winter, 1990 ⁷⁸ UK Poor	Hydrocolloid: 5 infections reported	Paraffin Gauze: 4 infections reported	Wound deterioration reported in 3 patients in hydrocolloid group and 1 in paraffin gauze group	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, 1992 ⁷⁹ US Fair	NR	NR	NR	NR	NR	NR

Evidence Table 5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate
Yapucu Gune, 2007 ⁸⁰ Turkey Fair	NR	NR	NR	NR	NR	NR
Yastrub 2004 ⁸¹ US Poor	NR	NR	NR	NR	NR	NR

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

Evidence Table 5b: Dressings Observational Studies

Author, year Country Overall Quality Rating	Study Type	Confounders Assessed in Analysis	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/Severity at Baseline (Intervention Onset)
Meaume, 2007 ⁸² France Poor	Observational	NR	Hospitalized in geriatric institutions Acute or chronic wounds in the granulation phase, less than 100 cm ² in size and not presenting any sign of clinical infection	Presence of any progressive neoplastic lesion Any known hypersensitivity to carboxymethylcellulose or who were receiving radiotherapy, chemotherapy or were taking immunosuppressive drugs	NR/NR/43/43 PU N=7	PU group only Age(Mean): 80 years Female: 57.1% Race: NR	Localization: Upper Limb: N=1 Lower Limb: N=5 Thorax: N=0 Others: N=1 Surface area 8.5 +/-4.0 cm ²
Parnell 2005 ⁸³ Country Not Reported Poor	Observational	NR	At least one Stage II or Stage III pressure ulcer with a minimum area of 1.0 cm ² Have used a low-air-loss support surface (Dyna Medics Corporation; Keller, Tex.) for at least the previous 14 days. Use of the low-air-loss support surface was continued throughout the study. Ulcers with a treatment history that included enzymatic debridement had to be at least 7 days post-treatment to avoid any residual chemical or debridement affects on healing.	Presence of a 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): NR Female: NR Race: NR	Stage II: N=3, average area at baseline 3.15cm ² Stage III: N=7, average area at baseline 10.49 cm ²
Stoker 1990 ⁸⁴ UK Poor	Observational	NR	NR	NR	NR/NR/42/36 (29 patients with 36 PU)	Age(Mean): 70.4 Female: NR Race: NR	Stage 1: N=1 Stage 2: N=16 Stage 3: N=15 Stage 4: N=4 Localization: Left Heel: N= 3 Right Heel: N=3 Left Buttock: N=6 Right Buttock: N=5 Buttock: N=6 Sacrum: N=10 Left Ankle: N=1 Right Foot: N=1

Evidence Table 5b: Dressings Observational Studies, continued					
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Duration of Treatment/Followup	Study setting
Meaume, 2007 ⁸² France Poor	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
Parnell 2005 ⁸³ Country Not Reported Poor	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 1990 ⁸⁴ UK Poor	Dressing: Comfeel Pressure Relieving Dressing	NA	NA	Until wound healing was complete	Hospital

Evidence Table 5b: Dressings Observational Studies, continued								
Author, year Country Overall Quality Rating	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate	Recurrence Rate	Pain	Other: Specify
Meaume, 2007 ⁸² France Poor	14.2% healed	Mean PU surface area reduced by 74.8%	1 PU healed after 21 days of treatment	One patient in the pressure ulcers group ... presented secondary infection of the wound on day 6, considered by the investigating physician as not related to the study treatment"	NR	NR	NR	Condition of perilesional skin improved during the trial. In 100% of PU cases, perilesional skin was considered to be "healthy" vs. 55% "healthy" at the start of the trial
Parnell 2005 ⁸³ Country Not Reported Poor	N=5 (50%)	NR, though authors report four Stage III ulcers "improved"	Average healing time: Stage II: 3.3 weeks (range 1-7 weeks) Stage III: 6.5 weeks (range 2-11)	NR	NR	NR	NR	NR
Stoker 1990 ⁸⁴ UK Poor	NR	Mean percent change per day in trial: Buttock: 3.1091 cm ² SD 9.5641 Sacrum: -.0346 cm ² SD 2.0187 Heel: -1.8405 cm ² SD 4.8918	Mean % change for total sample (excluding two patients who healed within the first two weeks of the trial): 1.66% per day	NR	NR	NR	NR	NR

Evidence Table 5b: Dressings Observational Studies, continued									
Author, year Country Overall Quality Rating	Pain	Dermatologic Complications	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Meaume, 2007 ⁸² France Poor	NR	NR	NR	One patient experienced a secondary infection on the 6th day of trial, though the event was not considered to be related to the study	NR	NR	Patient with secondary infection withdrawn from study	NR	NR
Parnell 2005 ⁸³ Country Not Reported Poor	Special attention was given for recording pain, itching, burning, and/or irritation upon application; subjects offered no complaints when specifically asked	NR	NR	NR	NR	No dressing-related adverse events were reported. Two serious adverse events, the deaths of two subjects were not related to the treatment or the wound.	NR	NR	NR
Stoker 1990 ⁸⁴ UK Poor	One patient withdrew from the study because they found the dressing uncomfortable	One patient withdrew because of a rash related to the dressing	NR	NR	NR	NR	2 patients (dressing uncomfortable and rash)	NR	Coloplast Ltd.

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

Evidence Table 5c: Topical Application Trials

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Agren 1985 ⁸⁵ Sweden Fair	Geriatric patients with one or more necrotic pressure ulcers	NR	NR/NR/28/28	Age (Median): 84 vs. 86 years Female: 64% vs. 78% Population: elderly	Topical	Stage III Location: Trochanter, ischial, knee, foot, lower leg, other	Topical streptokinase-streptodor-nase (Varidase) – 100,000 IU streptokinase + 25,000 IU streptodor-nase dissolved into 20 ml sterile isotonic saline solution and applied on a sterile gauze compress Dressings changed 2x/day for 8 weeks	Zinc oxide – premedicated compresses with 400 mcg ZnO/cm ² Dressings changed 1x/day for 8 weeks	NA	8 weeks/NR	(Mixed) Hospitals/ outpatient

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Alvarez 2000 ⁸⁶ US Fair	Patients >18 years of age who completed two week screening period to stabilize the wound and institute physical and supportive therapies. The pressure ulcer must require debridement and must have nonviable tissue attached to the base of the wound.	Clinical signs of infection, cellulitis, osteomyelitis, inadequate nutrition, uncontrolled diabetes and other clinically significant medical conditions that would impair wound healing including renal, hepatic, hematologic, neurological or immunological disease. Patients receiving corticosteroids, immunosuppressive agents, radiation or chemotherapy within one month prior to entry into the study were excluded.	NR/ NR/ 22/ 21	Collagenase Debriding ointment vs. Papain urea Debriding ointment Age (Median): 80 vs. 84 years Female: 50% vs. 36.4% Race: NR	Topical: collagenase deriding ointment	Collagenase debriding ointment vs. papain/urea debriding ointment Ulcer area, mean (range) mm ² : 878.1(175- 5150) vs. 1062.5 (125- 3025) Ulcer Depth- stage Partial thickness-II: 1 vs. 2 Full thickness- III-IV: 9 vs. 9	Collagenase debriding ointment - 250 bacterial collagenase units/g applied over surface of nonviable tissue 1x/day and covered with dry gauze dressing	Papain/urea debriding ointment containing papain 1.1x10 ⁶ units of activity per gram and urea 100 mg per gram	NA	4 weeks	Nursing home
Burgos 2000 ⁸⁷ Spain Good	Hospitalized or institutionalized patients of either gender aged 55 years or over presenting with stage III pressure ulcers for <1 year. Ulcers staged according to the American Pressure Ulcer Advisory Panel.	End-stage diseases, localized or systemic signs and/or symptoms of infection or hypersensitivity to collagenase.	NR/NR/102/ 86	Age (Mean) 78.8 years Female 64.7% Race: NR	Topical: Collagenase ointment at 24 hours	Mean(SD) (range) ulcer age, months: 3.3 (2.3) (1-11)	Collagenase ointment application - at 24-hour intervals for a maximum of 8 weeks (or until complete healing of the ulcer, whatever occurred first).	Collagenase ointment application - at 48- hour intervals for a maximum of 8 weeks (or until complete healing of the ulcer, whatever occurred first).		8 weeks/NR	Hospital or institution

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Chuangsuwanich 2011 ⁸⁸ Thailand Poor	In and out patients with pressure ulcers staged II or IV (NPAUP scale)	NR	NR/NR/45/4 0	Silver sulfazide cream: Age(Mean): 69.10 years Female: 55% Race: NR Silver mesh: Age(Mean): 62.60 years Female: 60% Race: NR	Dressing: silver mesh dressing vs. silver sulfazide cream	Silver sulfazide cream: Mean ulcer area 22.82cm ² PUSH score 13.4 Localization: Sacrum: N=14 Rt. Greater Trochanteric: N= 3 Lt. Greater Trochanteric: N=2 Rt. Ischium: N=1 Silver mesh: Mean ulcer area 12.17cm ² PUSH score 11.4 Localization: Sacrum: N=16 Rt Greater Trochanteric: N=1 Rt. Ischium: N=2 Lt Ischium: N=1	Silver sulfide cream covering wound, changed twice daily N=20	Silver mesh covering wound changed every three days N=20	NA	8 weeks	Siriraj Hospital

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Felzani, 2011 ⁸⁹ Italy Poor	Hospitalized patients of both sexes, aged >18 years, with foreseen hospitalization period of >15 days, with stage I-III decubitus ulcers	Patients unable to cooperate with hygienic measures to be adopted for treatment of sores, those with history of intolerance to hyaluronic acid, those in need of concomitant local and/or general antibiotic therapy for skin lesions or for systemic disease	Number screened: NR ? (12 patients with 4 sores not included) Eligible: 25 in stage 1, 24 in stage 2, 10 in stage 3 Enrolled: 50 residents (20 in stage 1, 20 in stage 2, 10 in stage 3) Analyzed: 50 residents (20 in stage 1, 20 in stage 2, 10 in stage 3); Stage 3 subjects had 14 lesions analyzed (two subjects had 2 lesions and one had 3 lesions)	Age(Mean): 56 years Female: 58% Race: NR	Topical: Sodium hyaluronate acid vs. lysine hyaluronate acid	Grouped by stages; Stage 1, Stage 2, Stage 3	Sodium hyaluronate acid plus standard of care (nutrition supplements, patient mobilization) Stage 1: n=10 Stage 2: n=10 Stage 3: n=7	Lysine hyaluronate acid plus standard of care Stage 1: n=10 Stage 2: n=10 Stage 3: n=7	NA	15 days of treatment	Hospital

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Gerding 1992; Gerding, 1992 #6637 US Poor	Presence of newly diagnosed Stage I or II skin lesion and treatment with an emollient ordered by the attending physician. Patients with one or more lesions were included.	NR	NR/NR/74 patients (137 ulcers)	Age (Mean): NR Female: NR Race: NR	Topical: oxyquinoline-containing ointment (DermaMend) vs. A&D ointment	Stage I: n=69 Stage II: n=68 <u>Size of lesions at start, cm²</u> Stage I: DermaMend 18.9, A&D 4.3 Stage II: DermaMend 1.0, A&D 1.2	Oxyquinoline-containing ointment (DermaMend) Stage I: n=29 residents, 41 lesions Stage II: n=26 residents, 45 lesions	A&D ointment Stage I: n=14 residents, 28 lesions Stage II: n=13 residents, 23 lesions	NA	28 days after initial treatment or until wound resolution	Long term care facilities
Graumlich 2003 ⁹⁰ US Good	18 years and older; at least one pressure, stage II or III	Hypersensitivity to collagen or bovine products; concomitant investigational therapy; osteomyelitis; cellulites; malnutrition; ulcers covered by eschar or necrotic material; ulcers covered by orthopedic casts or devices; burn ulcers; diabetic ulcers	NR/NR/NR/65	Age (Median): 81.3 years Female: 80% Race: NR	Topical: collagen vs. hydrocolloid	<u>Stage II, III</u>	Topical collagen applied 1x/day for 8 weeks	Hydrocolloid applied 2x/week for 8 weeks	NA	8 weeks/Median Follow-up 35 days	Nursing Home

Evidence Table 5c: Topical Application Trials, continued											
Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Hollisaz 2004 ⁹¹ Iran Poor	Paraplegia caused by spinal cord injury; Pressure ulcer stage I and II according to Shea classification or NPUAP; informed consent; smoothness of ulcer area to establish whether adhesive could be used at the site.	(Addiction; heavy smoking (more than 20 cigarettes a day or more than 10 packs per year); concomitant chronic disease (e.g. diabetes mellitus or frank vascular disease such as Buerger's disease).	2015/151/83 / 83	Age (Mean): hydrocolloid: 36. years phenytoin: 36.5 years simple dressing: 36.6 years Female: 0% Race NR	Topical: hydrocolloid/p henytoin	Hydrocolloid: 13 stage I and 18 stage II. Phenytoin: 9 stage I and 21 stage II. Simple dressing: 11 stage I and 19 stage II.	Phenytoin cream	Simple dressing	NA	4 months after completion of 8 week trial	Other
Hsu 2000 ⁹² Taiwan Poor	Inpatients with "the largest and deepest" ulcers	NR	NR/NR/32/32	<u>Treatment</u> Age, years: 68.96+/-9.67 Female: n=10 (42%) Race: NR <u>Routine Medical care:</u> Age, years: 73.63+/-10.29 Female: n=3 (38%) Race: NR	Topical: Sheng-Ji-San formula and routine medical care vs. routine medical care	<u>Treatment</u> Surface area (cm ²) = 26.71+/-29.37 Depth (stage) = 3.04+/-0.62 <u>Routine Medical care:</u> Surface area (cm ²) = 35.09+/-40.35 Depth (stage) = 3.00+/-0.53	Sheng-Ji-San formula plus routine medical care	Routine medical care (including mobilization, repeated turning every 2 hours, wound cleaning with normal saline and Betadine one-two times per day, wet dressing with gauze, nutritional support, control of infection with antibiotics and control of intercurrent illness)	NA	3 weeks of treatment	Hospital

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Kuflik 2001 ⁹³ US Poor	Elderly, immobile patients with Stage I or Stage II ulcers	Patients with pressure ulcers who also had complex underlying etiologies like venous stasis, severe diabetes	NR/NR/20/1 5 patients (16 ulcers)	Age (Mean): Elderly, no further details reported Female: Males and females, no further details reported Race: European back-ground, no further details reported	Topical: Resurfix ointment (new, non prescription medication) vs. petrolatum ointment	<u>Treatment</u> Stage I: n=6 Stage II: n=4 Mean size before treatment, cm/diam: 1.9 <u>Comparator</u> Stage I: n=6 Stage I to II: n=1 Stage II: n=2 Mean size before treatment, cm/diam: 1.2	Resurfix ointment plus nutrition, n=10 patients, 11 ulcers at start; n=8 patients, 9 ulcers at end of study	Petrolatum ointment plus nutrition, n=9 patients, 9 ulcers at start; n=7 patients, 7 ulcers at end of study	NA	6 weeks	Rehabilitat ion Center and Nursing Center (two sites)

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Levasseur, 1991 ⁹⁴ Australia Poor	NR	NR	NR/NR/34/21 patients (21 ulcers)	Age (Mean): 82.5 vs. 81.5 Female: 52% Race: NR Population: elderly	Topical: Active cream F14001 vs. placebo non active cream	F14001 (active based cream) N= 8 Initial size (cm ²): 96 Ulcer Location: Iliac crest: N=1 Greater Trochanter: N=1 Ischium: N=4 Lateral Malleolus: N=2 Placebo (non- active based cream) Initial size (cm ²) 90 N= 13 Ulcer Location: Sacrum: N=5 Ischium: N=4 Lateral Malleolus: N=1 Foot: N=2 Lower leg: N=1	F14001 (active based cream)	Placebo (non active based cream)	NA	6 weeks	Hospital and Long- term care

Evidence Table 5c: Topical Application Trials, continued											
Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Muller 2001 ⁹⁵ Germany and The Netherlands Poor	Inpatients with stage IV pressure sores on the heel following orthopaedic surgery	Patients with a life expectancy of less than 6 months	NR/NR/24/2 3	Age (Mean): Collagenase group mean 74.6, hydrocolloid group mean 72.4 Female: 100% Race: NR	Topical: Collagenase vs. hydrocolloid	All patients had stage IV pressure sores on the heel	Collagenase ointment - treated once a day with a collagenase- containing ointment (Novuxol®), paraffin gauze (Jelonet®) and absorbent bandages after the wound had been cleaned with saline 0.9%. N= 12	Hydrocolloid dressing (DuoDerm ®) twice a week. N=11	NA	treatment continued until total epithelialization was achieved	Hospital
Nisi 2005 ⁹⁶ Italy Poor	NR	Decompensating diabetes, hypertension, severe hypoalbuminosis(<3.00g/ 100ml), clinical evidence of arterial or venous insufficiency, hematocrit values <41% for males and 36% for females, treatments with steroids or immunosuppressive drugs	NR/NR/80/8 0	Age (Mean): 45 years Female: 33.8% Race: NR	Topical: Protease- modulating matrix ointment	NR	Protease- modulating matrix BID or TID (consisting of 55% freeze- dried collagen and 45% oxidized regenerated cellulose Promogran) according to wound exudation + covering with hydropolymer patch	50% povidone iodine solution, saline wash, positioning of viscose-rayon gauze soaked in white Vaseline and covering with a hydropolymer patch.	NA	NR	Hospital

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Pullen 2002 ⁹⁷ Germany Fair	Patients with Seiler stage 2,3, or 4 PU with fibrinous and/or necrotic slough	History of alcohol or drug dependency, hypersensitivity to collagenase or fibrinolysin/DNAse, planned co-medication with local antiseptics, antibiotics, occlusive wound dressings, hydrogels, or hydrocolloids PU covered with black eschar only or whose localization did not permit parallel positioning of the reference scale	NR/NR/135/ 121	Age (Mean): 79 years Female: 51% vs. 47% Population: Elderly	Topical: Collagenase ointment	Stage I, II, IV (Seiler stage 2, 3, or 4)	Collagenase, N= 60	Fibrinolysin and deoxyribonuclease (DNAse), N=61	NA	4 weeks	LTC or home
Rhodes 2001 ⁹⁸ US Fair	>60 years old Stage II PU	Signs and symptoms of wound infection, anemia, malnutrition, folate deficiency, chronic use of immunosuppressant medications, receiving or having a history of adverse effect caused by oral phenytoin	NR/NR/47/3 9 PU N=47	Age (Mean): 79 vs. 76 years Female: 8% Population: elderly	Topical: Phenytoin vs. Collagen dressing (DuoDerm) vs. Triple antibiotic ointment	Stage II	Topical Phenytoin	Collagen Dressing (DuoDerm)	Triple antibiotic ointment	8 weeks or complete wound healing	Long-term care

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Sayag 1996 ⁹⁹ France Good	>60 and had been hospitalized for at least 8 weeks with a stage II or IV PU (Yarkony classification)	More than half the ulcer area comprised of granulated tissue, if the PU was covered with necrotic plaque, or if there was active infection. Renal failure requiring dialysis or heel ulcers combined with end stage arteriopathy of the lower limbs.	NR/NR/92/9 2 PU N=92	Age (Mean): 81.9 vs. 80.4 years Female: 74% Race: NR Population: elderly, limited mobility	Topical: Calcium alginate vs. Dextranomer	Calcium alginate: N=47 Ulcer Stage (Yarkony's classification): III: N=33 (70%) IV: N=14 (30%) Ulcer location: Pelvis area: N=14 (30%) Heel: N=30 (64%) Other: N=3 (6%) Dextranomer: N= 45 Ulcer Stage (Yarkony's classification): III: N=30 (67%) IV:N=15 (33%) Ulcer location: Pelvis area: N=23 (51%) Heel: N=22 (49%) (Article uses Yarkony: Stage III, IV ulcers)	Calcium alginate, N=47	Dextranomer, N=45	NA	8 weeks	Long-term care and dermatolog y centers

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Shamimi Nouri 2008a ¹⁰⁰ Iran Good	18 years and older with bedsores; PU size must be at least 1cm ² with occurrence within the last 2 weeks.	Acute infection or bone exposure; presence of disease or situation that would impair ulcer improvement; alcohol and drug abuse, dialysis and renal failure, corticosteroid consumption, use of immune suppressive agents, radiotherapy, chemotherapy and drug hypersensitivity.	NR/18/18/18	Age (Mean): 47.9 vs. 46 years, p=0.899 Female: 22%, vs. 22% p=1.0 Race: NR	Topical Semelil herbal extract vs. conventional treatment	Mean PU area: 56.1cm ² vs. 19.5cm ² , p=0.264	Herbal extract, topical Semelil (Brand name ANGIPARS) 3% gel daily	Conventional treatment	NA	1 year	Hospital
Shamimi Nouri 2008b ¹⁰¹ Iran Good	PU resulted from spinal inconveniences, amputation, chronic diseases and fractures due to osteoporosis. PU at least 1cm ² in size and occurring within the last 2 weeks	Acute infection or bone exposure; presence of disease or situation that would impair ulcer improvement; alcohol and drug abuse, dialysis and renal failure, corticosteroid consumption, use of immune suppressive agents, radiotherapy, chemotherapy and drug hyper-sensitivity.	NR/18/18/18	Age (Mean):46 vs. 46 years, p=0.982 Female: 22% vs. 22%, p=1.00 Race NR	Topical Semelil herbal extract	Mean PU area: 57.2cm ² vs. 19.5cm ² , p=0.446	4 mL ANGIPARS diluted in 100mL of salt solution, infused for 30 minutes every other day for 4 weeks	Placebo: balanced salt solution	NA	4 weeks	Hospital

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Siponnen 2008 ¹⁰² Finland Poor	Patients with one or several severe pressure ulcers (stage II-IV) with or without infection, not considered suitable for surgical treatment	NR (dropouts were not included in any data at baseline or end of study)	Number screened: NR Eligible: NR Enrolled, randomized: 37 patients, 45 ulcers Analyzed: 22 patients, 29 ulcers	Age (Mean): 80 vs. 74years Female: n=7 (54%) vs. n=6 (67%) Race: NR	Topical: Norway spruce resin mixed with butter vs. sodium carboxymethyl cellulose hydrocolloid polymer without or with ionic silver (Aquacel+/-Ag)	Stage II: n=7 (39%) vs. n=5 (45%) Stage III: n=9 (50%) vs. n=5 (45%) Stage IV: n=2 (11%) vs. n=1 (9%) p=0.938 Width, mean (cm): 3.2+/-2.4 vs. 4.2+/-2.8, p=0.387 Depth, mean (mm): 5.2+/-10.3 vs. 5.3+/-6.5, p=0.580 Note: Dropouts are not included in above data	Norway spruce resin mixed with butter for 6 months Dressing changed daily if ulcer was infected or producing discharge and changed every third day otherwise n=21 patients, 27 ulcers at baseline; n=13 patients, 18 ulcers at end of study	Sodium carboxymethylcellulose hydrocolloid polymer without or with ionic silver (Aquacel+/-Ag); silver used when ulcer found to be infected on bacterial culture for 6 months Dressing changed daily if ulcer was infected or producing discharge and changed every third day otherwise for 6 months n=16 patients, 18 ulcers at baseline; n=9 patients, 11 ulcers at end of study	NA	6 months	Primary care hospitals

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Subbanna 2007 ¹⁰³ India Good	Paraplegic patients aged 10 to 55 years with stage 2 pressure ulcers without necrotic tissue	Patients with anemia, hypoalbuminemia, elevated serum creatinine, abnormal liver function tests, history of smoking, peripheral vascular disease, diabetes mellitus, malignancy, connective tissue disorders, psychiatric illness	Number screened: 43 Eligible: 28 Enrolled, randomized: 28 Analyzed: 26	Age (Mean):34.25 vs. 31.64years Female: n=1, 7.2% vs. n=2, 14.3% Race: NR	Topical: Phenytoin solution vs. saline solution	<u>Treatment</u> Pressure Ulcer Scale for Healing (PUSH) 3.0 mean rating: 13.5+/-1.16 Ulcer volume, mean (ml): 3.70+/-2.85 <u>Comparator</u> PUSH 3.0 mean rating: 13.21+/-1.42 Ulcer volume, mean (ml): 4.85+/-3.75	Treatment: Phenytoin solution daily for 15 days n=14 enrolled, 12 analyzed	Comparator: Normal saline solution daily for 15 days n=14 enrolled and analyzed	NA	15 days of treatment, measures on Day1 before treatment and Day 16	Rehabilitation ward
Tytgat 1988 ¹⁰⁴ Belgium Poor	Multiple sclerosis patients with decubitus ulcers	NR	NR/NR/16/16	Ketanserin vs. placebo Age (Mean): 58 vs. 60 years Female: 50% vs. 50% Race: NR	Topical: Ketanserin 2% BID	NR		Placebo	NA	3 weeks	NR

**Evidence Table 5c:
Topical
Application Trials,
continued**

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Zeron, 2007 ¹⁰⁵ Mexico and Spain Good	65 years and older with stage II or III pressure ulcer	Prior surgical treatment of pressure ulcers; septic state; mechanical breathing support; state of coma or brain death; ingestion of steroids; abandonment of the patient by their family.	NR/NR/NR/ 24	Age (Mean): 65-90 Female: 83% vs. 75% Race: NR Population: general	Topical: Collagen- polyvinylpyrrol idone (clg-pvp)	Experimental group mean ulcer diameter: 3.4cm Experimental group mean ulcer diameter: 2.9cm	Zinc oxide paste + collagen- polyvinylpyrroli done (clg-pvp) - a total of 1.5 ml of medication was injected intradermally into the patient, equally applied at four points equidistant from the edges of the wound applied 1x week for 3 weeks	Zinc oxide paste + placebo (not described) - a total of 1.5 ml of placebo was injected intradermally into the patient, equally applied at four points equidistant from the edges of the wound applied 1x week for 3 weeks	NA	3 weeks/3 weeks	Hospital

Evidence Table 5c: Topical Application Trials, continued							
Author, year Country Overall Quality	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Agren 1985 ⁸⁵ Sweden Fair	NR	NR	Disappearance of necrotic tissue: Varidase – 43% Wound area reduction: Varidase – 18.7%	Disappearance of necrotic tissue: Zinc oxide – 50% Wound area reduction: Zinc oxide – 2.4%	NR	NR	NR
Alvarez 2000 ⁸⁶ US Fair	NR	NR	% reduction in wound area from baseline with (SD) Week 1: 1.9 (7.6) Week 2: 23.7 (25.8) Week 3: 34.8 (25.2) Week4: 55.4 (33.5)	Percent reduction in wound area from baseline with (SD) Week 1: 5.8 (17.4) Week 2: 19.9 (29.2) Week 3: 27.3 (28.5) Week 4: 33.9(26.17)	Mean time to 50% granulation (time in days for 50% of the wounds to be covered by granulation tissue): 6.8	Mean time to 50% granulation (time in days for 50% of the wounds to be covered by granulation tissue) 28 No significant difference in healing rates between 2 groups	Bacterial count at baseline 5.6 CFU/mL Bacterial count at 4 weeks 4.6CFU/mL
Burgos 2000 ⁸⁷ Spain Good	closure and epithelialization (24 hour interval group): n=12 difference between 2 groups: p=0.451 Relative risk of non-healing between 2 groups when granulation tissue covered 11-30% of the ulcer surface was 1.097 (95% CI, 0.86 to 1.39)	closure and epithelialization(48 hour interval group): n=9	ITT analysis: Change from baseline in wound area at 8 weeks (24 hour interval): - 5.1 cm ² (Change from baseline in both groups F=0.31.17, p<0.0005), difference between 2 groups: F=0.219, p=0.641 Per Protocol analysis: Change from baseline in wound area at 8 weeks (24 hour interval): -5.4, (change from baseline in both groups F=31.75, p<0.0005)difference between 2 groups: F=0.514, p=0.595	ITT analysis: Change from baseline in wound area at 8 weeks (48 hour interval):- 6 cm ² Per Protocol analysis: Change from baseline in wound area at 8 weeks (48 hour interval): -7cm ²	NR	NR	NR
Chuangsuwanich 2011 ⁸⁸ Thailand Poor }	NR	NR	Cream: 18.22 cm ² at week 8	Silver Mesh: 7.96 cm ² at week 8	Cream: Healing rate 25.06%	Silver mesh: Healing rate 36.95% p=value 0.507	NR

Evidence Table 5c: Topical Application Trials, continued							
Author, year Country Overall Quality	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Felzani, 2011 ⁸⁹ Italy Poor	Lys-HA arm - 15 days of treatment: Group 1 (stage 1 ulcers) (n=10): Healing of 90% of the lesion 10/10(100%) Group 2 (stage 2 ulcers) (n=10): Healing of 70% of the lesion 10/10 (100%) Group 3 (stage 3 ulcers) (n=5): healing of 5/5 (100%) ulcers	Comparator arm - 15 days of treatment: Group 1 (stage 1 ulcers) (n=10): Healing of 70% of the lesion in 10/20 (50%) Group 2 (stage 2 ulcers) (n=10): Healing of 40% of the lesion in 10/10(100%) Group 3 (stage 3 ulcers) (n=2): healing of 2/2 (100%) ulcers	NR	NR	Lys-HA arm: treatment period necessary to reach 50% Regression Group 1 - 9 days Group 2 - 9.5 days Group 3 - 12.9 days	Comparator arm: treatment period necessary to reach 50% Regression Group 1 - 15 days, p<0.05 Group 2 - 15 days, p<0.05 Group 3 - 19.2 days, p<0.05	NR
Gerding 1992 {Gerding, 1992 #6637 US Poor	<u>Resolved lesions (%)</u> Stage I: 58.5% Stage II: 44.5%	<u>Resolved lesions (%)</u> Stage I: 57.1% Stage II: 21.8%, p<0.03	NR	NR	<u>Day to resolve</u> Stage I: 6.2 Stage II: 7.8	<u>Days to resolve</u> Stage I: 7.3 Stage II: 13.0, p<0.05	NR
Graumlich 2003 ⁹⁰ US Good	Topical collagen - 51% p=0.89	Hydrocolloid – 50%	NR	NR	Area healed per day: (mm ² /day, mean, SD) Topical collagen - 6+/-19 p=0.94	Area healed per day: (mm ² /day, mean, SD) Hydrocolloid - 6+/-16	NR

Evidence Table 5c: Topical Application Trials, continued							
Author, year Country Overall Quality	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Hollisaz 2004 ⁹¹ Iran Poor	<p>The completion of healing, regardless of location and stage, was better in the hydrocolloid group compared to the phenytoin group. [23/31 (74.19%) vs. 12/30 (40%); difference 34.19% CI: 10.85 to 57.52 (p < 0.01)].</p> <p>Completion of healing of stage I ulcers in the hydrocolloid group [11/13 (85%)] was also better than the simple dressing [5/11 (45%); difference 40%, 95% CI: 4.7 to 75.22, (p < 0.05)] or the phenytoin [2/9 (22%); difference 63%, 95% CI 29.69 to 96.3, (p < 0.005)] groups.</p> <p>Completion of healing of stage II ulcers was better in the hydrocolloid group [12/18 (67%)] than in the simple dressing group [3/19 (16%); difference 51%, 95% CI: 23.73 to 78.26, (p<0.005)], but there was no significant difference from the PC group [10/21 (48%); difference 19%; 95% CI: -11.47 to 49.47m (p >0.05).</p>	<p>The completion of healing, regardless of location and stage, was better in the hydrocolloid group compared to the phenytoin group. [23/31 (74.19%) vs. 12/30 (40%); difference 34.19% CI: 10.85 to 57.52 (p < 0.01)].</p> <p>Completion of healing of stage I ulcers in the hydrocolloid group [11/13 (85%)] was also better than the simple dressing [5/11 (45%); difference 40%, 95% CI: 4.7 to 75.22, (p < 0.05)] or the phenytoin [2/9 (22%); difference 63%, 95% CI 29.69 to 96.3, (p < 0.005)] groups.</p> <p>Completion of healing of stage II ulcers was better in the hydrocolloid group [12/18 (67%)] than in the simple dressing group [3/19 (16%); difference 51%, 95% CI: 23.73 to 78.26, (p<0.005)], but there was no significant difference from the PC group [10/21 (48%); difference 19%; 95% CI: -11.47 to 49.47m (p >0.05).</p>	NR	NR	NR	NR	NR
Hsu 2000 ⁹² Taiwan Poor	Effective treatment=complete or incomplete healing, 20/24 had effective treatment, 1/20 had complete healing	Effective treatment in 3/8, 0/3 had complete healing	<p>Decreased surface area from 26.71+/-29.37 cm² to 18.33+/-28.28 cm², p<0.005</p> <p>Reduction ratio of surface area (RSA) = (initial area - final area) / initial area x 100% RSA = 33.83%=-33.32%</p>	<p>Increased surface area from 35.09+/-40.35 cm² to 41.59+/-53.11 cm², not significant</p> <p>RSA = -2.85%+/-47.54%, p<0.05 compared to Treatment A</p>	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued							
Author, year Country Overall Quality	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Kuflik 2001 ⁹³ US Poor	5/10 ulcers completely resolved (4 Stage I, 1 Stage II)	2/9 ulcers resolved (both Stage I)	Mean size after treatment, cm/diam: 0.9 (those who terminated treatment not included, n=2)	Mean size after treatment, cm/diam: 1.8 (those who terminated treatment not included, n=2)	NR	NR	NR
Levasseur, 1991 ⁹⁴ Australia Poor	NR	NR	Reduction in both groups	Reduction in both groups (p <.001)	F14001: 18 days	Placebo: 29 days (p=0.08)	NR
Muller 2001 ⁹⁵ Germany and The Netherlands Poor	Collagenase group: 11 out of 12 (91%) patients	Hydrocolloid group: 7 out of 11 patients (63.6%)	NR	NR	Collagenase group: wound healing ranged from 6 to 12 weeks, mean 10 weeks	Hydrocolloid group: wound healing ranged from 11-16 weeks, mean 14 weeks	NR
Nisi 2005 ⁹⁶ Italy Poor	Group A:90% difference between group A vs. B p=0.59	Group B: 70%	NR	NR	time to wound healing: 2-6 weeks in group A (2nd phase results)	Time to wound healing: 2-8 weeks in group B (2nd phase results)	NR
Pullen 2002 ⁹⁷ Germany Fair	NR	NR	Collagenase: Decrease in necrotic wound area N= 37 (61.7%)	Fibrinolysin DNase: Decrease in necrotic wound area N= 35 (57.4%)	NR	NR	NR
Rhodes 2001 ⁹⁸ US Fair	Topical Phenytoin: Mean time=35 days	Collagen dressing (DuoDerm) vs. Triple antibiotic ointment: Mean time=52 days vs. 54 days	NR	NR	Topical Phenytoin: mean time to healing 35.3,p=0.005	DuoDerm vs. TAO mean time to healing 51.8 vs. 53.8	No infection occurred in any of the groups
Sayag 1996 ⁹⁹ France Good	Calcium alginate: Complete wound healing: NR 75% healed at 8 weeks: 32%	Dextranomer: Complete wound healing: NR 75% healed at 8 weeks: 13%	Calcium alginate: 1) 40% reduction in wound area: 74% 2) Mean surface area reduction: 2.39 cm ²	Dextranomer: 1) 40% reduction in wound area: 42% 2) Mean surface area reduction: 0.27 cm ²	Calcium alginate: Mean reduction in surface area per week, 2.39cm ²	Dextranomer: Mean reduction in surface area per week, .27cm ² (p=0.0001)	Calcium alginate: 2 infections occurred
Shamimi Nouri 2008a ¹⁰⁰ Iran Good	67% of wounds healed	No complete healing in the comparator group	NA	Mean surface area reduced to 7.8cm ² p=0.008	Mean surface area reduced to 16.7cm ²	67% healed completely in 1 year 33% healed by 50-80% in 1 year	11% of patients had PU that healed by 50-80% in 1 year
Shamimi Nouri 2008b ¹⁰¹ Iran Good	44% of wounds healed	No complete healing in the comparator group	NR	Mean surface area reduced to 20cm ² p=0.008	Mean surface area reduced to 16.7cm ² p=0.144	44% healed completely in 1 year 56% healed by 50-80% in 1 year	11% of patients had PU that healed by 50-80% in 1 year

Evidence Table 5c: Topical Application Trials, continued							
Author, year Country Overall Quality	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Siponnen 2008 ¹⁰² Finland Poor	<u>6 months</u> 12/13 patients (92%) 94% ulcers	<u>6 months</u> 4/9 patients (44%), p=0.003 compared to Treatment A 36% of ulcers, p=0.003 compared to Treatment A	NR	NR	Speed of ulcer healing was significantly faster in resin group (p=0.013)	Figure 2, Text p.1058: speed of ulcer healing was significantly faster in resin group (p=0.013)	<u>1 month</u> 10 ulcers with positive cultures, 1 patient given antibiotics Note: although not routinely done, 2 ulcers were positive for bacteria at 6 months
Subbanna 2007 ¹⁰³ India Good	NR	NR	NR	NR	NR	NR	NR
Tytgat 1988 ¹⁰⁴ Belgium Poor	Ketanserin 2% Epithelialization comparison with baseline Week 1, mean (SEM): 1.8 (0.23), p=significant Week 2, mean (SEM):2.2 (0.35), p=significant Week 3, mean (SEM): 2.3 (0.31), p=significant	Placebo Epithelialization comparison with baseline Week 1, mean (SEM):1.4 (0.46) Week 2, mean (SEM):1.4 (0.50), p=significant Week 3, mean (SEM): 1.3 (0.49)	Ketanserin 2% Reduction in wound area at 3 weeks :81% Difference between Ketanserin vs. placebo is significant Wound area (comparison with baseline) mm ² Week 1, mean (SEM): -1255 (703.1), p=significant Week 2, mean (SEM): -2776 (1608.0), p=significant Week 3, mean (SEM): -3080 (1773.0), p=significant	Placebo Reduction in wound area at 3 weeks: 16% Wound area (comparison with baseline) mm ² Week 1, mean (SEM): -155 (102.7) Week 2, mean (SEM): -263 (77.9), p=significant Week 3: mean (SEM)-195 (92.7)	NR	NR	NR
Zeron, 2007 ¹⁰⁵ Mexico and Spain Good	42% complete wound healing in experimental group	33% complete wound healing in comparator group	Reduction in ulcer size (mean): clg-pvp – from 3.4 to 1.14 cm	Placebo – 2.9 to 1.58 cm p= nonsignificant	Mean ulcer reduction of 6.6mm/week	NR	NR

Evidence Table 5c: Topical Application Trials, continued									
Author, year Country Overall Quality	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify	Pain	Pain (Comparator)	Dermatologic Complications
Agren 1985 ⁸⁵ Sweden Fair	NR	NR	NR	NR	NR	NR	NR	NR	NR
Alvarez 2000 ⁸⁶ US Fair	Bacterial count at baseline 5.4CFU/mL Bacterial count at 4 weeks: 5.0 CFU/mL	NR	NR	NR	NR	<p>Papain /urea vs. collagenase Reduction in non-viable tissue at 2 weeks: 68.3% vs. 22.3% at 3 weeks: 86.5% vs. 37.3%, p<0.05, at 4 weeks 95.4% vs. 35.8%, p<0.01</p> <p>% reduction in area of necrotic tissue (slough) from baseline at Week 3: 73.4 vs. vs. 32.7, at Week 4: 93.3 vs. 34.0 % reduction in area of necrotic tissue (eschar) from baseline at Week 3: 90.8 vs. 46.7, at Week 4: 98.5 vs. 43.1</p> <p>% reduction of necrotic tissue by planimetry from baseline Week 1: 13.5 vs. 7.5, Week 2: 68.3 vs. 22.3, Week 3: 86.5 vs. 37.3 (p<0.05 between groups), Week 4: 95.4 vs. 35.8 (p<0.01 between groups)</p> <p>Debridement of necrotic tissue by clinical evaluation Week 1: 3.9 vs. 2.0, Week 2 4.5 vs. 2.0, Week 3 4.9 vs. 2.2, Week 4 5.5 vs. 1.3 (Relative score 1=76-100%, covered with necrotic tissue, 2=51-75%, 3=26-50%, 4=11-25%, 5=1-10%, 6=none)</p> <p>Overall wound response 4.5 vs. 1.1 9p<0.01, (0=wound deteriorated, 1=no change, 2=minimal change, 3=average improvement, 4=significant improvement, 5=necrotic tissue resolved.</p>	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued									
Author, year Country Overall Quality	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify	Pain	Pain (Comparator)	Dermatologic Complications
Burgos 2000 ⁸⁷ Spain Good	NR	NR	NR	NR	NR	Granulation tissue formation increased p<0.0005 and exudate production decreased in both groups (24 hour group p=0.012, 48 hour group p=0.04), differences between treatment groups NS.	ITT analysis: Pain intensity decrease from baseline p=0.001 Difference between intervention and comparator favored 24 hour interval group: p=0.004 Per protocol analysis: pain intensity decrease from baseline p=0.001, difference between intervention and comparator=NS	Pain intensity decrease from baseline, NS ITT and Per protocol analysis	Three patients (6.5%) in the 24-hour group presented one adverse reaction each (rash, one patient; necrosis in ulcer bed,
Chuangsuwanich 2011 ⁸⁸ Thailand Poor	NR	NR	NR	NR	NR	PUSH (Pressure Ulcer Scale for Healing) Score reduction: Cream group, 34.51% Silver Mesh group, 28.15% P value .473	NR	NR	NR
Felzani, 2011 ⁸⁹ Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gerding 1992†Gerding, 1992 #6637 US Poor	NR	NR	NR	NR	NR	DermaMend vs. A&D <u>Improved Lesions (%)</u> Stage I: 31.7 vs. 21.4 Stage II: 42.2 vs. 34.8 <u>No change lesions (%)</u> Stage I: 9.8 vs. 14.3 Stage II: 11.1 vs. 30.4 <u>Worse lesions (%)</u> Stage I: 0 vs. 7.2 Stage II: 2.2 vs. 13.0 <u>Resolved/improved (%)</u> Stage I: 90.2 vs. 78.0 Stage II: 86.7 vs. 56.6 <u>No change/worse (%)</u> Stage I: 9.8 vs. 21.5 Stage II 13.3 vs. 43.4	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued									
Author, year Country Overall Quality	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify	Pain	Pain (Comparator)	Dermatologic Complications
Graumlich 2003 ⁹⁰ US Good	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hollisaz 2004 ⁹¹ Iran Poor	NR	NR	NR	All completely healed ulcer patients were followed up by monthly visits from general practitioners for a further 4 months after the end of the trial. No recurrence of ulceration was observed in any of the trial groups during this period.	All completely healed ulcer patients were followed up by monthly visits from general practitioners for a further 4 months after the end of the trial. No recurrence of ulceration was observed in any of the trial groups during this period.	NR	NR	NR	NR
Hsu 2000 ⁹² Taiwan Poor	NR	NR	NR	NR	NR	Effective ratio (ER) = Number effectively treated / Number treated x 100% ER: 83% in treatment group vs. 38% in comparator group, p<0.05 Multivariate analysis performed to account for age, gender, disease type and SJS as independent variables; only SJS had significant correlation with RSA, P=0.03 and ER, OR 9.5, 95% CI 1.41-64.6	NR	NR	NR
Kuflik 2001 ⁹³ US Poor	NR	NR	NR	NR	NR	Erythema noted in tables by ulcer, but no collapsed data available	NR	NR	NR
Levasseur, 1991 ⁹⁴ Australia Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued									
Author, year Country Overall Quality	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify	Pain	Pain (Comparator)	Dermatologic Complications
Muller 2001 ⁹⁵ Germany and The Netherlands Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Nisi 2005 ⁹⁶ Italy Poor	NR	NR	NR	NR	NR	Group A vs. Group B 2nd phase results No. of dressings performed: n= 6-15 vs. 14-52 Overall hospitalization (days): 360 vs. 1164	NR	NR	NR
Pullen 2002 ⁹⁷ Germany Fair	NR	NR	NR	NR	NR	NR	NR	NR	Collagenase: 6 skin related adverse events reported in 5 patients
Rhodes 2001 ⁹⁸ US Fair	NR	NR	NR	In the phenytoin group, one patient had ulcers that continually recurred after healing	NR	In the phenytoin group the appearance of healthy granulation tissue appeared within 2-7 days in all subjects . Those in the standard treatment groups required 6-21 days to produce new granulation tissue.	NR	NR	NR
Sayag 1996 ⁹⁹ France Good	Dextranomer: 2 infections occurred	NR	NR	NR	NR	NR	Calcium alginate: 0 patients reported pain	Dextranomer: 5 patients reported pain	NR
Shamimi Nouri 2008a ¹⁰⁰ Iran Good	NR	NR	NR	NR	NR	NR	NR	NR	NR
Shamimi Nouri 2008b ¹⁰¹ Iran Good	NR	NR	NR	NR	NR	NR	NR	NR	NR
Siponnen 2008 ¹⁰² Finland Poor	<u>1 month</u> 14 ulcers with positive cultures, 6 patients given antibiotics Note: no results shown at 6 months	NR	NR	NR	NR	Treatment A vs. Treatment B <u>6 months</u> Width, mean (cm): 0.2+/-0.7 vs. 1.8+/-1.9, p=0.011 Depth, mean (mm): 0.6+/-2.4 "Significantly better": n=1 (6%) vs. n=6 (55%) "unimproved": n=0 vs. n=1 (9%), p=0.003	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued									
Author, year Country Overall Quality	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify	Pain	Pain (Comparator)	Dermatologic Complications
Subbanna 2007 ¹⁰³ India Good	NR	NR	NR	NR	NR	<p>Reduction in PUSH 3.0 rating (%), Treatment A vs. Treatment B 19.53+/-17.70 vs. 11.39+/-11.09, difference 8.14 (95% CI -4.3, 20.5), p=0.261</p> <p>Reduction in ulcer size (%), Treatment A vs. Treatment B 47.83+/-20.94 vs. 36.03+/-17.63, difference 11.8 (95% CI -3.8, 27.4), p=0.132</p> <p>Reduction in ulcer volume (%), Treatment A vs. Treatment B 53.94+/-31.20 vs. 55.76+/-27.75, difference -1.81 (95% CI -25.6, 22.0), p=0.777</p>	NR	NR	NR
Tytgat 1988 ¹⁰⁴ Belgium Poor	NR	NR	NR	NR	NR	<p>Ketanserin 2% vs. placebo Change from baseline in granulation (p=significant vs. baseline for ketanserin at Week1,2 and 3) Week 1, mean (SEM): 1.1 (0.23) vs. 1.0 (0.46) Week 2, mean (SEM):1.6 (0.37) vs. 1.0 (0.57) Week 3, mean (SEM):1.9 (0.41) vs. 0.0 (0.38) % of patients with pronounced granulation at Week 3: 75% vs. 0</p> <p>Change from baseline in Erythema Week1,mean (SEM): 0.5 (0.51) vs. 0.2 (0.21) Week 2, mean (SEM): 0.4 (0.57) vs. 1.3 (0.38) (p=significant vs. baseline for placebo) Week 3, mean (SEM): 0.0 (0.34) vs. 0.5 (0.28)</p>	NR	NR	NR
Zeron, 2007 ¹⁰⁵ Mexico and Spain Good	NR	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued										
Author, year Country Overall Quality	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Agren 1985 ⁸⁵ Sweden Fair	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Alvarez 2000 ⁸⁶ US Fair	NR	NR	NR	Bacterial count at baseline 5.6 CFU/mL Bacterial count at 4 weeks 4.6 CFU/mL	Bacterial count at baseline 5.4CFU/mL Bacterial count at 4 weeks: 5.0 CFU/mL	NR	NR	0 (1 person died prior to treatment)	0	NR
Burgos 2000 ⁸⁷ Spain Good	24 hour group rash, necrosis in ulcer bed, ulcer worsening: 2.2% (each) 48 hour group necrosis in ulcer bed: 4.3%	NR	NR	24 hour interval group 0	48 hour interval group n (%): 1 (2.2%)	NR	NR	24 hour interval vs. 48 hour interval n=1 vs. 2	24 hour interval group vs. 48 hour interval group 6.5% vs. 6.5%	Knoll SA, Madrid
Chuangsuwanich 2011 ⁸⁸ Thailand Poor	NR	NR	NR	Infection rates not reported, however bacterial cultures were taken and compared	Infection rates not reported, however bacterial cultures were taken and compared	NR	NR	NR	NR	NR
Felzani, 2011 ⁸⁹ Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gerding 1992{Gerding, 1992 #6637 US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	Supported in part by grant from InnoVisions, Inc.
Graumlich 2003 ⁹⁰ US Good	NR	NR	NR	NR	NR	NR	No adverse events related to treatment.	NR	NR	Retirement research foundation

Evidence Table 5c: Topical Application Trials, continued										
Author, year Country Overall Quality	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Hollisaz 2004 ⁹¹ Iran Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	Jaonbazan Medical and Engineering Research Center
Hsu 2000 ⁹² Taiwan Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	Funding from Department of Health
Kuflik 2001 ⁹³ US Poor	NR	NR	NR	NR	NR	NR	NR	<u>Treatment</u> One patient with Stage II ulcer discontinued due to non-improvement without deterioration (also had unrelated cardiorespiratory difficulty), one patient with Stage I ulcer terminated due to medical conditions <u>Comparator</u> Two patients with Stage I ulcers terminated due to worsening	NR	Topix Pharmaceuticals, Inc.
Levasseur, 1991 ⁹⁴ Australia Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	Schumacher Pharmaceuticals
Muller 2001 ⁹⁵ Germany and The Netherlands Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR	Knoll AG, Ludwigshafen, Germany

Evidence Table 5c: Topical Application Trials, continued										
Author, year Country Overall Quality	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Nisi 2005 ⁹⁶ Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR. Stated in publication "No occurrence of adverse reactions, inflammatory or allergic phenomena or wound regressions in the patients treated with protease-modulating matrix.	NR
Pullen 2002 ⁹⁷ Germany Fair	Collagenase: 6 skin related adverse events reported in 5 patients Fibrinolysin/ DNase: 5 skin related adverse events reported in 5 patients	NR	NR	NR	NR	NR	54 serious events in 16 patients in the collagenase group, and 24 in 11 patients in the fibrinolysin/ DNase group, none of which were evaluated to be related to the study treatment	NR	118 adverse events reported in 45 patients in the collagenase group and 103 in 34 patients in the fibrinolysin/ DNase group	NR
Rhodes 2001 ⁹⁸ US Fair	NR	NR	NR	No infection occurred in any group	NR	NR	NR	NR	NR	NR

Evidence Table 5c: Topical Application Trials, continued										
Author, year Country Overall Quality	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Sayag 1996 ⁹⁹ France Good	Dextranomer: 1 patient had skin irritation, 1 reported pruritus	Calcium alginate: no bleeding reported	Dextranomer: 3 patients had bleeding during dressing changes	Calcium alginate: 2 patients had infection	Dextranomer: 2 patients had infection	Hypergranulation: 1 patient in the calcium alginate group, and 3 in the dextranomer group had hypergranulation. Deterioration of PU or stagnation after four weeks of treatment: 2 patients in calcium alginate and 15 in dextranomer group	NR	NR	Calcium alginate: 4 adverse events, dextranomer, 15 adverse events	Les Laboratories Brothier
Shamimi Nouri 2008a ¹⁰⁰ Iran Good	NR	NR	NR	NR	NR	NR	NR	“All patients completed the study and there were no losses to follow-up, no treatment withdrawals, no changes in trial group and no adverse events.”	NR	ParsRoos Co.
Shamimi Nouri 2008b ¹⁰¹ Iran Good	NR	NR	NR	NR	NR	NR	NR	“All of the patients continued treatment until completion of the trial and none of them experienced severe adverse consequence related to the treatment”	NR	ParsRoos Co.
Siponnen 2008 ¹⁰² Finland Poor	n=1 (13%) allergic skin reaction	NR	NR	See outcomes	See outcomes	Number of wound revisions, Treatment A vs. Treatment B n=5 (28%) vs. n=7 (64%), p=0.078	NR	n=1 (13%) in Treatment A group due to allergic skin reaction	NR	Lappish Cultural Foundation grant to A.S. (author)
Subbanna 2007 ¹⁰³ India Good	NR	NR	NR	NR	NR	NR	NR	NR	None of the patients reported any local or systemic adverse events; serum phenytoin concentrations were negligible	Intramural research funds from Christian Medical College, Vellore

Evidence Table 5c: Topical Application Trials, continued										
Author, year Country Overall Quality	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Tytgat 1988 ¹⁰⁴ Belgium Poor	NR	NR	NR	NR	NR	NR	NR. Reports no side effects with ketanserin	NR. Reports no side effects with ketanserin	NR. Reports no side effects with ketanserin	NR
Zeron, 2007 ¹⁰⁵ Mexico and Spain Good	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5d: Topical Application Observational Studies

Author, Year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting:
Hindryckx 1990 ¹⁰⁶ Belgium Poor	Unmatched prospective cohort	Inpatients with a decubitus ulcer with bacterial and/or fungal contamination	Leukopenia, general anti- biotherapy treatment during treatment with silver sulfadiazine cream, pregnancy, known allergy to sulfanilamides and/or components of the silver sulfadiazine cream excipient	NR/NR/21/21	Age(Mean) 75.7 years Female: n=13 (62%) Race: NR	NR	Topical: Silver sulfadiazine cream plus pressure relief measures (e.g. position changes, gel cushions, water mattress)	NA	NA	Minimum of 3 weeks (results up to week 8 of followup shown)	Hospital
Narayanan 2005 ¹⁰⁷ US Fair	Retrospective review	Documentation of at least 1 ulcer (stage 1 or 2) during the study period.	NR	NR/NR/861/861	Age: < 60 years:10.0% 60-69 years: 10.1% 70-79 years:22.1% 80-89 years: 36.4% 90+ years: 20.6% % female: 67.1% Caucasian: 83.3% African American: 15.1% Hispanic: 0.4% Other: 1.3%	Treatment A vs. B vs. C Stage 1 % of patients: 24.6% vs. 8.8% vs. 66.7% Stage 2 % of patients: 10.6% vs. 21.8% vs. 67.7%	NR	473/861 or 54.9%	balsam Peru, hydrogenated castor oil and trypsin (BCT) ointment- Xenaderm	BCT ointment + Other (other includes another topical wound dressing or prescriptive product at some time during the course of the wound episode.	Nursing home

Evidence Table 5d: Topical Application Observational Studies, continued								
Author, year Country Overall Quality Rating	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate	Recurrence Rate	Pain	Other: Specify
Hindryckx 1990 ¹⁰⁶ Belgium Poor	NR	18/21 had positive clinical evolution of pressure sores (disappearance of necrosis, development of granulation tissue, decrease in size) 3/21 had negative clinical evolution of pressure sores (increase in size)	NR	12/21 had secondary microorganisms in wounds	NR	NR	0/21 reported pain during dressing changes; 17/21 had wound pain at start of treatment, 11/17 pain had subsided during treatment	10/21 achieved wound sterilization (no bacteria found for at least 2 consecutive weeks); sterilization achieved in 1-3 weeks for heel ulcers (n=6) and 1-5 weeks in sacrum ulcers (n=4); sterilization achieved in 4 cases of <i>S. Aureus</i> primary infection after 1 week and in an infection with gram-negative bacteria after 1-5 weeks
Narayanan 2005 ¹⁰⁷ US Fair	NR	Treatment groups A vs. B vs. C Mean duration of treatment for all ulcers in days (healed, not healed) Initial stage 1 wounds 72.1 vs. 94 vs. 87.6 Initial stage 2 wounds 81.4 vs. 151.5 vs. 157.2	Time to heal, adjusted for covariates, all treated wounds with complete MDS data Treatment groups A vs. B vs. C Initial stage 1 Mean no. of days, 95% CI: 31.3 (-7.7-70.4) vs. 74.9 (42.6-107.2) vs. 62.3(45.5-79.2) Initial Stage 2 Mean no. of days, 95% CI: 57.2 (44.0-70.4) vs. 70.5 (60.9-80.2) vs. 63.6 (58.9-68.3)	NR	NR	NR	NR	Percent of patients with wounds healed, adjusted for covariates, all patients with MDS data Treatment groups A vs. B vs. C Initial stage 1, % patients, 95% CI: 74.3% (47.6%- 101.0%) vs. 63.7% (44.4%-83.0%) vs. 37.4% (27.3% - 47.6%) Initial Stage 2, % patients, 95% CI 53.1% (37.7%- 68.5%) vs. 37.2% (28.5%-45.9%) vs. 37.1% (32.9%-41.4%) Initial stage 1 or 2, % patients, 95% CI (p<0.05 for Group A vs. B or C) 58.6% (45.8% -71.4%) vs. 42.8% (35.0%-50.7%) vs. 37.1% (33.2% to 41.0%)

Evidence Table 5d: Topical Application Observational Studies, continued								
Author, year Country Overall Quality Rating	Pain	Dermatologic Complications	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate
Hindryckx 1990 ¹⁰⁶ Belgium Poor	0/21 reported pain during dressing changes; 17/21 had wound pain at start of treatment, 11/17 pain had subsided during treatment	Local skin allergies not observed; Formation of pseudomembrane not observed	NR	12/21 had secondary microorganisms in wounds	NR	NR	NR	NR
Narayanan 2005 ¹⁰⁷ US Fair	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Danon 1997 ¹⁰⁸ Israel Poor	Trial (non- randomized)	Patients with PU hospitalized during 1 year in a geriatric hospital	No exclusion criteria	NR/NR/ NR /199	Age(Mean): 82 vs. 79 years Female: 67% vs 45% Race: NR	Local Wound Applications: Biologics	Number of ulcers:131 vs. 248 ulcers	Macrophage suspension (0.05 mL/injection) injected at 0.5-1 cm from the ulcer's edge all around the ulcer's periphery, at 1 cm between injection points. Ringer solution compress on a cotton gauze pad, kept moist with Ringer solution, and changed daily 1x daily/12 months n=72	Conventional treatments of ulcers, including Polydine, Eusol, Silverol, Debrizan, Ringer, Saline, Granuflex, hydrogels, etc., were used in the comparator group (not described in detail) n=127	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Hirshberg 2001 ¹⁰⁹ US Poor	Trial	Pressure ulcer surface area between 15-120 cm ² , calcium alginate mold weight of ≥10 g following debridement at baseline visit, target ulcer present for at least 4; weeks, serum albumin concentration ≥2.5 g/dL, ulcer, bacterial counts of <105 per gram of tissue and no beta-hemolytic streptococci or malignancy on biopsy	Osteomyelitis, alginate mold weight ≤10 g after debridement, use of topical antibiotics or disinfectants autolytic or enzymatic debridement agents applied to target ulcer, experimental, nonapproved or investigational drug use within one month or during trial, malignancy, use of systemic corticosteroids >20 mg per day, or immunosuppressive therapy, patients whose target ulcer failed to heal with previous cytokine therapy or who received radiation therapy at target ulcer site, women who were pregnant, nursing, or of childbearing age and not using birth control	270/NR/NR/14	<u>Age(Mean):</u> 51 vs. 34 vs 48 years <u>Female:</u> 75% vs. 20% vs. 40% <u>Race:</u> NR	Local Wound Applications: Biologics	<u>Stage III, IV</u> <u>Treatment A</u> Mean target ulcer volume (cm3): 32.6 +/- 29.2 Mean target ulcer surface area (cm2): 45.1 +/- 25.2 <u>Treatment B</u> Mean target ulcer volume (cm3): 31.5 +/- 14.2 Mean target ulcer surface area (cm2): 46.6 +/- 13.1 <u>Treatment B</u> Mean target ulcer volume (cm3): 28.1 +/- 14.7 Mean target ulcer surface area (cm2): 43.2 +/- 14.1	Treatment A 1.0 mcg/cm2 transforming growth factor-beta3 (TGF-beta3) plus standardized wound care (included adequate debridement of nonviable tissue, cleansing of wound with saline, maintenance of moist wound environment, treatment of infection, off-loading of pressure from affected area using low-air-loss surfaces, nutritional support), n=4	Treatment B: 2.5 mcg/cm2 TGF-beta3 plus standardized wound care, n=5	Treatment C: Placebo gel plus standardized wound care, n=5	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Landi 2003 ¹¹⁰ Italy Good	Trial	Pressure ulcer , from 1 cm ² to 30 cm ² in total area	Lesions developed >1 month before admission, patients with terminal illness, patients with diabetes, patients with peripheral vascular disease	Number screened: NR/70/38/36	<u>Age(Mean):</u> 80.2 vs. 80.2 years Female: 72% vs. 72% Race: NR	Local Wound Applications: Biologics	<u>Treatment A</u> Ulcer area, mm ² : 1012 +/- 633 Stage: 3.2 +/- 0.8 Stage 2: n=3 Stage 3: n=9 Stage 4: n=5 Stage 5: n=1 <u>Treatment B</u> Ulcer area, mm ² : 1012 +/- 655 Stage: 3.0 +/- 0.7 Stage 2: n=3 Stage 3: n=13 Stage 4:n=1 Stage 5: n=1	Treatment: 2.5S murine nerve growth factor solution plus daily local care (irrigation with normal saline, use of debriding enzymes, application of opaque hydrocolloid occlusive barriers) n=18	Comparator: Salt solution plus daily local care (irrigation with normal saline, use of debriding enzymes, application of opaque hydrocolloid occlusive barriers) n=18	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Mustoe 1994 ¹¹¹ US Poor	Trial	Stage III, IV PU in an adult, surface area between 4-100 cm ² , no evidence of cellulitis or malignant neoplasms	Venous or arterial vascular disorder directly implicated in the cause of the ulcer; significant endocrine disease, immunosuppressive disease, sepsis, pregnancy or lactation, active abuse of alcohol/drugs, unstable renal hepatic, hematological or cardiac disease; evidence of malignant neoplasms; use of immunotherapy, cytotoxic chemotherapy, or investigational drugs	NR/NR/52/44 41 had complete alginate mold weight data and were used as n for some analyses	Age: 73.5 vs. 67.5 vs. 73.4 Female: 73.3 vs. 58.3 vs. 64.3 Race, : Caucasian: 46.7% vs. 66.7% vs. 42.9% African-American: 53.3% vs. 33.3% vs. 50.0% Hispanic: 0.0% vs. 0.0% vs. 7.1%	Local wound application Biologic	<u>Treatment A:</u> <u>Volume: 5.5 cm²</u> Stage, %: 3: 26.7 4: 73.3 Location, %: Ischium: 0.0 Sacrum: 33.3 Trochanter: 26.7 Other: 20.0 <u>Treatment B:</u> <u>Volume: 7.1 cm²</u> Stage, %: 3: 25.0 4: 75.0 Location, %: Ischium: 16.7 Sacrum: 41.7 Trochanter: 16.7 Other: 25.0 <u>Treatment C:</u> <u>Volume: 10.8 cm²</u> Stage, %: 3: 21.4 4: 78.6 Location, %: Ischium: 28.6 Sacrum: 42.9 Trochanter: 21.4 Other: 7.1	100 µg/mL rDPGF-BB topical spray (daily) in addition to moist saline gauze dressings and mechanical debridement as needed	300 µg/mL rDPGF-BB topical spray (daily) in addition to moist saline gauze dressings and mechanical debridement as needed	Placebo	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Payne 2001 ¹¹² US Good	Trial	Pressure ulcers involving any tissue from a bony prominence to the subcutaneous tissue (grad III, IV)	None	NR/NR/61/59 Complete follow-up data for 54	Age NR: 73.5 vs. 67.5 vs. 73.4 years Female: NR Race: NR	Local Wound Applications: Biologics	NR	Sequential topical GM-CSF/bFGF	bFGF alone	GM-CSF	Placebo
Payne 2004 ¹¹³ US Good	Trial	Age > 18 years; stage III sacral PU; ulcer free of necrotic tissue and debridement; ulcer present for 2-24 months; ulcer area is > 5 cm ² and < 50 cm ² ; if more than one ulcer, the distance between ulcers is > 10 cm; ulcer is due solely to pressure damage.	Stage I, II, IV PU; more than 3 stage III, IV PUs; evidence of undermining, tunneling, or sinus tracts > 1 cm after debridement; previous treatment with a surgical flap procedure; bacterial colonization; decrease or increase in ulcer size of 50% during the screening period; underlying non-pressure ulcer etiology.	NR/NR/34/34	Age (Mean): 69.4 vs 69.1 years Female: 33% vs. 31% Race: Caucasian: 83% vs 81% African-American: 11% vs 19% Other: 6% vs 0%	Local Wound Applications: Biologics	Stage III Mean area: 19.8 cm ² vs 21.1 cm ² Mean volume: 13.5 g vs 12.2 g Location: Sacral: 67% Trochanter: 24% Ischium: 9%	Derma graft (human dermal fibroblast-derived substitute) in conjunction with conventional treatment	Non-adherent dressing, saline-moistened gauze and Allevyn.	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Rees 1999 ¹⁴ US Fair	Trial	≥18 years, 1 - 3 chronic (stage III or IV NPUAP) PU (primary or recurrent) without involvement of bone tissue, PU volume between 10 ml and 150 ml, inclusive, following debridement at the baseline visit, PU present for at least 4 weeks despite previous treatment, located where pressure could be off loaded for the duration of the study, and albumin concentrations >2.5g/dl, total lymphocyte count > 1000 and concentrations of vitamin A & C within the normal range	Osteomyelitis, after debridement PU volume <10ml or >150ml, topical antibiotics, antiseptics, enzymatic debriding agents or other agents that would interfere with study, evaluations had been used within 7 days preceding randomization, PU from electrical, chemical or radiation insult, cancer patients ,concomitant diseases, treatment or medication that would deleteriously affect healing or interfere w/ evaluation of study medication, pregnant, nursing or of childbearing potential and not using birth control	NR/NR/124/ 124	Age(Mean): 48 vs 49 vs 51 vs. 50 years Female: vs 16% vs16% vs 13% vs. 19% Race: NR	Becaplermin gel 100µg/gm QD alternated with placebo gel every 12 hours	Target ulcer volume(ml)median (IQR): 16.6 (15.1) vs 17.2 (19.7) vs 17.6 (33.8) vs. 19.6 (21.9)	Becaplermin gel 100µg/g alternated with placebo gel every 12 hours n=31	Becaplermin gel 300 µg/g alternated with placebo gel every 12 hours n=32	Becaplermin gel 100 µg/g 2x daily n=30	Placebo gel n=31

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Robson 1992a ¹¹⁵ US Fair	Trial - double-blind, placebo-controlled, phase I/II study	Consenting adult inpatients (ages 21-56) with such ulcers, of area 25-95 cm ² , was randomly allocated placebo or rPDGF-BB at 1 Mug/ml, 10Mug/ml, or 100 Mug/ml, daily for 28 days.	Patients with diabetes	NR/NR/20/20	Age(Range) : 21-56 years Sex: NR Race: NR	Topical: Recombinant human BB homodimeric platelet derived growth factor (rPDGF-BB)	NR	1, 10, or 100 Mug/ml rPDGF- BB (0.01, 0.1, or 1.0 Mug per cm ulcer area) 1x/day/29 days Total test material applied daily was calculated from a dose of 0.01 ml/cm ulcer surface. After the daily treatment, the wound was left open for 15 min to allow absorption of rPDGF-BB by the wound surface. The ulcer crater was packed with fresh sterile gauze and sealed closed with 'Biobrane' Pressure-relieving devices were used as appropriate. Patients were repositioned every 2 h throughout the treatment period	Placebo (not described)	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Robson 2000 ¹¹⁶ US Poor	Trial	Hospitalized patients at 2 sites aged 18-65 years with pressure sores extending from the bone to the subcutaneous tissue (stage III/IV), measuring 10-200 cm ³ with mechanical debridement (if required) performed at least 24 hours before initiation of treatment and normal or clinically insignificant abnormalities on pretreatment laboratory findings (all patients were denervated in area of ulceration secondary to congenital or acquired spinal cord pathology)	Arterial or venous disorder or vasculitis as cause for ulcerated wound, clinically significant systemic disease, significant malnutrition, recent use of steroidal therapy, penicillin allergy	NR/NR/50/49	Age(Mean): 37.8 vs. 37.9 years Female: 14% vs. 36%, p=0.124 Race: Caucasian – 24% vs. 12.2% Black – 37% vs. 10.2% Hispanic: 10.2% vs. 6.1%	Local Wound Applications: Biologics	Text states that there was no statistical difference in initial size of sores between groups, but data not reported	100 µg/mL, 500 µg/mL or 1000 µg/mL of recombinant bFGF Patients received treatment according to different schedules for periods up to 22 days, depending on tier of study n=35 Standard pressure relieving devices were used as appropriate; patients not on air-fluidized beds were repositioned at 2-hour intervals throughout treatment period	Placebo Patients received treatment according to different schedules for periods up to 22 days, depending on tier of study n=14	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Robson 1992b ¹¹⁷ US Fair	Trial - randomized, blinded, placebo- controlled trial	Patients aged 18- 65 years, pressure sores: 10-200 cm ³ as measured by alginate mold, hospitalized patients, mechanical debridement (if necessary): at least 24 hr before initiation of treatment, laboratory findings: normal or clinically insignificant abnormalities on pretreatment CBC, coagulation, chemistry, urinalysis panels	Arterial or venous disorder, or vasculitis as cause for ulcerated wound, clinically significant systemic disease, significant malnutrition, recent use of steroidal therapy, penicillin allergy	NR/NR/50/4 9	Age(Mean): 37.8+/-13.2 vs. 37.9+/- 12.8 Female: 5/35 vs. 5/14, p=0.124 Race: Caucasian, Black, Hispanic: n=12, n=18, n=5 vs. n=6, n=5, n=3, p=NS	Topical: Recombinant basic fibroblast growth factor (bFGF) versus placebo Standard pressure relieving devices were used as appropriate; patients not on air-fluidized beds were repositioned at 2-hour intervals throughout treatment period	NR	Recombinant basic fibroblast growth factor(bFGF): 1x day/22 days Tier 1: Low-dose bFGF (100 mcg/mL/cm ²) Tier 2: High-dose bFGF (1000 mcg/mL/cm ²) Tier 3: Intermediate- dose bFGF (500 mcg/mL/cm ²) Drug application was performed according to the specific tier after irrigation of the ulcer crater with normal saline. The given drug dosage was applied from a spray applicator, after which the wound was exposed to the ambient air for 15 minutes to allow the medication to adsorb to the wound surface. After this time, the ulcer crater was packed with fresh saline-moistened sterile gauze. 12 hours later the saline- moistened gauze was changed, but no additional medication was applied.	Placebo (not described)	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Scevola, 2010 ¹¹⁸ Italy Poor	Prospective randomized controlled open clinical pilot trial	Patients were in a compensated stable nutritional status.	Metabolic, endocrine and collagen pathologies, ischemic cardiopathy, corticosteroid or immunosuppressive therapy, obesity, malignancies, and organ failure	NR/NR/13/13 16 ulcers: 10 sacral 6 ischiatic	Age: NR Female: 3/13(23.1%) Race: NR	Topical: Allogenic Platelet Gel	NR	(GEL dressing) Allogenic Platelet Gel Protocol - gel applied directly to the clean wound bed using a sterile syringe; the ulcer was then covered with a polyurethane sponge/semi- permeable film dressing system Platelet gel prepared in a Petri dish blending 4–8 ml of concentrated platelet preparation, including at least 2 × 10 ¹⁰ platelets, with 2– 4 ml of plasma activated with Calcium Chloride Ulcers were treated 2x/week for 8 weeks (total of 16 applications)	(NO GEL dressing) Standard Protocol - Detorsion: Saline at room temperature Dressing: Packing with 10% iodoform impregnated gauzes or Sodium/Alginate foams or Cadexomer Iodine powder and/or Vacuum Assisted Closure therapy Perilesional areas: Zinc Oxide paste or Silver Sulfadiazine in high contamination risk area (i.e. perineum)	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued											
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Zuloff-Shani 2010 ¹¹⁹ Isreal Good	Prospective 2- armed, non- parallel, open controlled trial	Patients admitted to the rehabilitation wards following acute stroke, hip fractures, amputations, or deconditioning following acute illnesses. Patients were eligible once they suffered at least one pressure ulcer at stage III and/or IV, as defined by the European Pressure Ulcers Advisory Panel (EPUAP) (Cuddigan and Frantz, 1998), lasting >30 days, regardless of gender or associated comorbidities. Included patients could also have anemia, renal or hepatic disease, hypoalbuminemia, use of steroids, chemotherapy, or other immunocompromising drugs	Patients with ulcers at stages other than stage III and/or IV, or a significant acute life threatening medical condition that might interfere with treatment results	NR/NR/131/ 100 213 ulcers (75 vs. 141 ulcers): 129 leg ulcers 56 sacral ulcers 21 trochanteric ulcers 7 trunk ulcers	Age (Mean): 77.7 vs. 77.8 years, p=0.95 Females: 27/38(31%) vs. 31/66(46%) , p=0.02 Race: NR	Topical : recombinant human BB homodimeric platelet derived growth factor (rPDGF-BB)	1 µg/ml of rPDGF vs 10 µg/ml of rPDGF vs 100 µg/ml of rPDGF vs Placebo Ulcer depth (cm): 1.7+/-0.5 (range 0.5-2.7) vs 1.6+/-0.6 (range 0.8-3.5) vs 2.8+/-1.0 (range 1.6-6.8) vs 2.8+/-0.4 (range 1.5-5.2), p=NS Ulcer volume (cm3): 13.8+/-4.8 (range 5-26) vs 15.8+/-4.0 (range 9-28) vs 11.6+/-5.5 (range 4-33) vs 12.9+/-3.8 (range 5-33), p=NS	SOC (comparator) group: Wounds were surgically debrided, if necessary, and then treated by a variety of SOC treatments, including alginate containing dressings, polyurethane dressings, carboxymethylcellulose dressings, activated charcoal dressings with silver, hydrocolloids, hydrogels, silver containing dressings, gauze pads absorbed with Ringer (Hartman) solution, eusol, antibiotics and ointments containing steroids, silver containing ointments	AMS (treatment) group: Activated macrophage suspension (AMS) injected by a sterile disposable 2 ml syringe with a 25G needle. The AMS suspension (0.1 ml/injection) was injected at the entire wound bed, at 1 cm between injection points. (for deep wounds, AMS was poured directly into the wound). Following AMS, sterile gauze well soaked with AMS was applied for 24 hours. Wounds were covered either with gauze pads absorbed with lactated Ringer's (Hartman) solution or one of the following dressings: alginate containing dressings, polyurethane dressings, or carboxymethylcellulose dressings. In case of extensive exudates, silver containing dressings were applied. AMS injection was repeated in accordance with the wound condition (mean time between injections - 4 weeks)	NA	NA

Evidence Table 5e: Biological Therapies Trials, continued

Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Danon 1997 ¹⁰⁸ Israel Poor	12 months / 2- week intervals after treatment	Geriatric Hospital	27% complete wound healing. (36/131 ulcers)	6% of comparator group had complete wound healing p<0.001 (15/248 ulcers)	NR	NR	NR	NR	NR
Hirshberg 2001 ¹⁰⁹ US Poor	16 weeks of treatment or until ulcer healed	Wound care center	None	Treatment B: n=1 achieved complete wound closure with no drainage	Mean relative surface area of target ulcer at visit 4, cm ² 0.8 Mean relative surface area of target ulcer at termination of trial, cm ² 0.3	Mean relative surface area of target ulcer at visit 4, cm ² Treatment B: 0.5 Treatment C: 0.9 Mean relative surface area of target ulcer at termination of trial, cm ² Treatment B: 0.4 Treatment C: 0.7 Significant reduction in mean relative surface areas, Treatment B vs. Treatment C, p<0.05 The mean relative volumes at termination were as follows: Group 1 = 0.7 cm ³ , Group 2 = 0.2 cm ³ , and Group 3 = 0.3 cm ³ .	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Landi 2003 ¹¹⁰ Italy Good	6 week	Nursing home	n=8 (44%)	n=1 (6%), p=0.009 compared to treatment A	6 weeks Mean area, mm2: 274 +/- 329 Reduction in ulcer area (raw), mm2: 738 +/- 393 Reduction in ulcer area (adjusted), mm2: natural log of area reduction 6.5 +/- 0.3 adjustment for confounders including baseline ulcer area, location, ulcer duration	6 weeks Mean area, mm2: 526 +/- 334, p=0.022 compared to Treatment A Reduction in ulcer area, mm2: 485 +/- 384, p=0.034 compared to Treatment A Reduction in ulcer area (adjusted), mm2: natural log of area reduction 5.9 +/- 0.3, p<0.001 compared to Treatment A adjustment for confounders including baseline ulcer area, location, ulcer duration	Topical application of Treatment A showed statistically significant acceleration of healing process (no number provided) 4 weeks total area reduced by nearly 50% in all ulcers of treatment group Complete healing within 3 weeks, n=2 Complete healing within 4 weeks, n=2 Complete healing within 5 weeks, n=1 Complete healing within 6 weeks, n=3	Complete healing within 3 weeks, n=1	NR
Mustoe 1994 ¹¹¹ US Poor	28 days/5 months	Nursing homes and hospitals	Treatment A 12.5% of PU had complete wound healing Treatment B 0%	Treatment C 7.1% of PU had complete wound healing	% Decrease in volume at day 29 (25 th to 75 th Percentiles): Treatment A 0% - 74% Treatment B 26%-73% Treatment C 18%-110%	NR	No statistically significant difference in 50% healing time	No statistically significant difference in 50% healing time	NR
Payne 2001 ¹¹² US Good	35days/1 year	Nursing Home	p>0.05	p>0.05	NR	NR	p>0.05	p>0.05	NR

Evidence Table 5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Payne 2004 ¹¹³ US Good	26 weeks	NR	11% complete wound healing	13% complete wound healing	Median ulcer area reduction at week 12: 50% for patients who had complete healing 39% for patients who had incomplete healing Median ulcer volume reduction 41% for patients who had complete healing	Median ulcer area reduction 34% for patients who had complete healing 17% for patients who had incomplete healing Median ulcer volume reduction 17% for patients who had complete healing	NR	NR	17% (3 patients)

Evidence Table 5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Rees 1999 ¹⁴ US Fair	16weeks	Multi-center	Treatment A: 23% (p0.005) Treatment B: 19% (p=0.008) Treatment C: 3% (p=NR)	0%	NR	NR	NR	NR	3% in comparator 3% in 100 µg/g BID

Evidence Table 5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Robson 1992a ¹¹⁵ US Fair	29-day trial/Followup at 2 weeks and 1, 2, 3 and 5 months post discharge and treatment	NR	NR	Mean volume of the ulcer on day 29: 6.4 (4.0)%	Mean volume of the ulcer on day 29: 21.8 (5.6)%, p=0.12	NR	NR	NR	NR
Robson 2000 ¹¹⁶ US Poor	30 days acute phase of followup then patients discharged with followup evaluations at 1, 3 and 5 months	Hospital	NR	NR	NR	NR	NR	NR	NR
Robson 1992b ¹¹⁷ US Fair	30 days acute phase of followup then patients discharged with followup evaluations at 1, 3 and 5 months	>70% Wound Closure at 21 days: 9/13, p=0.041	NR	70% volume reduction: 21/35 (60%)	70% volume reduction: 4/14(29%)	NR	NR	NR	NR
Scevola, 2010 ¹¹⁸ Italy Poor	8 weeks/14 weeks after start of treatment (6 weeks after end of treatment)	NR	NR	Mean ulcer volume at 6 weeks(ml): 40,000 Mean ulcer volume at 8 weeks(ml): 35,000 Mean ulcer volume at 10 weeks (ml): 33,000 No statistically significant difference could be demonstrated in volume reduction between the two groups (p=0.76)	Mean ulcer volume at 6 weeks(ml): 32,000 Mean ulcer volume at 8 weeks(ml): 27,000 Mean ulcer volume at 10 weeks (ml): 22,000	NR	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Complete Wound Healing	Complete Wound Healing (Comparator)	Wound Surface Area	Wound Surface Area (Comparator)	Healing Time	Healing Time (Comparator)	Infection Rate
Zuloff-Shani 2010 ¹¹⁹ Israel Good	12 months/NR	<p>Complete wound healing: (leg ulcer subset) Complete wound healing: (leg ulcer subset): 18% vs. 69.9%, p<0.001</p> <p>Number of patients with all wounds fully closed: 2 (5.3%) vs. 39 (59.1%), p<0.001</p> <p>Wounds Completely Closed: wound level - 13.3% vs. 69.5%, p<0.001 patient level - 33.7% vs. 76.2%, p<0.001</p>	<p>Complete wound healing: All patients (includes diabetic ulcers) Percentage of completely closed wounds significantly better for AMS. (p<0.001)</p>	NR	NR	<p>Median healing time: 117.7 (38–368) days</p> <p>Median healing time: (leg ulcer subset): SOC – 125 days (range: 26-368)</p>	<p>Median healing time: 86.7 (15–422) days, p=0.49</p> <p>Median healing time: (leg ulcer subset): AMS – 57 days (range:1-394)</p>	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued						
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify
Danon 1997 ¹⁰⁸ Israel Poor	NR	NR	NR	NR	NR	NR
Hirshberg 2001 ¹⁰⁹ US Poor	NR	None	Treatment B: n=2	NR	NR	<p>Surface volumes Volume decreased significantly, Treatment A vs. Treatment C, p<0.05</p> <p>Mean relative volumes (cm3) at termination were Treatment A 0.7, Treatment B 0.2, Treatment C 0.3</p> <p>At visit 4, Treatment B showed significant reduction in relative ulcer bed surface area and volume vs. Treatment C; reduction in relative size was not significant over 16 weeks of trial</p> <p>Wound closure No significant difference in closure between Treatment A and Treatment B at visits 10 and 16 secondary to increased closure rates in Treatment C at these points</p>
Landi 2003 ¹¹⁰ Italy Good	NR	NR	NR	NR	NR	<p>Treatment A vs. Treatment B Ulcer improvement by >3 stages, n=5 (28%) vs. 0 Ulcer improvement by 2 stages, n=9 (50%) vs. n=2 (11%) Ulcer improvement by 1 stage, n=4 (22%) vs. n=8 (44%), P<0.001 No ulcer improvement, n=8 (44%) of Treatment B</p>
Mustoe 1994 ¹¹¹ US Poor	8%(1)	NR	NR	0%	14.3% of PU healed during treatment and recurred during followup	NR
Payne 2001 ¹¹² US Good	NR	NR	NR	Overall recurrence rate of 17%	Overall recurrence rate of 17%	NR
Payne 2004 ¹¹³ US Good	19% (3 patients)	NR	NR	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued						
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify
Rees 1999 ¹¹⁴ US Fair	NR	Treatment A: 6% Treatment B: 3% Treatment C: 3%	0%	NR	NR	Becaplermin 100µg/g vs. 300µg/g vs. 100µg/g BID vs. placebo Incidence of ≥90% healing: 58% vs. 59% vs. 405 vs. 29%, p value for 100µg/g vs. placebo=0.021, 300µg/g vs. placebo=0.014 Median relative ulcer volume at 16 weeks: 0.07 vs. 0.05 vs. 0.15 vs. 0.27, p value for 100µg/g vs. placebo=0.013, 300µg/g vs. placebo=0.011
Robson 1992a ¹¹⁵ US Fair	NR	NR	NR	NR	NR	NR
Robson 2000 ¹¹⁶ US Poor	NR	NR	NR	NR	NR	Treatment A vs. B vs. C vs. D Day 36 ulcer volume, mean (cm ³): 12.02+/-11.88 vs. 7.24+/-6.11 vs. 16.83+/-25.75 vs. 14.24+/-13.66 All patients: 12.65+/-16.24 Day 36 ulcer volume, median (cm ³): 9.29 (range 0.88-40.62) vs. 4.42 (range 0.22-20.80) vs. 7.48 (range 0.22-99.65) vs. 8.85 (range 2.12-45.84), p=0.57 All patients: 7.26 (range 0.22-99.65) Percent wound closure on day 36, mean: 67+/-24 vs. 75+/-19 vs. 68+/-21 vs. 71+/-11 All patients: 70+/-19 Percent wound closure on day 36, median (range): 70 (3-93) vs. 79 (42-99) vs. 73 (29-98) vs. 72 (39-84), p=0.69 All patients: 73 (3-99) Text: significantly more patients treated with cytokine achieved >85% decrease in ulcer volume (p=0.03); significantly more patients in Treatment B had >85% (p=0.02) and >90% closure (p=0.04) compared to Treatment D; significantly more patients in Treatment C had >85% healing (p=0.10) compared to Treatment D; patients receiving bFGF (Treatment B and C) at any point healed significantly better than Treatment D with >85% (p=0.02) and >90% (p=0.04) closure. The paper also comments on change in cytokine levels in the ulcer, histology, cost and ease of closure with treatment
Robson 1992b ¹¹⁷ US Fair	NR	NR	NR	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued						
Author, year Country Overall Quality Rating	Infection Rate (Comparator)	Osteomyelitis Rate	Osteomyelitis Rate (Comparator)	Recurrence Rate	Recurrence Rate (Comparator)	Other: Specify
Scevola, 2010 ¹¹⁸ Italy Poor	NR	NR	NR	NR	NR	"Pre-albumin (p=0.08) and albumin (p=0.041) values appeared slightly improved in both groups at the end of the study"
Zuloff-Shani 2010 ¹¹⁹ Israel Good	NR	NR	NR	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued						
Author, year Country Overall Quality Rating	Pain	Pain (Comparator)	Dermatologic Complications	Dermatologic Complications (Comparator)	Bleeding	Bleeding (Comparator)
Danon 1997 ¹⁰⁸ Israel Poor	NR	NR	NR	NR	NR	NR
Hirshberg 2001 ¹⁰⁹ US Poor	NR	NR	NR	NR	NR	NR
Landi 2003 ¹¹⁰ Italy Good	NR	NR	NR	NR	NR	NR
Mustoe 1994 ¹¹¹ US Poor	NR	NR	Tunneling of the ulcer, exuberant granulation tissue, erythema with purulent drainage	NR	NR	NR
Payne 2001 ¹¹² US Good	NR	NR	NR	NR	NR	NR
Payne 2004 ¹¹³ US Good	NR	NR	NR	NR	NR	NR
Rees 1999 ¹¹⁴ US Fair	NR	NR	Skin ulceration, rash erythema-numbers NR	Skin ulceration, rash erythema-numbers NR	NR	NR
Robson, 1992 ¹¹⁵ US Fair	NR	NR	NR	NR	NR	NR
Robson 2000 ¹¹⁶ US Poor	NR	NR	NR	NR	NR	NR
Robson, 1992 ¹¹⁷ US Fair	NR	NR	NR	NR	NR	NR
Scevola, 2010 ¹¹⁸ Italy Poor	NR	NR	NR	NR	NR	NR
Zuloff-Shani 2010 ¹¹⁹ Israel Good	NR	NR	NR	NR	NR	NR

Evidence Table 5e: Biological Therapies Trials, continued							
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Danon 1997 ¹⁰⁸ Israel Poor	NR	NR	NR	No severe adverse events	NR	NR	Teva Medical LTD, Israel.
Hirshberg 2001 ¹⁰⁹ US Poor	NR	NR	2 subjects in Treatment B developed osteomyelitis	NR	Treatment B: n=2 developed osteomyelitis Treatment C: n=1 due to unsatisfactory therapeutic effects	21%	Office of Research and Development, Medical Research Service, Department of Veterans Affairs
Landi 2003 ¹¹⁰ Italy Good	NR	NR	NR	NR	NR	No patients in either group had systemic or local side effects	Progetto Finalizzato Invecchiamento of the Italian National Research Council, <i>interRAI</i>
Mustoe 1994 ¹¹¹ US Poor	None	1	Treatment A: Tunneling of the ulcer: 1 exuberant granulation tissue.; 1 erythema with purulent drainage: 1	None	None	10%	Amgen Inc.
Payne 2001 ¹¹² US Good	NR	NR	NR	NR	NR	NR	NIAMS, National Institutes of Health, Schering-Plough Research Institute, Scios, Inc.
Payne 2004 ¹¹³ US Good	NR	NR	NR	NR	NR	NR	Smith and Nephew, Inc.
Rees 1999 ¹¹⁴ US Fair	Treatment A: 0 Treatment B: 0 Treatment C: 1	1	Becaplermin 100µg/g vs. 300µg/g vs. 100µg/g BID vs. placebo Sepsis: 0 vs. 1 vs. 0 vs. 0 Condition aggravated: 0 vs. 1 vs. 1 vs. 0	None	n=1 (3.2%) in Becaplermin 100µg/g group	Authors assert that no adverse events were related to study medication	Johnson & Johnson, Inc.

Evidence Table 5e: Biological Therapies Trials, continued							
Author, year Country Overall Quality Rating	Infection	Infection (Comparator)	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Robson 1992a ¹¹⁵ US Fair	NR	NR	NR	NR	NR	No hematological, chemical or urinalysis abnormalities appeared that were attributable to Treatment A; serum levels of and antibodies to recombinant bFGF were not detectable	Grant from California Biotechnology, Inc.
Robson 2000 ¹¹⁶ US Poor	NR	NR	NR	NR	NR	NR	National Institutes of Health
Robson, 1992 ¹¹⁷ US Fair	See outcomes	See outcomes	Surgical ablation not required by any patients in Treatment C but required in 8 patients from other groups combined (p=0.09)	NR	NR	No hematologic, chemical, or urinalysis abnormalities appeared that were attributable to the topical administration of recombinant bFGF.	NR
Scevola, 2010 ¹¹⁸ Italy Poor	NR	NR	NR	NR	NR	NR	NR
Zuloff-Shani 2010 ¹¹⁹ Isreal Good	NR	NR	NR	NR	NR	There were no adverse and/or serious adverse events related to AMS treatment. However, during the study an overall of 18.2% (12/66) of the patients in the AMS group and 23.7% (9/38) in the SOC group died (p=0.61).	RoseTree London, MDA Isreal

Evidence Table 6: Local Wound Applications (Dressings, Topical Applications, and Biological Therapies) Quality Rating

Evidence Table 6a: Local Wound Applications Trial Quality Rating

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Agren 1985 ⁸⁵ Sweden	No	No	Yes	Yes	Yes	a)Yes b)Unclear c)Unclear d)Unclear	No	Yes	Yes	Fair	NR
Alm 1989 ⁴⁰ Sweden	No	Unclear	Yes	No	Yes	a)Yes b)Unclear c)Unclear d)Unclear	Yes	Unclear	Yes	Fair	NR
Alvarez 2000 ⁸⁶ US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Bale 1998 ⁴¹ UK	No	Unclear	Yes	Yes	Not Reported	a) Yes b) Unclear c) Unclear d) Unclear	No	Unclear	Yes	Poor	NR
Banks 1994a ⁴² UK	Unclear	Unclear	No	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Unclear	Poor	Calgon Vestal
Banks 1994b ⁴³ UK	No	No	Yes	Yes	No	a) No b) No c) No d) No	Yes	Yes	Yes	Fair	NR
Belmin 2002 ⁴⁴	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Fair	Laboratoires Urgo
Brod 2000 ⁴⁵ US	No	No	Yes	Yes	No	a)No b)No c)Unclear d)No	Yes	No	Yes	Poor	Acme/Chaston Division, National Patent Development Corp

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Brown-Etris 2008 ⁴⁶ US	Unclear	Unclear	Yes	Yes	No	a)No b)No c)No d)No	Yes	Yes	Yes	Fair	3M
Burgos, 2000 ⁸⁷ Spain	Yes	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Good	Laboratories Knoll
Burgos, 2000 ¹²⁰ Spain	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Fair	Knoll, SA
Chang 1998 ⁴⁷ Malaysia	Unclear	Unclear	Unclear	Yes	No	a)No b)No c)No d)No	Yes	Yes	Yes	Poor	Bristol-Myers Squibb
Chuangsuwanich 2011 ⁸⁸ Thailand	Yes	No	Yes	Yes	No	a)No b)No c)No d)No	Yes	Yes	Yes	Poor	NR
Colin 1996 ⁴⁸ Multinational	Unclear	Unclear	Yes	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Unclear	Poor	NR
Colwell 1991 ⁴⁹ US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Poor	Bristol Myers Squibb
Darkovich 1990 ⁵⁰ US	No	No	Unclear	Yes	No	a)No b)Unclear c)Unclear d)Unclear	Unclear	Unclear	Yes	Poor	NR
Day 1995 ⁵¹ US, UK and Canada	No	No	Yes	Yes	Unclear (NA?)	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Fair	NR

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Felzani, 2011 ⁸⁹ Italy	No	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Unclear	Poor	NR
Gerding 1992 ¹²¹ US	Yes	Yes	Unclear	Yes	Yes (Blinded)	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Unclear	Poor	NR
Gorse 1987 ⁵² US	No	No	Yes	Yes	Not Reported	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Yes	Yes	Fair	NR
Graumlich 2003 ⁹⁰ US	Yes	Yes	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Good	Retirement research foundation
Guthrie 1989 ¹²²	Yes	Yes	Yes	Yes	Yes (reported)	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Harding 1996 ¹²³ US	No	No	Unclear	Unclear	Unclear	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	NR
Hindryckx 1990 ¹⁰⁶ Belgium	No	No	Unclear	Yes	Unclear	a) No b) No c) No d) No	Yes	Unclear	Yes	Poor	NR
Hirshberg 2001 ¹⁰⁹ US	Unclear	Unclear	No	Yes	Unclear	a) No b) No c) Yes d) No	No	Yes	Yes	Poor	US Dept of Veterans Affairs
Hollisaz 2004 ⁹¹ Iran	Yes	Yes	Yes	Yes	Yes	a) No b) No c) No d) No	Yes	Yes	Yes	Good	Iran government agency

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Honde 1994 ⁵³ Japan	Yes	Unclear	Yes	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Yes	Fair	Synthelabo Recherche
Hsu 2000 ⁹² Japan	No	No	Yes	Yes	Unclear	a)Unclear b)Unclear c)Unclear d)Unclear	Unclear	Yes	Yes	Poor	NR
Kaya 2005 ⁵⁴ Turkey	Unclear	Unclear	Yes	Yes	Unclear	a)No b)No c)No d)No	Yes	Unclear	No	Poor	NR
Kerihuel 2010 ⁵⁵ France	Yes	Yes	No	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Good	Systagenix
Kim 1996 ⁵⁶ Korea	Unclear	Unclear	No	Yes	Unclear	a) No b) Yes c) No d) No	Yes	Yes	Yes	Poor	NR
Kloth 2002 ¹²⁴ US	No	No	Unclear	Yes	Unclear	a) Unclear b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Poor	Augustine Medical Inc
Kraft 1993 ⁵⁸ US	Unclear	Unclear	Unclear	Yes	Unclear	a) No b) No c) Yes d) No	Yes	Yes	No	Poor	Calgon Vestal
Kuflik 2001 ⁹³ US	Unclear	Unclear	No	No	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Unclear	Poor	Topix Pharmaceuticals
Kurzik-Howard 1985 ⁵⁹ US	No	No	No	No	No	a) No b) No c) Yes d) No	No	Unclear	No	Poor	Acme United

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Landi 2003 ¹¹⁰ Italy	Yes	Yes	Yes	Yes	Yes	a) NA b) No c) No d) No	Yes	Yes	Yes	Good	Italian National Research Council
Le Vasseur 1995 ⁹⁴ Australia	No	No	No	No	Yes	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Poor	NR
Matzen 1999 ⁶⁰ Denmark	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) Yes d) No	Yes	Yes	Yes	Poor	NR
Meaume 2003 ⁶² France	Yes	Yes		Yes	No	a)No b)No c)No d)No	Yes	Yes	Yes	Fair	NR
Meaume 2005 ⁶¹ France	Yes	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Good	NR
Moody 1991 ¹²⁵ US	NA (observational)	Yes	Yes	Yes	Yes	a)Yes b)NA c)NA d)NA	Yes	Yes	Yes	Fair	NR
Motta 1999 ⁶³ US	Unclear	Unclear	No	Yes	Unclear	a)No b)No c)No d)No	Yes	Yes	Unclear	Poor	AcryMed
Mulder 1993 ⁶⁴ US	Yes	Unclear	No	Yes	No	a) No b) No c) Yes d) No	Yes	No	Yes	Poor	NR
Muller 2001 ⁹⁵ Germany and The Netherland	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) Yes d) No	Yes	No	Yes	Poor	Knoll AG

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Mustoe 1994 ¹¹¹ US	Unclear	Unclear	Yes	Yes	Unclear	a)Yes b) No c) Yes d) No	No	No	Yes	Poor	Amgen
Neill, 1989 ⁶⁵ US	No	No	Yes	Yes	No	a)Unclear b)Unclear c)Unclear d)Unclear	Unclear	Unclear	Yes	Poor	3M Company, Medical-Surgical Division
Nisi 2005 ⁹⁶ Italy	Unclear	Unclear	Unclear	Yes	Unclear	a)No b)No c)No d)No	Unclear	Unclear	Unclear	Poor	NR
Ohura, 2004 ³⁰ Japan	No	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	Yes	No	Yes	Poor	NR
Oleske 1986 ⁶⁶ US	Unclear	Unclear	No	Yes	No	a) Yes b) No c) No d) No	Yes	Yes	No	Poor	Chicago Community Trust
Payne 2001 ¹¹² US	Yes	Yes	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Good	Grant O01- AR42967 from NIAMS, National Institutes of Health <i>Schering-Plough Research Institute and Scois, Inc., provided cytokines used in this study</i>
Payne 2004 ¹¹³ US	Yes	Yes	Yes	Yes	No	a)Yes b) No c) Yes d) No	Yes	Yes	Yes	Good	Smith & Nephew, Inc.

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Payne 2009 ⁶⁷ US	Yes	Unclear	No	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Yes	Poor	NR
Price, 2000 ⁶⁸ UK	Yes	Yes	Yes	Yes	NA	a) Yes b) No c) No d) No	Yes	Yes	Yes	Good	NR
Pullen 2002 ⁹⁷ Germany	No	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	NR
Rees 1998 ¹²⁶ Rees 1999 ¹¹⁴	Unclear	Unclear	Yes	Yes	Unclear	a)No b)No c)No d)No	Yes	Yes	Yes	Fair	Johnson & Johnson
Rhodes 2001 ⁹⁸ US	No	No	Yes	Yes	Unclear (NA?)	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Robson 1992a ¹¹⁵ Robson 1992b ¹¹⁷ US	No	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Robson 1992c ¹²⁷ US	No	No	Unclear	Yes	YES	a)No b)Unclear c)Unclear d)Unclear	Unclear	Unclear	Yes	Poor	NR
Robson 2000 ¹¹⁶ US	No	No	Yes	Yes	Yes	a)No b)Unclear c)Unclear d)Unclear	Unclear	Unclear	Yes	Poor	NR
Sayag, 1996 ⁹⁹ France	Yes	Yes	Yes	Yes	NA	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Good	NR

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Scevola 2010 ¹¹⁸	Unclear	Unclear	Unclear	Yes	No	a) No b) No c) Yes d) No	No	Unclear	Yes	Poor	NR
Sebern 1986 ⁶⁹ Sebern 1989 ⁷⁰ US	Yes	No	Yes	Yes	NA	a) Yes b) Unclear c) Unclear d) Unclear	Yes	No	Yes	Fair	NR
Seeley 1999 ⁷¹ US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Fair	NR
Shamimi Nouri 2008a ¹⁰⁰ Iran	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Yes	Good	ParsRoos C.
Shamimi Nouri 2008b ¹⁰¹ Iran	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Yes	Good	ParsRoos C.
Sipponen, 2008 ¹⁰² Finland	No	No	No	No	No	a)No b)No c)No d)No	Unclear	Yes	Yes	Poor	NR
Small 2002 ⁷² South Africa	Yes	Unclear	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Good	NR
Stoker, 1990 ⁸⁴	No	No	Unclear	Unclear	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Poor	NR
Subbanna, 2007 ¹⁰³ India	Yes	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Good	NR

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Thomas 1997 ⁷³	NA	NA	Yes	Yes	No	a)Unclear b)Unclear c)Unclear d)Unclear	Unclear	Unclear	Unclear	Poor	NR
Thomas, 1998 ⁷⁴	No	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	No	Unclear	Yes	Poor	Seebum Laboratories
Thomas, 2005 ⁷⁵	Yes	Yes	Yes	Yes	NA	a)Unclear b)Unclear c)Unclear d)Unclear	Yes	Yes	Yes	Good	NR
Tytgat 1988 ¹⁰⁴	No	No	Unclear	Unclear	Unclear	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	NR
Whitney 2001 ⁷⁷ US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	Augustine Medical Inc
Winter 1990 ⁷⁸ UK	No	No	Yes	Yes	Not Reported	a)Yes b)Yes c)Yes d) No	Yes	Unclear	Yes	Poor	Coloplast LTD
Xakellis1992 ⁷⁹ US	No	Unclear	Yes	Yes	No	a)Unclear b)Unclear c)Unclear d)Unclear	Yes	Yes	Yes	Fair	Family Health Foundation of America and ConvaTec
Yapucu Gunes 2007 ⁸⁰ Turkey	No	No	Yes	Yes	No	a) Unclear b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Yastrub 2004 ⁸¹ US	Unclear	Unclear	Unclear	No	Unclear	a) No b) No c) Yes d) No	Yes	No	Yes	Poor	NR

Evidence Table 6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention- to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Zeron 2007 ¹⁰⁵ Mexico	Yes	Yes	Yes	Yes	Yes	a) Unclear b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Good	NR
Zuloff-Shani 2009 ¹¹⁹ Israel	No	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	Unclear	Yes	Yes	Good	NR

Evidence Table 6b: Local Wound Applications Observational Studies Quality Rating

Author Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important loss to follow-up or overall high loss to follow-up?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality	Funding Source
Danon 1997 ¹⁰⁸	Yes	No	Unclear	No	Unclear	No	No	Unclear	Unclear	Poor	NR
Kallianinen 2000 ¹²⁸	Yes	Unclear	No	No	Unclear	Yes	No	Yes	Unclear	Poor	NR
Meaume 2007 ⁸² France	Unclear	No	No	Unclear	Unclear	Yes	No	No	No	Poor	NR
Narayanan 2005 ¹⁰⁷	NA retrospective	Yes	NA	Yes	NA retrospective	NA retrospective	Yes	No	Yes	Fair	NR
Parnell 2005 ⁸³	No	No	No	Unclear	Unclear	Yes	No	No	Unclear	Poor	NR
Viamontes 2003 ⁷⁶	Yes	No	No	Unclear	No	NA (retrospective)	No	NA (retrospective)	Unclear	Poor	NR

Evidence Table 7: Surgery

Evidence Table 7a: Surgery Trials*

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)	Proportion Treatment Naïve	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Juri, 1987 ¹²⁹ Argentina Poor	Nursing home patients admitted to hosp 2/2 PU, stage III and IV	Mentally incapacitating diseases and possibility of social recovery, 'associated conditions that could have influenced the results of the study', young patients transferred immediately after surgery	66/NR/60/60	Age:67 vs.66 years Female: NR Race: NR	Surgery - debridement with closure by tissue flap or skin graft	Stage III or IV	NR	CO2 laser surgery	Conventional surgery	NA	Until hospital discharge - up to 76 days	Hospital

**Evidence Table 7a: Surgery
Trials, continued**

Author, year Country Overall Quality Rating	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate	Recurrence Rate	Pain	Other: Specify
Juri, 1987 ¹²⁹ Argentina Poor	NR	NR	NR	L 11/30 (36.7%), C 14/30 (46.7%), p<0.005	NR	Failure rate: L 5/26 (19.2%), C 6/25 (24%), NS	NR	Hospital Days: L 25 +/- 3, C 58 +/- 8, p<0.01

**Evidence Table 7a: Surgery
Trials, continued**

Author, year Country Overall Quality Rating	Pain	Dermatologic Complications	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate
Juri, 1987 ¹²⁹ Argentina Poor	NR	NR	Blood Loss: L 2.1cm ³ /cm ² +/- 0.1 (1.0-2.7), C 2.6 +/- 0.1 (2.3-2.8), p<0.01	NR	NR	Mortality L 4/30 (13.3%), C 5/30 (16.7%), NS	NR	NR

* Observational studies for the Surgical interventions section of the report were assessed and data was extracted into evidence tables, however, due to the paucity of reported data, we have opted to present only the key details and results of these studies in the in-text summary tables included within the body of the report (Table 12)

Evidence Table 8: Surgery Quality Rating

Evidence Table 8a: Surgery Trials Quality Rating

Author, Year Country	Appropriate Randomization Technique?	Allocation Concealment Adequate?	Groups (Intervention and Control) Similar at Baseline?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of: a) Attrition, b) Crossovers, c) Adherence, d) Contamination?	Dropout Rate <20 Percent?	Intention-to- treat Analysis?	Appropriate Statistical Analyses?	Overall Quality Rating	Funding Source
Juri, 1987 ¹²⁹ Argentina	No	No	No (NR)	No	No	a) No b) No c) No d) No	Yes	Unclear	Yes	Poor	NR

Evidence Table 8b: Surgery Observational Studies Quality Rating

Author, Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Overall Quality Rating	Funding Source
Foster, 1997a ¹³⁰ US	Yes	Yes	Unclear	Unclear	No	NA	Yes	Unclear	Yes	Fair	NR
Foster, 1997b ¹³¹ US	Yes	Unclear	Unclear	Unclear	No	NA	Yes	No	Yes	Fair	NR
Kierney, 1998 ¹³² US	Yes	Unclear	Unclear	Yes	No	No	Yes	No	Yes	Fair	NR
Schyvers, 2000 ¹³³ Canada	Yes	No	No	Unclear	No	No	Unclear	No	Yes	Fair	NR
Tavakoli, 1999 ¹³⁴ Australia	No	Unclear	Unclear	Unclear	No	No	Yes	No	Yes	Fair	NR
Yamamoto, 1997 ¹³⁵ Japan	Unclear	Unclear	Unclear	Unclear	No	No	Yes	No	Yes	Fair	NR

Evidence Table 9: Adjunctive

Evidence Table 9a: Adjunctive Trial and Observational Studies

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
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Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Adegoke 2001 ¹³⁶ Nigeria Fair	Randomized trial	Patients presenting with multiple pressure ulcers admitted to the neurology wards of the University College Hospital, Ibadan, Nigeria.	Patients that were smokers	NR/NR/7/6	Age (Mean):52.7 vs. 35.0 years Female: NR Race: NR	Adjunctive: Electrical Stimulation vs. sham	Stage: 100% Stage IV Size (mean): 15.8 vs. 15.4 mm ² Location: greater trochanter - 2 vs. 1 sacrum - 1 vs. 2
Adunsky, 2005 ¹³⁷ Israel Fair	Randomized trial	Only in-patients, with stage III degree non-diabetic pressure ulcers lasting 30 days, age>18 years, informed consent, ulcer duration less than 24 months, ulcer size greater than 1 cm ² but smaller than 50 cm ² , no recent history (minimum of 30 days) of growth factors or vacuum-assisted treatment.	Patients with ulcers other than 3 degree (stage III), liver function enzymes higher than twice the upper limit of normal values, renal failure with creatinine>2 mg%, anemia (hemoglobin<10 g%), albumin<2.6 g%, and patients having a pacemaker. Patients with significant medical disorder that might interfere with treatment results, patients with recent (2 months) use of steroids, chemotherapy, or other immunocompromising drugs.	NR/NR/63/63	Age (Mean): 71.8 vs. 71.4 years Female: 53.6% vs. 62.8% Race: NR	Adjunctive: Electrical Stimulation vs. sham	Stage: NR Size (mean): 7.5 vs. 7.6 cm ² Location: sacrum – 25 trochanters – 13 legs – 13 buttocks – 4 ischium – 2
Ahmad, 2008 ¹³⁸ India Fair	Randomized trial	Chronic pressure ulcer, Stage II ulcers (Article uses Yarkony-Kirk grade criteria)	Cardiac pacemaker; peripheral vascular diseases; active osteomyelitis; pregnant; receiving long-term radiation therapy, steroid therapy or chemotherapy.	NR/NR/60/60	Age (Mean): 38.4 vs. 38.47 vs. 39.4 vs. 39.4 Female: 60% vs. 53% vs. 47% vs. 40% Race: NR	Adjunctive: Electrical Stimulation (high voltage pulsed galvanic current (HVPC))	Stage: II Size (mean cm ²): 7.12 vs. 7.12 vs. 7.14 vs. 7.21 Location: NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Baker, 1996 ¹³⁹ US Fair	Randomized trial	Patients with spinal cord injuries (SCI) and one or more pressure ulcers	NR	NR/NR/80/80	Age (Mean): 34 vs. 40 vs. 36 vs. 33 years Female: 15% vs. 24% vs. 15% vs. 16% Race: White - 50% vs. 50% vs. 40% vs. 33% Black - 25% vs. 33% vs. 20% vs. 37% Other - 25% vs. 17% vs. 40% vs. 30%	Adjunctive: Electrical Stimulation	Stage: NR Size (mean): 6.6 vs. 2.4 vs. 8.5 vs. 8.6 cm ² Location: foot - 13% vs. 9% vs. 7% vs. 8% thigh - 15% vs. 23% vs. 26% vs. 16% ischial - 30% vs. 33% vs. 24% vs. 40% sacral - 30% vs. 33% vs. 24% vs. 36% other - 5% vs. 5% vs. 14% vs. 36%
Dehlin, 2003 ¹⁴⁰ Denmark Fair	Randomized trial	Patients with stage III (Shea grade II or III score) pressure ulcer, ulcer location on the trunk or foot, ulcer age 2 weeks to 6 months, initial area 1-20 cm ² , and patients age >65 years	Patients with unstable diabetes mellitus (HbA1c >10%), serious or terminal malignancy or terminal illness, treatment with radiotherapy or cytotoxins, suspected or proven osteomyelitis, antibiotic treatment of ulcer within 2 weeks , use of corticosteroids, (>10mg/day of prednisone) significant abnormal blood tests in the month before inclusion, pacemaker, photosensitivity or sensitivity to electromagnetic radiation, life expectancy < 3 months, and participation in any other clinical study during the last month	NR/NR/201/16 4	Age (Mean):83 vs. 85 years Female: 69 % vs. 62% Race: NR	Adjunctive: Light Therapy	Stage: (Shea) Stage II - 56% vs. 50% Stage III - 44% vs. 50% Size (mean): NR Location: Foot - 55% vs. 55% Trunk - 45% vs. 45% Ulcer age (mean): 49 vs. 57 days
Dehlin, 2007 ¹⁴¹ Denmark Fair	Randomized trial	Patients with stage III (Shea grade II or III score) pressure ulcer, ulcer location on the trunk or foot, ulcer age 2 weeks to 6 months, initial area 1-20 cm ² , and patients age >65 years	Patients with unstable diabetes mellitus (HbA1c >10%), serious or terminal malignancy or terminal illness, treatment with radiotherapy or cytotoxins, suspected or proven osteomyelitis, antibiotic treatment of ulcer within 2 weeks , use of corticosteroids, (>10mg/day of prednisone) significant abnormal blood tests in the month before inclusion, pacemaker, photosensitivity or sensitivity to electromagnetic radiation, life expectancy < 3 months, and participation in any other clinical study during the last month	NR/NR/163/16 3 (including 87 subjects from 2003 study)	Age (Mean): 84 vs. 84 years Female: 65% vs. 60% Race: NR	Adjunctive: Light Therapy	Stage: (Shea) Stage II/III – 100% Size (mean): 4.1 vs. 4.7cm ² Location: Foot - 41% vs. 46% Trunk - 59% vs. 54% Ulcer age (mean): 41 vs. 46 days

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Durovic, 2008 ¹⁴² Serbia Fair	Prospective, randomized, single-blind study	Patients with stage I–III ulcer; absence of relative contraindications for using of polarized light; absence of deterioration of a common disease or attack of new disease; and a patient’s agreement to participate in the study.	Patients previously in the study to treat their current pressure ulcer; skin grafting was planned within one week; nutrition was poor, as indicated by albumin levels below 3.0 g/dL; presence of local or general infection, particularly the sacral (pilonidal) sinus or the sacral osteomyelitis; necessity for drugs that can affect the skin and delay in healing, specially steroids, immunosuppressive agents, antineoplastic drugs and anticoagulants.	NR/48/40/40	Age (Mean):61.85 vs. 68.65 years Female: 45% vs. 45% Race: NR	Adjunctive: Light Therapy	Stage: I-III Size (mean):Surface Area (cm ²) - 15.10 vs. 19.15, p=0.18 Location: Low part of back - 0 vs. 5% Right-low part of back 5% vs. 0 Right buttock - 5% vs. 0 Left buttock - 5% vs. 5% Both buttocks - 0 vs. 10% Sacral area - 50% vs. 25% Right sacral-buttock area - 5% vs. 0 Right iliac spine - 0 vs. 5% Left hip - 15% vs. 15% Right hip - 0 vs. 5% Right heel - 5% vs. 20% Left heel - 10% vs. 10%
Ford, 2002 ¹⁴³ US Fair	Randomized trial	Presence of stage III or IV ulcer for 4 or more weeks; albumin greater than or equal to 2.0; age 21–80; and ulcer volume after debridement = 10–150 ml.	Fistulas to organs or body cavities; malignancy in the wound; pregnant or lactating female; Hashimoto thyroiditis, Graves disease, iodine allergy, systemic sepsis; electrical burn, radiation exposure, chemical exposure; cancer, connective tissue disease, chronic renal or pulmonary disease, uncontrolled diabetes, corticosteroids or immunosuppressive agents; cardiac pacemaker; ferromagnetic clamps; or recent placement of orthopedic hardware.	NR/NR/28/22	Age (Mean): 41.7 vs. 54.4 years Female: NR Race: NR	Adjunctive: Negative Pressure Wound Therapy	Stage Size (mean) Location: Ischial - 25.7% Sacral - 48.6% Lateral malleolar - 11.4% Trochanteric - 2.9% Calcaneal - 11.4%

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Gentzkow, 1991 ¹⁴⁴ US and Canada Fair	Randomized trial	Patients with open pressure ulcers at Stage II,III or IV at 9 centers in the US and Canada	Ulcers were excluded if they were totally occluded by eschar, had bleeding or involved major blood vessels; located presternal, periorbital, or laryngeal/pharyngeal; occurred in pregnant patients; patients with cardiac pacemakers; osteomyelitis or peripheral vascular problems predisposing them to thrombosis; cancerous; patients on long-term steroid therapy, chemotherapy, radiation therapy, or were very obese	NR/NR/49(ulce rs)/40(ulcers)	Age (Mean): 62.2 vs. 63.3 years Female: 52.6% vs. 38.1% Race: NR	Adjunctive: Electrical Stimulation	Stage: Stage II - 5% vs. 0% Stage III - 73% vs. 76% Stage IV - 21% vs. 24% Size (mean): 12.5 vs. 19.2 cm ² Location: Hip/Ischium - 32% vs. 42% Sacrum/Coccyx - 42% vs. 19% Leg/Foot - 26% vs. 38%
Griffin, 1991 ¹⁴⁵ US Fair	Randomized trial	Male, complete/incomplete spinal cord injury (SCI), pelvic pressure ulcer stage II-IV	Severe cardiac disease; cardiac arrhythmia; uncontrolled autonomic dysreflexia or used a pacemaker.	NR/NR/20/17	Age (median years): 32.5 vs. 26.0 Female: 0% Race: NR	Adjunctive: Electrical Stimulation	Treatment vs. placebo stage II: 25% vs. 22.2% stage III: 62.5% vs. 66.6% stage IV: 12.5% vs. 11.1% Size (mean mm ²): 234.1 vs. 271.8 Location: pelvic area
Gupta, 2009 ¹⁴⁶ India Fair	Randomized trial	inpatients with neurological disorders having one or more stage III or IV clean and non-infected ulcers	Patients with cardiac pacemakers and pregnant women were excluded from the study. Nonischemic ulcers and ulcers with underlying osteomyelitis were also excluded from the study.	NR/NR/12/12	Age(Mean): 27.83 years Female:3/12 (25%) Race: 100% non- white	Adjunctive: Electromagnetic Therapy	Stage: Stage III - 37% Stage IV - 43% Size (mean): NR Location: NR

**Evidence Table 9a:
Adjunctive Trial and
Observational Studies,
continued**

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Ho, 2010 ¹⁴⁷ US Fair	Cohort - Multicenter, observational study	Hospitalized inpatients at the SCI centers associated with 10 VA Medical Facilities; male or female inpatients (aged ≥18 years) with SCI and at least 1 Stage III/IV (indicating a severe wound) ulcer of the pelvic region.	Patients elected to have reconstructive flap surgery of the target pressure ulcer; patients with known osteomyelitis who had not been, or refused to be, adequately treated with appropriate antibiotic treatment and/or surgical procedures (as determined by the patients' physician); no resolution of osteomyelitis after 3 months of antibiotic and/or surgical care; psychopathology (documentation in the medical record or history of self-abusive behavior specific to PrU healing, which may or may not include major or minor psychiatric illness) that may conflict with study objectives; previous diagnosis of active malignant disease; suspicion of skin cancer at the PrU site; previous radiation therapy in the PrU field at any time during the patient's lifetime; life expectancy <12 months; history of nephrosis, hemodialysis, or chronic ambulatory peritoneal, dialysis therapy; history of AIDS, at immunologic risk of infectious complications defined as any of the following: (1) CD4 count <100 cells/mL or (2) CD4 count 100 – 200 cells/mL and white blood cell count <4000 cells/mL or (3) a confirmed viral load within the past 6 months; administration of oxandrolone or another anabolic agent (not including testosterone replacement therapy) within the past 6 months; known hypersensitivity to anabolic steroid medications (specifically oxandrolone); coronary artery disease (defined by angina pectoris, myocardial infarction, or diagnostic testing), significant occlusive vascular disease, or congestive heart failure; or inability or unwillingness of the subject or surrogate to provide informed consent.	NR/NR/86/86	Age (Mean):55 vs. 55 years Female: 4% vs. 0% Race: White - 57% vs. 55% African American - 38% vs. 36% Asian - 2% vs. 0% Hispanic - 0% vs. 9%	Adjunctive: Negative Pressure Wound Therapy	Stage: Stage III (mean) - 1 vs. <1 ulcers Stage IV(mean) - 2 vs. 2 ulcers Size (mean) - NR Location: Ischial - 42% vs. 52% Perineal - 2% vs. 0% Sacral - 43% vs. 48% Trochanter - 13% vs. 0%

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Houghton, 2010 ¹⁴⁸ Canada Good	Randomized trial	paraplegia/ quadriplegia caused by congenital, medical or traumatic SCI, 18 years and older, living in the community, stage II-IV PU, 1-20cm ² for at 3+ months, able to participate for at least 3 months	Serious or multiple medical conditions that would limit healing, condition that was contraindicated fro EST (cardiac pacemaker, osteomyelitis, pregnancy, cancer)	67/34/34/31	Treatment vs. comparator Age (Mean years): 50.8 vs. 50.3 Female: 33.3% vs. 50% Race: NR	Adjunctive: Electrical Stimulation	Stage: stage II: 22.2% vs. 6.2% stage III: 22.2% vs. 37.5% stage IV: 55.5% vs. 43.7% stage X: 0% vs. 12.5% Size (mean cm ²): 2.73 vs. 3.38 Location: buttock region, foot, ankle and knee (NPUAP stage X: unstageable)
Iordanou, 2002 ¹⁴⁹ Greece Fair	Randomized trial	Patients with pressure ulcers of 1st, 2nd and 3rd grades (Torrance); pressure ulcers on the buttocks, trochanters, sacrum, shoulders and legs; each patient had to have two pressure ulcers, one of which received the polarized therapy (experimental) and the other acting as comparator; and the larger ulcer of each patient was chosen as the experimental ulcer.	Presence of skin necrosis on the ulcers; previous or planned surgical excision of the pressure ulcer; and patients in palliative care (in very poor clinical status).	NR/NR/55/32	Age (mean): 67.1 years Female: NR Race: NR	Adjunctive: Light Therapy	Stage (Torrance): 1-3 Stages I-III : 100% Size (mean): 2.84 vs. 2.10 cm ² Location: Buttocks/trochanters/ sacrum/shoulders/legs - 100%
Kloth, 1988 ¹⁵⁰ US Fair	Randomized trial	Patients between 20 and 89 years of age, All patients in the study had intact peripheral nervous systems and stage IV ulcers that had eroded into or through muscle	NR	NR/NR/16/ 16	Age (Mean): 71 vs. 66 years Female: NR Race: NR	Adjunctive: Electrical Stimulation	Stage: Stage IV - 100% Size (mean) - 4.08 cm ² Location:

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Lucas 2003 ¹⁵¹ Netherlands Fair	Randomized trial	Consecutive patients with stage III pressure ulcers	Patients with ulcers other than stage III (full- thickness skin defect extending into adipose tissue)	NR/NR/86/79	Age (Mean):83.5 vs. 81.3 years Female: 61% vs. 64% Race: NR	Adjunctive: Laser Therapy	Stage III - 100% Size (mean): 350 vs. 317 mm ² Location (n= 47 vs. 39): Gluteal - 8 vs. 4 Sacrum/Coccyx - 14 vs. 14 Greater trochanter - 1 vs. 0 Med. Femoral condyle - 0 vs. 1 Calcaneus - 14 vs. 13 Med. Fem. Cond. - 1 vs. 1 Lat. Malleolus - 5 vs. 3 Other - 0 vs. 0
Lucas, 2000a ¹⁵² Netherlands Fair	Randomized trial	Consecutive patients with stage III pressure ulcers	Patients with ulcers other than stage III (full- thickness skin defect extending into adipose tissue)	NR/NR/20/16	Age (Median):87.5 vs. 88 years Female: 75% vs. 100% Race: NR	Adjunctive: Laser Therapy	Stage III - 100% Size (mean): 94 vs. 82.5 mm ² Location (n= 8 vs. 8): Gluteal - 1 vs. 3 Sacrum/Coccyx - 2 vs. 2 Calcaneus - 2 vs. 2 Med. Fem. Cond. - 1 vs. 1 Lat. Malleolus - 2 vs. 0 Other - 0 vs. 0
Maeshige, 2010 ¹⁵³ Japan Fair	Randomized trial	Treatment naive inpatients who were receiving standard wound care including surgical debridement, topical antimicrobials and pressure redistribution, presence of National Pressure Ulcer Advisory Panel (NPUAP) stage III or IV pressure ulcers	clinical signs of local wound infection, extensive necrotic tissue, diabetes mellitus type 2 and/or peripheral arterial disease	NR/NR/5/5	Age (Mean): 81.8 years Female: 3/5(60%) Race: 100% non- white	Adjunctive: Ultrasound	7 ulcers/5 patients Stage III: 4/7 ulcers Stage IV: 3/7 ulcers Size (mean): 14.65 cm ² Location: ilium - 1/7 lateral malleolus - 2/7 sacrum - 2/7 fibula/tibia - 2/7

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
McDiarmid, 1985 ¹⁵⁴ UK Fair	Randomized trial	Patients over 18 years or age with pressure sores referred by physiotherapy and nursing staff in three Bristol hospitals; pressure sores had not had radiotherapy in the area over the past 6 months;	Evidence of deep vein thrombosis (DVT); sores not limited to superficial tissue not extending beyond the dermis; pressure on the sore not capable of being removed; malignancies in the area to be treated	NR/NR/40/18	Age (Mean): NR Female: NR Race: NR	Adjunctive: Ultrasound	Stage: NR Size (mean) NR: Location: NR
Nussbaum, 1994 ¹⁵⁵ UK Fair	Randomized trial	Hospitalized patients at Lyndhurst Spinal Cord Centre with a diagnosis of spinal cord injury (SCI) and skin wounds	NR	NR/NR/20/20	Age (Mean):36 vs. 42.2 vs. 42 years Female: 16% vs. 0% vs. 17% Race: NR	Adjunctive: Laser Therapy	Stage: NR Size (mean): 2.1 vs. 1.9 vs. 2.8 cm ² Location: NR
Onigbinde, 2010 ¹⁵⁶ South Africa Poor	Randomized trial	Absence of previous skin breakdown or wound prior to being admitted, presence of bilateral pressure sores on the lower limbs; a stable regimen of medications during the course of the study including the antibiotic ciproflaxin; a wound duration of at least 8 weeks; and age between 35- 55 years	Patients with diabetes, malnutrition, dermatitis, or with metallic implants	NR/NR/10/10	Age (Mean): 45.3 years Female: 80% Race: NR	Adjunctive: Light Therapy	Stage: NR Size (mean): 76.5 vs. 43.8 cm ² Location: gluteal - 60% heel - 40%

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Salzberg, 1995 ¹⁵⁷ US Fair	Randomized trial	Spinal cord-injured patients with pressure ulcers admitted to the Veteran's Administration Medical Center at Castle Point, NY over a 2-year period	Patients with more than 1 ulcer, recent ulcer surgery, with a cardiac pacemaker, intercurrent disease, active cellulitis, sepsis, terminal illness or end-stage renal disease (ESRD), and patients with Stage I or IV pressure ulcers	NR/NR/30/30	Age(Mean): 50 vs. 58 years Female: NR Race: NR	Adjunctive: Electromagnetic Therapy	Area: 14 vs. 33cm ² , p=0.089 Granulation %: 23 vs. 45, p=0.210 Epithelization %: 8 vs. 10, p=0.222 Stage II - partial thickness skin loss involving epidermis and dermis, superficial presenting as deep crater, abrasion, blister, or shallow crater Stage III - full thickness skin loss involving damage or necrosis of subcutaneous tissue which may have extended down to, but not through, underlying fascia and presenting as a deep crater with or without undermining adjacent tissue
Schubert, 2001 ¹⁵⁸ Sweden Fair	Randomized trial	Elderly patients with Stage 2 or 3 pressure ulcer, newly admitted to an orthopedic or a geriatric ward, were asked to enter the study.	NR	NR/NR/74/59	Age (Mean): 85 vs. 85 years Female: 68% vs. 60% Race: NR	Adjunctive: Light Therapy	Stage: Stage 2/3 - 100% Size (under 10.0 cm ²): 92% vs. 94% Location: Trunk - 68% vs. 83%
Schwien, 2005 ¹⁵⁹ US Poor	Retrospective cohort study	Start of care and end of care between July 1, 2002 and September 30, 2004; one Stage III or one Stage IV pressure ulcer; and primary diagnosis of 707.0 decubitus chronic skin ulcer.	Patients who died at home; enteral or parenteral nutrition therapy; high risk factors of heavy smoking, alcohol dependency, or drug dependency; poor or unknown overall prognosis; or secondary diagnoses of uncontrolled diabetes, cancer, systemic infections, or related to malnutrition/anemias/proteinemia.	1,941,039/ 134,147/ 2,348/ 2,348(60 NPWT)	Age (Mean): 65 vs. 71.4 Female: 53% vs. 58% Race: NR	Adjunctive: Negative Pressure Wound Therapy	Stage: Stage III - 7/60(24%) vs. 756/2288 (44%) Stage IV - 14/60(45%) vs. 337/2288(59%) Size (mean): NR Location:

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Taly, 2004 ¹⁶⁰ India Good	Randomized trial	Patients with spinal cord disorders and admitted to the rehabilitation ward with pressure ulcers or who developed ulcers during their stay in the ward were eligible for the study. Pressure ulcers were divided into the conventional 4 stages: stage 1, nonblanching erythema of intact skin; stage 2, partial thickness skin loss; stage 3, full-thickness skin loss; and stage 4, extension into muscle and one.7 Pressure ulcers of the conventional stages 2, 3, and 4 were included in the study.	Subjects with photosensitivity, ulcers from other causes, necrotic tissue in ulcers that would interfere with the application of laser, flask-shaped ulcers that cannot be adequately exposed to laser, pressure ulcers with underlying osteomyelitis, or pressure ulcers requiring surgical intervention at the time of first assessment were excluded.	129/40/35/29	Age (Mean): 32 years Female: 22.9% Race: NR	Adjunctive: Laser Therapy	Stage:2/3/4; 21 (32.8%) on the sacrum, 18 (28.1%) on the greater trochanter, 9 (14.1%) on the gluteal region, 2 (3.1%) on the lateral malleolus, 2 (3.1%) on the elbow, 1 (1.6%) on the ischial tuberosity, 1 (1.6%) on the heel, and 10 (15.6%) on other sites. Size (mean) Location: 55 at stage 2, 8 at stage 3, and at stage 4. Most ulcers evolved after hospitalization: 33 ulcers (51.6%) developed in an acute care facility, 13(20.3%) in a rehabilitation ward, and 18 (28.1%) at home. These ulcers could be attributed to prolonged lying in bed, 49 (76.6%); improper transfers, 10 (15.6%); and prolonged sitting, 5 (6.3%).

**Evidence Table 9a:
Adjunctive Trial and
Observational Studies,
continued**

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
ter Riet, 1995 ¹⁶¹ ter Riet, 1996 ¹⁶² Netherlands Good	Randomized trial	Patients with stage II, III, or IV pressure ulcers (i.e., partial-thickness skin loss or worse") from 11 nursing homes and one hospital located in the south of the Netherlands. If a patient had multiple ulcers, we used two hierarchical criteria to choose one ulcer for inclusion in the trial.	Patients with difficulties with swallowing or frequent vomiting (poor compliance with AA regimen); osteomyelitis in the ulcer area (healing very unlikely); idiopathic hemochromatosis, thalassemia major, and sideroblastic anemia (in these three diseases, AA supplementation is contraindicated); and Cushing's syndrome or Cushing's disease, pregnancy, radiotherapy in the ulcer area, and the use of antineoplastic agents or systemic glucocorticosteroids (all because of hormonal alterations in collagen synthesis). A high probability to drop out within the 12-week followup period (terminally ill patients; patients for whom surgical treatment of the ulcer, other than debridement, had been planned) also led to exclusion. Furthermore, we excluded patients if they were already taking vitamin C supplements in excess of 50 mg per day. Patients with stage II ulcers (partial-thickness skin loss) could participate only if deep ithelialization had persisted for at least 7 days without interruption. Patients with leg ulcers had to have a positive history of pressure on that site to be eligible.	NR/NR/88/88	Age (Mean): 82 vs. 80 years Female: 77.8% vs. 72.1% Race: NR	Adjunctive: Ultrasound	Stage: Stage II/III - 80% vs. 83.7% Stage IV - 20% vs. 16.3% Size (mean): Wound surface area cm ² (%) 0.01-1.00 - 42.2% vs. 34.9% 1.01-5.00 - 40% vs. 44.2% 5.01-10.0 - 15.6% vs. 11.6% >10.0 - 2.2% vs. 9.3% Location: Trunk - 60% vs. 58.1%

**Evidence Table 9a:
Adjunctive Trial and
Observational Studies,
continued**

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Wanner, 2003 ¹⁶³ Switzerland Fair	Randomized trial	Patients admitted with a pressure sore of the pelvic region, deeper than stage II (Daniel et al.,: at least a penetration in the subcutaneous fat).	Pressure sores not in the pelvic region; depth of the pressure sore was less than stage III.	34/24/24/22	Age (Mean): 49 vs. 53 years Female:36.3% vs. 27.2% Race: Each group consists of 11 paraplegic or tetraplegic patients. The mean age was 53 (34–77) years in the traditional group and 49 (25–73) years in the vacuum assisted group. The male to female distribution was 8 to 3 in the traditional and 7 to 4 in the vacuum-assisted group.	Adjunctive: Negative Pressure Wound Therapy	Stage: II+ (Daniel et al.) Size (mean): 50ml vs. 42 ml Location: Pelvic region
Wood, 1993 ¹⁶⁴ US Fair	Randomized trial	Chronic Pressure Ulcers	NR	NR/NR/71/71	Age (mean years): 75.6 vs. 74.9 Female %: 36.5 vs. 50 Race: all patients were white PU stage II-III (article uses grade PU criteria)	Adjunctive: Electrical Stimulation	Stage: Stage III - 100% Size (mean) - NR Location: leg - 15/31 vs. 16/41 coccyx - 7/31 vs. 9/41 hip - 2/31 vs. 10/41 buttock - 5/31 vs. 5/41 other - 2/31 vs. 3/41

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Adegoke 2001 ¹³⁶ Nigeria Fair	A: IDC plus nursing care - after cleaning ulcers covered with sterile gauze soaked in 0.9% saline. 2 pieces of aluminum plate electrodes were cut to sizes slightly larger than the individual ulcers, wrapped in 6 layers of lint soaked in 0.9% saline. IDC turned on and gradually increased intensity until a "minimal perceptible contraction" was observed, then reduced slightly so no visible contraction could be observed. The rest to surge ratio was 2:1 at 30 Hz with rectangular wave forms for a duration of 45 minutes	B: placebo IDC plus nursing care - after cleaning ulcers covered with sterile gauze soaked in 0.9% saline. 2 pieces of aluminum plate electrodes were cut to sizes slightly larger than the individual ulcers, wrapped in 6 layers of lint soaked in 0.9% saline. IDC turned on and gradually increased intensity until a "minimal perceptible contraction" was observed, then reduced slightly so no visible contraction could be observed. The rest to surge ratio was 2:1 at zero Hz with rectangular wave forms for a duration of 45 minutes	NA	NA	NR	Change in surface area: baseline to week 4 - 22.2% vs. 2.6%	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Adunsky, 2005 ¹³⁷ Israel Fair	A: Treatment Group (TG): DDCT treatment, electrical currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20- min sessions daily, reduced to two daily sessions after 14 days. Ulcers were covered with hydrocolloid or collagen dressings after treatment Treatment period lasted for 8-weeks	B: Placebo Group (PG): placebo-DDCT treatment, zero currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20-min sessions daily, reduced to two daily sessions after 14 days. ulcers were covered with hydrocolloid or collagen dressings after treatment Treatment period lasted for 8-weeks	NA	NA	End of followup: 10/35(35.7%) vs. 9/28(25.7%), p=0.28 End of treatment: 5/35(14.3%) vs. 3/28(10.7%), p=0.39	Day 45: 11.15 vs. 16.7 cm ² , p=0.9 Day 147: 2.53 vs. 2.88 cm ² , p=0.31	Speed of wound closure: Mean time to complete closure: 63.4 vs. 89.7, p=0.16).	NR	NR
Ahmad, 2008 ¹³⁸ India Fair	A: HVPC for 45 minutes daily for 7 days	B: HVPC for 60 minutes daily for 7 days	C: HVPC for 120 minutes daily for 7 days	Comparator: VPC for 45 minutes daily for 7 days (voltage maintained at zero)	NR	Wound surface areas decreased (cm ²) to: 5.1 vs. 0.6 vs. 0.64 vs. 5.39, p<0.001	Mean healing rate: 0.40 vs. 1.30 vs. 1.30 vs. 0.27 cm ² /week	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Baker, 1996 ¹³⁹ US Fair	A: Asymmetric biphasic (A) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - below contraction Phase duration - 100 µsec frequency - 50 pulses/s	B: Symmetric biphasic (B) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - below contraction Phase duration - 300 µsec frequency - 50 pulses/s	C: Microcurrent (MC) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - 4 mA Phase duration - 10 µsec frequency - 1 pulses/s	D: Comparator (C) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - 0 Phase duration - 100 µsec frequency - 1 pulses/s	NR	Change in surface area (%/week): 36.4 vs. 29.7 vs. 23.3 vs. 32.7	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Dehlin, 2003 ¹⁴⁰ Denmark Fair	<p>A: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings</p> <p>monochromatic phototherapy treatment - probe containing 30 diodes emitting infrared light at 956 nm and 80 diodes emitting red light 637 nm, placed 3 cm above ulcer and administered in identical sequence for every session</p> <p>week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes</p>	<p>B: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings</p> <p>placebo light treatment - emitting no infrared or red light was administered for every session</p> <p>week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes</p>	NA	NA	Complete healing: 34/78(43.6%) vs. 34/78(39.5%), p=0.93	Reductions in wound surface area over time in both groups were statistically significant (p=<0.0001) but there was no statistically significant difference in reduction of wound surface area (p=0.18)	Time until total healing was assessed every week for 12 weeks or until complete healing	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Dehlin, 2007 ¹⁴¹ Denmark Fair	<p>A: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings</p> <p>monochromatic phototherapy treatment - probe containing 30 diodes emitting infrared light at 956 nm and 80 diodes emitting red light 637 nm, placed 3 cm above ulcer and administered in identical sequence for every session</p> <p>week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes</p>	<p>B: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings</p> <p>placebo light treatment - emitting no infrared or red light was administered for every session</p> <p>week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes</p>	NA	NA	Complete healing: 43/79(54.4%) vs. 50/84(59.5%), p=0.52	<p>Mean normalized reduction in pressure ulcer size at week 12 - 0.79 vs. 0.50, p=0.039</p> <p>normalized weekly reduction in pressure ulcer size over time - 15.1% vs. 10.9%</p>	Time until total healing was assessed every week for 12 weeks or until complete healing	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Durovic, 2008 ¹⁴² Serbia Fair	A: (E - experimental group) - standard cleaning and dressing - application of a gauze with normal saline (NaCl), then a dry gauze, next it a cotton wool and adhesive strip Polarized light therapy using a linear polarized light source (Bioptron lamp settings - wavelength: 400–2000 nm; degree of polarization: > 95%; power density: 40 mW/cm ² ; light energy: 2,4 J/cm ²) performed for 6 min/day at a distance of 10cm, 5 x week/4 weeks	B: (C - comparator group) - standard cleaning and dressing - application of a gauze with normal saline (NaCl), then a dry gauze, next it a cotton wool and adhesive strip	NA	NA	NR	Surface of the pressure ulcers (cm ²) - 10.80 vs. 22.97, p=0.0005	NR	NR	NR
Ford, 2002 ¹⁴³ US Fair	A: VAC dressings were changed Mondays, Wednesdays, and Fridays (manufacturer recommends dressing changes every 48 hours).	B: HP dressings were changed once or twice daily, depending on the degree of wound drainage. Strict pressure reduction with the appropriate beds and positioning was instituted. The Healthpoint System (HP) offers a second innovative approach to the management of pressure ulcers. It consists of three FDA-approved gel products—Accuzyme, Iodosorb, and Panafil—each targeted to optimize a particular macroscopic phase of wound healing.	NA	NA	Complete wound healing: 2/20(10%) vs. 2/15 (13%)	Change in wound surface area: 36.9 x 40.0 cm ² vs. 18.7 x 19.0 cm ² Mean reduction in ulcer volume - 57% vs. 25%	NR	NR	15/35 wounds (42.9%) were suspicious for osteomyelitis and underwent bone biopsy and MRI.

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Gentzkow, 1991 ¹⁴⁴ US and Canada Fair	A: Sham treatment	B: Dermapulse stimulator - pulsed electrical current for 30 minutes/2x daily/4 weeks pulse rate:2 pps/350 microseconds intensity: 0-150 mA	NA	NA	Complete wound healing: 23.4% vs. 49.8%, p=0.042	NR	NR	NR	NR
Griffin, 1991 ¹⁴⁵ US Fair	A: HVPC for 1 hour daily for 20 days	B: Placebo HVPC for 1 hour daily for 20 days, no current flowed through to patient	NA	NA	Complete wound healing was reported at 5 days, 10 days, 15 days and 20 days	Median wound surface area decrease of 80% at 20 days	Median wound surface area decrease at 5 days: 32% 10 days: 47% 15 days: 20%	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Gupta, 2009 ¹⁴⁶ India Fair	<p>A: Standard pressure ulcer care with daily dressing with normal saline</p> <p>PEMF: exposure to 1 Hz frequency sine waves with 30 milli-Ampere current intensity/45 minutes/day/5x week/30 sessions using “Pulsatron” equipment (couch encircled by a metallic frame. Homogenous pulsating electromagnetic field is generated by metallic frame which encircles a “couch” on which the subject lies either supine or prone for the duration of the treatment)</p>	<p>B: Standard pressure ulcer care with daily dressing with normal saline</p> <p>Placebo/Sham: 0 Hz frequency sine waves with 0 milli-Ampere current intensity/45 minutes/day/5x week/30 sessions using “Pulsatron” equipment</p>	NA	NA	<p>A (n=13 ulcers on 12 subjects) vs. B (b=11 ulcers on 6 subjects):</p> <p>Complete healing of pressure ulcers in less than 30 sessions: 2/12(16.7%) vs. 0/6(0%)</p> <p>Healing of the ulcers (NPUAP ulcer stage) at the end of the study A (p=0.008) vs. B (p=0.014), p=0.649</p> <p>BJWAT scores at admission and discharge A (p=0.001) vs. B (p=0.003), p=0.361.</p>	NR	<p>Mean duration of the illness at the beginning of study was 6.42 months (1 to 20 months)</p> <p>Mean duration of pressure ulcer was 103.75 days (10 to 420 days).</p>	NR	NR
Ho, 2010 ¹⁴⁷ US Fair	<p>A: Standard wound care - pressure relief (e.g., low-air-loss mattress, turning, etc), debridement (e.g., sharp, mechanical, enzymatic), routine dressing changes, biophysical modalities (e.g., hydrotherapy), and cleansing as appropriate.</p>	<p>B: Standard wound care - pressure relief (e.g., low-air-loss mattress, turning, etc), debridement (e.g., sharp, mechanical, enzymatic), routine dressing changes, biophysical modalities (e.g., hydrotherapy), and cleansing as appropriate.</p> <p>Negative Pressure Wound Therapy</p>	NA	NA	NR	<p>Wound Surface Area change - 50% vs. 43%, p= no significance</p>	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Houghton, 2010 ¹⁴⁸ Canada Good	A: HVPC frequency of 100Hz for 20 minutes, 10Hz for 20 minutes and 20 minutes off, 8 hours a day for at least 3 months + SWC	B: SWC included nutrition, wound dressing and continence management which was customized for each patient as necessary	NA	NA	42.9% achieved complete wound healing	70% mean decrease in wound surface area p=0.048	42.9% achieved complete wound healing at 3 months	NR	NR
Iordanou, 2002 ¹⁴⁹ Greece Fair	A: Standard care - turning the subjects every 2-3 hours, provision of electric pressure relieving overlay and a 30° lateral side-lying position given to avoid friction and shearing forces. Concerning the ulcers, these were of 1st, 2nd and 3rd grades without necrotic tissue; thus, the concentration was on two essential components of cleaning and dressing. Cleaning solution of choice was 0.9% sodium chloride and the dressing was chosen to match ulcer stage. Polarized light therapy - energies delivered were typically 4 J/cm ² per min, degree of polarization of > 95% using a 20 W Bioptron electrical lamp. The treatment consisted of polarized treatment for 5 min per day/5 days per week/2 weeks	A: Standard care - turning the subjects every 2-3 hours, provision of electric pressure relieving overlay and a 30° lateral side-lying position given to avoid friction and shearing forces. Concerning the ulcers, these were of 1st, 2nd and 3rd grades without necrotic tissue; thus, the concentration was on two essential components of cleaning and dressing. Cleaning solution of choice was 0.9% sodium chloride and the dressing was chosen to match ulcer stage.	NA	NA	NR	Change in Wound Size (mean): -.54 vs. -.06 cm ²	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Kloth, 1988 ¹⁵⁰ US Fair	A: Treatment group - DynaWave® Model 12 high voltage, monophasic twin-pulsed generator* in this study and arbitrarily set the stimulus variables at a frequency of 105 Hz, an intraphase interval of 50 µsec, and a voltage just below that capable of producing a visible muscle contraction (100-175 V). At 100 V with an intraphase interval of 100 µsec, the single-phase charge was calculated at about 1.6 µC with a total-pulse charge accumulation of 342 µC/sec. 45 minutes of ESTR applied to the ulcer site once a day, five days a week.	B: Comparator group - Comparator Group had electrodes applied in the same manner as patients in the Treatment Group, but the voltage was maintained at zero	NA	NA	Complete wound healing: 100% vs. NR	Change in surface area: 4.08 vs. 5.20cm ²	Mean healing rate: 44.8%/week vs. 11.59%/week	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Lucas 2003 ¹⁵¹ Netherlands Fair	A: Comparator - consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position.	B: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position. LLLT treatments - using an LLLT device with a microprocessor-controlled, multiple monochromatic optical source probe . The handheld probe with 12 70 W monochromatic infrared GaAs-diodes (gallium arsenide) operated at a wavelength of 904 nm in a 830 Hz, pulse frequency mode with an average beam power of 8 mW and a radiant exposure of 1 J/cm ² covered an area of 30 cm ² .	NA	NA	NR	Absolute improvement (mm ²) mean: 138 vs. 48, p=0.23	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Lucas, 2000a ¹⁵² Netherlands Fair	<p>A: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position.</p> <p>LLLT treatments - using an LLLT device with a microprocessor-controlled, multiple monochromatic optical source probe . The handheld probe with 12 70 W monochromatic infrared GaAs-diodes (gallium arsenide) operated at a wavelength of 904 nm in a 830 Hz, pulse frequency mode with an average beam power of 8 mW and a radiant exposure of 1 J/cm² covered an area of 30 cm².</p>	<p>B: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position.</p>	NA	NA	NR	Change in median wound surface area (mm ²): 83% vs. 95%	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Maeshige, 2010 ¹⁵³ Japan Fair	<p>A: ultrasound irradiation (US) administered to the pressure ulcer through the same dressing used for 2–4 weeks</p> <p>- The area of dressing in which exudate seeped fully was covered with US gel, US irradiation was applied with the dressing in place</p> <p>- 1 MHz was used for all ulcers at 0.5 W/cm² at the wound surface</p> <p>- 3 MHz was used for ulcers close to the bone at 0.5 W/cm² at the wound surface</p>	<p>B: standard treatment with dressings that promote a moist wound healing environment All pressure ulcers were covered with a hydrocolloid dressing.</p> <p>-To avoid US reflection, a polyurethane film was placed over the hydrocolloid dressing; any air bubbles between the layers were removed.</p> <p>- The area of dressing in which exudate seeped fully was covered with US gel, US irradiation was applied with the dressing in place</p> <p>- 1 MHz was used for all ulcers at 0.5 W/cm² at the wound surface</p> <p>- 3 MHz was used for ulcers close to the bone at 0.5 W/cm² at the wound surface</p>	NA	NA	<p>DESIGN score:</p> <p>A(n=4) vs. B (n=3)</p> <p>Stage III - 3/4 vs. 1/3</p> <p>Stage IV- 1/4 vs. 2/3</p> <p>End of Study Complete healing: NR</p>	Change in Wound Size (mean): 5.04 cm ²	Healing time (mean): 108.25 vs. 97 days		
McDiarmid, 1985 ¹⁵⁴ UK Fair	<p>A: Ultrasound: treatment minimum of 5 minutes for all pressure sores up to 3m2 (additional minute for each added 0.5 cm²) for a maximum 10 minutes/3x week</p> <p>Frequency - 3 MHz peak intensity - 0.8W cm²</p>	B: Mock ultrasound (placebo)	NA	NA	Healed at end of treatment: 10/21 (41%) vs. 8/19(42%)	NR	Mean: 32 vs. 36 days	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Nussbaum, 1994 ¹⁵⁵ UK Fair	A: Comparator - This group received standard wound care only, consisting of wound cleansing twice daily using Hygeol* (1:20),+ Jelonet dressings to keep the wound surface moist, and avoidance of lying the wound, using coupling gel for contact, for 5 minutes per 5 cm ² of wound area.	B: Ultrasound/Ultra-violet C (US/UVC) - Ultrasound treatment was applied using an Omnisound 3000, IP which was calibrated by the manufacturer at the start of the study. The size of the treatment head was 5 cm ² , and treatment was delivered at a frequency of 3 MHz and at an SATA intensity of 0.2 w/cm ² (1:4 pulse ratio). Ultrasound was applied to intact skin surrounding the wound, using coupling gel for contact, for 5 minutes per 5 cm ² of wound area. The US and UVC treatments were alternated daily for 5 days per week. Ultrasound was usually applied three times weekly, but in the case of purulent wounds, UVC was applied three times weekly.	NA	NA	NR	Change in wound surface area: 32.4% vs. 53.5% vs. 23.7%	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Onigbide, 2010 ¹⁵⁶ South Africa Poor	A: traditional saline-wet-to-moist (WM) wound dressing, and high-intensity ultraviolet B radiation - (UVB) lamp (Philips 8P3114) at 3 inches from the wound surface, using progressively increased exposure duration with each session (3/4, 1, 2, 2 1/2, 3, 4 and 5 minutes for the first 7 sessions). Wounds radiated 1x every 3 days/ 6 weeks. Skin surrounding wound was protected with 2 mm thickness of Vaseline and cotton wool	B: traditional saline-wet-to-moist (WM) wound dressing	NA	NA	NR	Change in Mean Ulcer Surface Area (cm ²): 59.9 vs. 16.4	NR	NR	NR
Salzberg, 1995 ¹⁵⁷ US Fair	A: Placebo (sham)	B: Diapulse current - 27.12 MHz at 80-600 pulses/sec, a pulse width of 65 microseconds, a duty cycle between 0.5% and 3.9%, and a per pulse power range between 293-975 peak watts	NA	NA	Stage II (n=10 vs. 10) week 1: 84% vs. 40%, p=0.01 End of Study Complete healing: 9/15 vs. 6/15 Stage III (n=5 vs. 5) week 1: NR End of Study Complete healing: 3/5(60%) vs. 0/5(0%)	Change in surface area: Stage II (n=10 vs. 10): NR Stage III (n=5 vs. 5): 70.6% vs. 20.7%	Mean Healing Time Stage II: NR Stage III: 43 days	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Schubert, 2001 ¹⁵⁸ Sweden Fair	A: (Group 1) Conventional/standard ulcer therapy - not described	B: (Group 2) Conventional/standard ulcer therapy - not described Phototherapy with pulsed monochromatic light (PML): A probe contained both 30 diodes, which could emit infrared light at 956 nm, and 80 diodes, which could emit red light at 637 nm. Treatments lasted 9 min each time using a regimen with pulse repetition frequency varied between 15.6 Hz and 8.58 kHz. Patients were followed for 10 weeks or until the ulcer was healed, whichever occurred first. The number of treatments given per week was as follows: Week 1: 5 x week; Week 2: 4 x week Week 3: 2 x week Week 4+: 1 x week	NA	NA	NR	NR	Healing rate (mm ² /week): 0.200 vs. 0.298, p<0.05 (healing rate was 49% higher in treatment group (Group 2) than in comparato r (Group 1)	NR	NR
Schwien, 2005 ¹⁵⁹ US Poor	A: Negative Pressure Wound Therapy (NPWT) - specific technologies and treatment used not reported	B: Comparison group - standard care through end of treatment, specific treatments not reported	NA	NA	NR	NR	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Taly, 2004 ¹⁶⁰ India Good	<p>A: Usual care - daily dressing with sterile gauze soaked in normal saline and pressure relief with either a water mattress or a split mattress.</p> <p>multi-wave light therapy - 14 treatments were given, 1 every alternate day, 3 times a week, until the ulcer healed or the ulcer received 14 exposures. Each ulcer was divided into 10cm² squares. During every session, each square was exposed for 60 seconds. The central 820nm laser source was surrounded by 45 supraluminous diodes of different wavelengths. Energy applied to the ulcer was calculated by using the formula: energy delivered = (power/spot size)(time). Energy given was 4.5J/cm².</p>	<p>B: Usual care - daily dressing with sterile gauze soaked in normal saline and pressure relief with either a water mattress or a split mattress.</p> <p>sham treatment - multi-wave light therapy - 14 treatments were given, 1 every alternate day, 3 times a week, during which the multi wavelength light therapy source was held over the ulcer after switching off the beam</p>	NA	<p>Ulcer healing was defined as the complete closure of the wound with healthy scar tissue. Eschar was removed before application of intervention. Ulcers with eschar at the end of the study period were considered not healed.</p> <p>Complete Healing (ulcers)- 18/35 (51%)vs. 14/29 (48%), p=0.802</p>	NR	<p>The mean time taken for the ulcers to heal from the day of randomization was 2.45 2.06 weeks in the treatment group and 1.78 2.13 weeks in the comparator group. This difference was not statistically significant (t .987, P .330). The PSST score and the stage of the 32 ulcers that did not heal during the study</p>	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
ter Riet, 1995 ¹⁶¹ ter Riet, 1996 ¹⁶² Netherlands Good	A: Sham treatment - duration varied according to formula: treatment area estimate + effective radiating area (at the face of the transducer) x 3 minutes (minimum treatment duration was 3 minutes 45 seconds) at 1 x day/5 days /week for 6 weeks (60 treatments) Frequency - 0 MHz Pulse duration - 0 ms Pulse repetition frequency - 0 Hz	B: Ultrasound therapy - Treatment duration varied according to formula: treatment area estimate + effective radiating area (at the face of the transducer) x 3 minutes (minimum treatment duration was 3 minutes 45 seconds) at 1 x day/5 days /week for 6 weeks (60 treatments) Frequency - 3.28 MHz Pulse duration - 2 ms Pulse repetition frequency - 100 Hz	NA	NA	NR	Mean surface reduction (cm ²) - 0.18 vs. 0.31, p=0.09	Mean healing rate (cm/week) - 0.18 vs. 0.13, p=0.18	NR	NR
Wanner, 2003 ¹⁶³ Switzerland Fair	A: In the vacuum-assisted group we used the equipment obtained from KCI Mediscus consisting of drainage tubes, polyvinyl foam, a transparent polyurethane dressing, and a vacuum suction pump (Fig. 1a). Continuous subatmospheric pressure of 125 mm Hg was applied. The dressings were changed after two to seven days, depending on the amount of fluid produced by the wound (when the canister was full).	B: Our standardized treatment of deep pressure sores is surgical debridement followed by a period of wound preparation and, Nelly closure with a flap. After debridement we started the local treatment on the first day after the operation. In the wet-to- dry/wetto-wet (traditional) group the dressings consisted of gauze soaked with Ringer's solution. These dressings were changed three times a day until clean granulation tissue was observed. From then on, we kept the wound wet with Ringer solution and changed the dressings one to three times a day to keep the wound moist.	NA	NA		Wound size in the two groups (ml) (n = 11 in each group) Wound volume (ml) Vacuum- assisted closure Wet-to-dry/ wet-to-wet Range 3-132 5-68 Mean (SD) 50 (33) 42 (16)	Time to reach 50% health: 27 days vs. 28 days	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	Treatment A	Treatment B	Treatment C	Treatment D	Complete Wound Healing	Wound Surface Area	Healing Time	Infection Rate	Osteomyelitis Rate
Wood, 1993 ¹⁶⁴ US Fair	A: PLIDC of 600mA with frequency of approx 0.8Hz / 3x week until healing	B: non-PLIDC sham, current delivery output was impeded	NA	NA	Complete wound healing - 58% vs. NR	Change in surface area: NR vs. 72.9% decreased more than 80% in size	Speed of wound closure: NR vs. 58%(8 weeks)	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Recurrence Rate	Pain	Other: Specify	Duration of Followup	Study setting: Hospital Nursing Home/LTC facility Community Other: Specify	Pain	Dermatologic Complications
Adegoke 2001 ¹³⁶ Nigeria Fair	NR	NR	NR	NR	Hospital	NR	NR
Adunsky, 2005 ¹³⁷ Israel Fair	NR	NR	NR	147 days	Hospital	NR	Skin irritation - 2 vs. 0 patients
Ahmad, 2008 ¹³⁸ India Fair	NR	NR	NR	5 weeks	Investigating sites	NR	NR
Baker, 1996 ¹³⁹ US Fair	NR	NR	NR	Every 2-4 weeks until healing	Hospital	NR	NR
Dehlin, 2003 ¹⁴⁰ Denmark Fair	NR	NR	NR	Followup until complete healing	Hospital	NR	NR
Dehlin, 2007 ¹⁴¹ Denmark Fair	NR	NR	NR	Followup until complete healing	Hospital	NR	NR
Durovic, 2008 ¹⁴² Serbia Fair	NR	NR	Total PUSH score of the pressure ulcers - 7.35 vs. 11.85, p=0.00003	NR	Hospital	NR	NR
Ford, 2002 ¹⁴³ US Fair	NR	NR	NR	Followup ranged from 3 to 10 months.	Hospital	NR	NR
Gentzkow, 1991 ¹⁴⁴ US and Canada Fair	NR	NR	NR	4 weeks after end of treatment	Hospital	NR	NR
Griffin, 1991 ¹⁴⁵ US Fair	NR	NR	NR	20 days	Hospital	NR	NR
Gupta, 2009 ¹⁴⁶ India Fair	NR	NR	NR	The mean duration of stay in the rehabilitation unit was 98.66 days (24-193 days). The number of treatment sessions in patients ranged from 22-30, mean of 29.06.	Hospital	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Recurrence Rate	Pain	Other: Specify	Duration of Followup	Study setting: Hospital Nursing Home/LTC facility Community Other: Specify	Pain	Dermatologic Complications
Ho, 2010 ¹⁴⁷ US Fair	NR	NR	NR	NR	Hospital	NR	NR
Houghton, 2010 ¹⁴⁸ Canada Good	NR	NR	NR	6 months	Community	NR	NR
Jordanou, 2002 ¹⁴⁹ Greece Fair	NR	NR	NR	At the end of each week, experimental and comparator ulcers were reassessed and a detailed report was completed, no additional followup after end of treatment reported	Hospital	NR	NR
Kloth, 1988 ¹⁵⁰ US Fair	NR	NR	NR	NR	Hospital	NR	NR
Lucas 2003 ¹⁵¹ Netherlands Fair	NR	NR	NR	NR	Hospital	NR	NR
Lucas, 2000a ¹⁵² Netherlands Fair	NR	NR	NR	NR	Hospital	NR	NR
Maeshige, 2010 ¹⁵³ Japan Fair	NR	NR	NR	NR	Hospital	NR	
McDiarmid, 1985 ¹⁵⁴ UK Fair	NR	NR	NR	NR	Hospital	NR	NR
Nussbaum, 1994 ¹⁵⁵ UK Fair	NR	NR	NR	NR	Hospital	NR	NR
Onigbide, 2010 ¹⁵⁶ South Africa Poor	NR	NR	Change in Mean Ulcer Volume (ml): 26.2 vs. 2.1	NR	Hospital	NR	NR
Salzberg, 1995 ¹⁵⁷ US Fair	NR	NR	NR	NR	Hospital	NR	NR
Schubert, 2001 ¹⁵⁸ Sweden Fair	NR	NR	NR	NR	Hospital	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Recurrence Rate	Pain	Other: Specify	Duration of Followup	Study setting: Hospital Nursing Home/LTC facility Community Other: Specify	Pain	Dermatologic Complications
Schwien, 2005 ¹⁵⁹ US Poor	NR	NR	Rates of hospitalization: 35% vs. 48%, p<0.05. Rates of hospitalization due to wound problems: 5% vs. 14%, p<0.01. Rates of emergent care for wound problems: 0% vs. 8%, p=0.01.	NR	Home health agencies	NR	NR
Taly, 2004 ¹⁶⁰ India Good	NR	Change in Stage = Of the 9 ulcers that were at stages 3 and 4 at the time of randomization, the PSSST score and the ulcer stage were significantly lower in the treatment group (n 4) than in the comparator group (n 5) at the end of the study (table 5). 3/4 ulcers in the treatment group reached stage 2 by 2 weeks after starting treatment and stage 1 by 3 weeks. 0/5 ulcers reached stage 2 at the end of the second week, and only 1 ulcer reached stage 2 by 3 weeks. The mean time for ulcers in the treatment group to reach stage 2 was 2.25 0.5 weeks; in the comparator group, it took 4.33 1.53 weeks (t 2.621, P .047).	2 weeks after completion of treatment protocol	Hospital	NR	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Recurrence Rate	Pain	Other: Specify	Duration of Followup	Study setting: Hospital Nursing Home/LTC facility Community Other: Specify	Pain	Dermatologic Complications
ter Riet, 1995 ¹⁶¹ ter Riet, 1996 ¹⁶² Netherlands Good	NR	NR	NR	6 weeks after end of treatment	Hospital	Pain - 1/43 vs. 1/45 patients complained of the US therapy being painful at times	NR
Wanner, 2003 ¹⁶³ Switzerland Fair	NR	NR	NR	The endpoint was defined as when the wound volume had decreased by 50%, because all ulcers were then closed with a flap.	Hospital	NR	NR
Wood, 1993 ¹⁶⁴ US Fair	NR	NR	NR	8 weeks	Hospital	NR	NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Adegoke 2001 ¹³⁶ Nigeria Fair	NR	NR	NR	NR	NR	Withdrawal: 1/4 vs. 0/3	NR
Adunsky, 2005 ¹³⁷ Israel Fair	NR	NR	NR	NR	NR	Discontinuation - 5 vs. 5 patients Withdrawal - 11 vs. 4 patients - deterioration of ulcer status - 1 - acute clinical deterioration (massive pneumonia, urosepsis, ischemic colitis, installation of a cardiac pacemaker) - 8 - Excessive granulation - 2 vs. 0 patients - Other - 4	Lifewave Medical Devices Company
Ahmad, 2008 ¹³⁸ India Fair	NR	NR	NR	NR	NR	NR	NR
Baker, 1996 ¹³⁹ US Fair	NR	NR	NR	NR	NR	NR	National Institute on Disability Research and Rehabilitation
Dehlin, 2003 ¹⁴⁰ Denmark Fair	NR	NR	NR	NR	NR	NR	Biolight International AB

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Dehlin, 2007 ¹⁴¹ Denmark Fair	NR	NR	NR	NR	NR	Whole body - 27% vs. 20% Skin - 16% vs. 17% Gastrointestinal - 11% vs. 12% Respiratory - 9% vs. 10% Infection - 6% vs. 12% Genitourinary - 6% vs. 5% Metabolic-nutrition - 3% vs. 2% CNS - 1% vs. 4% Blood - 3% vs. 2% Musculo-skeletal - 2% vs. 1% Other (eyes, falls, tumors) - 7% vs. 9%	NR
Durovic, 2008 ¹⁴² Serbia Fair	NR	NR	NR	Death - 0 vs. 2	Withdrawal - 2/20 (10%) vs. 0	NR	Biolight International AB

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Ford, 2002 ¹⁴³ US Fair	NR	NR	NR	NR	NR	<p>Three patients with 3 wounds completed one 6-week trial of treatment followed by a second 6-week trial of the opposing treatment.</p> <p>. Overall, the mean percent reduction in volume was 51.8% with VAC and 42.1% with HP (p 0.46; Fig 1). The mean reductions in length, width, and depth respectively were 36.9 cm, 40.0 cm, and 33.6 cm in the VAC group compared with 18.7 cm, 19.0 cm, and 31.0 cm in the HP group (p 0.10, p 0.11, p 0.90 respectively; Fig 2). The mean changes in PMNs, lymphocytes, and capillaries respectively were 37.0/hpf, 6.2/hpf, and 5.1/hpf in the VAC group compared with 22.7/hpf, 45.0/hpf, and</p>	Alpha Omega Alpha Student Research Fellowship, Plastic Surgery Education Foundation Scientific Essay Award and grants by the Plastic Surgery Education Foundation and Kinetic Concepts (San Antonio, TX)
Gentzkow, 1991 ¹⁴⁴ US and Canada Fair	NR	NR	NR	Withdrawal - 9/49 (18%), unrelated to treatment/protocol violations	NR	NR	NR
Griffin, 1991 ¹⁴⁵ US Fair	NR	NR	NR	NR	NR	NR	Foundation for Physical Therapy Inc.

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
Gupta, 2009 ¹⁴⁶ India Fair	NR	NR	NR	NR	NR	AE: 0/12 vs. 0/6 of the patients there was worsening of pressure ulcers (both groups) and there were no complications attributable to pulsed electromagnetic field (PEMF) therapy	NR
Ho, 2010 ¹⁴⁷ US Fair	NR	NR	NR	NR	NR	NR	Department of Veteran Affairs (VA), SCI Service and Rehabilitation Research and Development Center for Excellence for the Medical Consequences of SCI
Houghton, 2010 ¹⁴⁸ Canada Good	NR	NR	NR	most common reaction to EST was red, raised, itchy skin beneath large adhesive electrode, which was replaced by nonadhesive carbon electrode	NR	NR	Ontario Neurotrauma Foundation, Prizm Medical, The Roho Group, Argentum medical and Dermasciences Canada
Iordanou, 2002 ¹⁴⁹ Greece Fair	NR	NR	NR	NR	NR	NR	NR
Kloth, 1988 ¹⁵⁰ US Fair	NR	NR	NR	NR	NR	NR	NR
Lucas 2003 ¹⁵¹ Netherlands Fair	NR	NR	NR	NR	NR	NR	NR
Lucas, 2000a ¹⁵² Netherlands Fair	NR	NR	NR	NR	NR	NR	Stichting Fondsenwervingsacties Volsgezondheid (Funding Health Charities, The Netherlands)
Maeshige, 2010 ¹⁵³ Japan Fair			Increase in wound size: 0/4 vs. 1/3.				NR

Evidence Table 9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	Bleeding	Infection	Other: Specify	Severe Adverse Events	Withdrawal due to Adverse Events	Overall Adverse Events Rate	Funding Source
McDiarmid, 1985 ¹⁵⁴ UK Fair	NR	NR	NR	Death - 2/21(9%) vs. 4/19(21%)	Withdrawal - 3/21(14%) vs. 6/19(32%)	NR	NR
Nussbaum, 1994 ¹⁵⁵ UK Fair	NR	NR	NR	NR	Discontinuation - 4/20 - Hospitalized - 2 vs. 0 vs. 1 - Withdrawal (elected surgery) - 2 vs. 0 vs. 0	NR	
Onigbide, 2010 ¹⁵⁶ South Africa Poor	NR	NR	NR	NR	NR	NR	NR
Salzberg, 1995 ¹⁵⁷ US Fair	NR	NR	NR	NR	NR	NR	Eastern Paralyzed Veterans Association (Jackson Heights, NY)
Schubert, 2001 ¹⁵⁸ Sweden Fair	NR	NR	NR	NR	NR	NR	Karolinska Institutet, Gun and Bertil Stohne's foundation, Biolight International
Schwieen, 2005 ¹⁵⁹ US Poor	NR	NR	NR	NR	NR	NR	Kinetic Concepts, Inc.
Taly, 2004 ¹⁶⁰ India Good	Ulcer infection - 2/35 (6%), treatment group unspecified	NR	NR	Withdrawal - 1/35 (3%), unrelated to treatment	Death - 2/35 (6%), treatment group unspecified	NR	National Institute of Mental Health and Neurosciences (Bangalore, India)
ter Riet, 1995 ¹⁶¹ ter Riet, 1996 ¹⁶² Netherlands Good	NR	NR	NR	Death - 3/43 vs. 5/45 Withdrawal - 2/43 vs. 1/45			NR
Wanner, 2003 ¹⁶³ Switzerland Fair	NR	NR	NR	NR	NR	NR	NR
Wood, 1993 ¹⁶⁴ US Fair	NR	NR	NR	NR	NR	NR	NR

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

Evidence Table 10: Adjunctive Quality Rating

Evidence Table 10a: Adjunctive Trial Quality Rating

Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout Rate <20 Percent	Intention -to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Adegoke, 2001 ¹³⁶ Nigeria	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	No	Yes	Fair	NR
Adunsky, 2005 ¹³⁷ Israel	Yes	Yes	Yes	Yes	Yes	a) No b) No c) No d) No	No	Yes	Yes	Fair	Lifewave Medical Devices Company
Ahmad, 2008 ¹³⁸ India	Unclear	No	Yes	Yes	Unclear	a) No b) No c) No d) No	Unclear	Unclear	Yes	Fair	NR
Arashi, 2010 ¹⁶⁵ Japan	No	No	Yes	Yes	No	a) No b) No c) No d) No	No	Yes	Yes	Fair	Risk-Taking Fund for Technology Development from the Japan Science and Technology Agency
Baker, 1996 ¹³⁹ US	Unclear	No	Yes	No	Yes	a) Yes b) Yes c) Yes d) No	Yes	Unclear	Unclear	Fair	National Institute on Disability Research and Rehabilitation
Burke, 1998 ¹⁶⁶ US	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	No	No	Yes	Fair	NR
Comorosan, 1993 ¹⁶⁷ Romania	Unclear	Unclear	Yes	No	Unclear	a) No b) No c) No d) No	Unclear	no	No	Poor	NR
Dehlin, 2003 ¹⁴⁰ Denmark	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	Yes	No	Yes	Fair	Biolight International AB
Dehlin, 2006 ¹⁴¹ Denmark	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) No d) No	Unclear	Yes	Yes	Fair	Biolight International AB

Evidence Table 10a: Adjunctive Trial Quality Rating											
Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout Rate <20 Percent	Intention- to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Durovic, 2008 ¹⁴² Serbia	Yes	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	No	Yes	Fair	NR
Edsberg, 2002 ¹⁶⁸ US	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	No	No	Yes	Fair	NR
Ford, 2002 ¹⁴³ US	Yes	Unclear	No	Yes	Yes	a) Yes b) Yes c) Yes d) No	Unclear	no	Yes	Fair	Alpha Omega Alpha Student Research Fellowship, Plastic Surgery Education Foundation Scientific Essay Award and grants by the Plastic Surgery Education Foundation and Kinetic Concepts (San Antonio, TX)
Gentzkow, 1991 ¹⁴⁴ Canada	Unclear	No	Yes	Yes	Unclear	a) Yes b) Yes c) No d) No	Yes	No	Yes	Fair	NR
Griffin, 1991 ¹⁴⁵ US	Unclear	No	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	No	Yes	Fair	Foundation for Physical Therapy Inc.
Gupta, 2009 ¹⁴⁶ India	Yes	No	Yes	Yes	Unclear	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Fair	None
Houghton, 2010 ¹⁴⁸ US	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Good	Ontario Neurotrauma Foundation, Prizm Medical, The Roho Group, Argentum medical and Dermasciences Canada
Kloth, 1988 ¹⁵⁰ US	Yes	Unclear	Yes	No	Unclear	a) Yes b) Yes c) No d) No	Yes	Yes	No	Fair	NR

Evidence Table 10a: Adjunctive Trial Quality Rating											
Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout Rate <20 Percent	Intention- to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Kloth, 2002 ³⁷ US	Yes	Yes	Yes	Yes	Yes	a) Yes b) No c) No d) No	No	no	Yes	Fair	NR
Larking, 2010 ¹⁶⁹ UK	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) No d) No	No	no	Yes	Fair	NR
Lucas 2003 ¹⁵¹ Netherlands	No	No	Yes	Yes	Yes	a) Yes b) Yes c) Yes d) Yes	Yes	No	Yes	Fair	NR
Lucas, 2000a ¹⁵² Netherlands	No	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Fair	Stichting Fondsenwervingsacties Volsgezondheid (Funding Health Charities, The Netherlands)
Maeshige, 2010 ¹⁵³ Japan	Yes	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Unclear	No	Fair	NR
McDiarmid, 1985 ¹⁵⁴ UK	Yes	Unclear	Unclear	Yes	unclear	a) No b) No c) No d) No	Unclear	no	Yes	Fair	NR
Nussbaum, 1994 ¹⁵⁵ UK	No	No	Yes	No	Yes	a) Yes b) No c) No d) No	No	No	Unclear	Fair	NR
Salzberg, 1995 ¹⁵⁷ US	No	Unclear	Yes	Yes	unclear	a) No b) No c) No d) No	No	no	Yes	Fair	Eastern Paralyzed Veterans Association (Jackson Heights, NY)
Schubert, 2001 ¹⁵⁸ Sweden	Yes	No	Yes	No	No	a) No b) No c) No d) No	Yes	No	Yes	Fair	Karolinska Institutet, Gun and Bertil Stohne's foundation, Biolight International

Evidence Table 10a: Adjunctive Trial Quality Rating											
Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout Rate <20 Percent	Intention- to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Schwieen, 2005 ¹⁵⁹ US	Unclear	Unclear	Unclear	No	unclear	a) No b) No c) No d) No	Unclear	no	Yes	Poor	NR
Taly, 2004 ¹⁶⁰ India	Yes	No	Yes	Yes	Yes	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Good	National Institute of Mental Health and Neurosciences (Bangalore, India)
ter Riet, 1995 ¹⁶¹ ter Riet, 1996 ¹⁶² Netherlands	Yes	Yes	Yes	Yes	unclear	a) No b) No c) No d) No	No	Yes	Yes	Good	NR
Wanner, 2003 ¹⁶³ Switzerland	No	No	No	Yes	No	a) Yes b) No c) No d) No	Yes	No	Yes	Fair	NR
Wood, 1993 ¹⁶⁴ US	No	No	Yes	No	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Yes	Fair	NR

Abbreviations: NR, not reported.

Evidence Table 10b: Adjunctive Observational Studies Quality Rating

Author, Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality	Funding Source
Ho, 2010 ¹⁴⁷ US	Unclear	Yes	Yes	Unclear	Unclear	No	No	No	Yes	Fair	Department of Veteran Affairs (VA), SCI Service and Rehabilitation Research and Development Center for Excellence for the Medical Consequences of SCI, NR
Iordanou, 2002 ¹⁴⁹ Greece	Unclear	Yes	Yes	Unclear	Unclear	Yes	No	No	Unclear	Fair	

Abbreviations: NR, not reported.

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