Appendix D. Evidence Table – Venous Ulcers

Background Care in RCTS of Venous Ulcers

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Andersen 2002 Denmark	**Age** 74 median **% male** 65 **Setting** Outpatient	99	Lab: ABI > 0.8	15 mo	Compare nonadhesive polyurethane foam dressing to hydrocellular dressing	**Tx** Rinse w/saline, compression, dressings changed every 7 days **Controls** Same as Tx			X	H	X		
Armstrong 1997 UK, France	**Age** 68 **% male** 52.2 **Setting** ND	44 (82% venous, 18% mixed/other)	Moderate or heavy exuding leg ulcer determined by frequency of dressing changes	10 mo (1-120)	Hydrofibre vs calcium alginate dressings	**Tx** Dressing changed with leakage, infection, patient in pain, or in place maximum of 7 days, rinse w/saline, compression **Controls** Same as Tx			X	H	X		
Arosio 2001 Italy	**Age** 62±11 **% male** Tx: 73 Ctrl: 67 **Setting** Outpatient clinics	183	Lab: Duplex US, ankle/arm arterial pressure index > 0.90	3 mo	To compare effect of mesoglycan to placebo on healing of ulcers	**Tx** Compression tx & topical wound care (cleansing with saline and local antiseptics); lifestyle/ postural instructions given, interval between dressing changes unknown **Controls** Same as Tx			X	D, C	X		

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Atillasoy 2000 USA	**Age** 18-85 **% male** 57 **Setting** Hospital	104	Venous reflux test, air plethysmography	> 4 wk	Graftskin & compression vs compression alone	**Tx** Three-layered compression system of nonadherent petroleum gauze primary & secondary dressings & pressure bandage, weekly dressing changes **Controls** Same as Tx				V	X		
Barwell 2004 UK	**Age** 73 **% male** 42 **Setting** Outpatient	500	Clinical & Lab: Duplex imaging, ABPI	5 mo	Assess effect of surgery + compression versus compression alone	**Tx** Compression bandaging changed weekly, elastic support stockings **Controls** Same as Tx					X		
Belcaro 2003 Italy	**Age** 55-70 **% male** 50 **Setting** Hospital	20	Ankle brachial index, color duplex scanning, ambulatory venous pressure measurements	Tx: 2.5 mo Ctrl: 2.9 mo	To compare effects of Crystacide on venous ulcers with placebo cream	**Tx** Ulcer cleaned daily with water and neutral soap, broad-spectrum oral antibiotic treatment, elastic compression stockings **Controls** Same as Tx			X		X	X	
Belcaro 2003 Italy	**Age** 50 **% male** 50 **Setting** Outpatient	80	Ankle-brachial index, microcirculatory tests, laser Doppler flow meter	3 mo	Evaluation of treatment with pentoxifylline versus placebo	**Tx** Compression bandages **Controls** Same as Tx					X		

Mean and standard deviation unless otherwise noted.

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Charles 2002 UK	**Age** 72 **% male** 44 **Setting** Outpatient	91	Clinical exam, ABPI ≥ 0.8	3 gp: 95 wk 104 wk 137 wk (1-1560)	Foam dressing vs two different hydrocolloid-based primary dressings	**Tx1** Secondary dressing of padding on bony prominences & short-stretch compression bandaging, dressing changed as needed **Tx2** Same as Tx1 **Tx3** Same as Tx1				H	X		
Coccheri 2002 Italy	**Age** 63 **% male** 46 **Setting** Outpatient	235	Clinical: Peripheral pulse & Lab: US (echo-color-Doppler)	66% up to 1y 34% > 1 y	Evaluate whether sulodexide (glycosamino-glycan) & local therapy favors healing of wounds	**Tx** Mechanical cleansing; detersion & removal of debris; local application of proteolytic enzymes, or autolysis with hydrogel; antisepsis; dressing of wound. Compression bandages of stretch elastic, adhesive, self-adherent, zinc oxide, or 4-layer; interval of dressing changes unknown **Controls** Same as Tx		X	X	C	X		

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Da Costa 1999 Portugal	**Age** 61.8 (30-84) **% male** 55 **Setting** Outpatient	60	Clinical exam	> 3 mo	Granulocyte-macrophage colony stimulating factor vs saline placebo	**Tx** Cleansing with isotonic saline & iodine-povidone solution, surgical debridement. Plain gauze & elastic compression (4 layer method), dressings changed @ 2 days **Controls** Same as Tx	X		X	D	X		
Dale 1999 UK	**Age** 70 **% male** 34 **Setting** Outpatient leg ulcer clinics	200	Ulcers with venous disease confirmed by ultrasound, where other causative factors could be excluded	≥ 2 mo	3 objectives: (1) Efficacy of Pentoxifylline 400 mg 3x daily (2) Comparison of 2 dressings (3) Comparison of 2 types compression	**Tx** Viscose or hydrocolloid dressing, dressings changed weekly; elastic single layer bandage vs. 4 layer bandaging system **Controls** Same as Tx				H	X		

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Danielsen 1998 Denmark	**Age** 72 **% male** 50 **Setting** Outpatient	40	Clinical & Lab: Doppler	20 mo	Compare long-stretch compression bandage to short-stretch	**Tx** Hydrocolloid dressing, in pts w/large ulcers or macertaion, ointment/gel was used, usually w/o antibacterial agents; if local infection, then use mupirocin, iodosorb, or flamazine; systemic antibiotics as needed. Bandage changed 1 to 7 days **Controls** Same as Tx, bandage changed daily or every second day				H	X	X	
DePalma 1999 USA	**Age** 61 **% male** ND **Setting** 3 University Vascular Surgery Clinics & 3 private medical offices	38	Clinical Diagnosis + Duplex exam for venous disease	27±55 in Unna Boot arm 12±14 in Thera-Boot arm	Compare the efficacy and costs of the Unna Boot vs Thera Boot for compression	**Tx** Cleansing and debridement as necessary, impregnated gauze dressing, interval between dressing changes unknown Tx care: Thera Boot **Controls** Same as Tx Control Care: Unna Boot	X		X	U			

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
De Sanctis 2002 Italy/UK	**Age** 64 **% male** 44 **Setting** Ambulatory	172	Unhealed ulcers > 2 mo., excluding patients with diabetes or vascular disease (ankle-brachial index > 1.1), duplex scan to confirm venous disease	> 2 mo	Efficacy of pentoxifylline 400 mg 3x daily	**Tx** 2 layer compression bandaging **Controls** Same as Tx					X		
Dmochowska 1999 Poland	**Age** Tx: 66.45 Ctrl: 63.68 **% male** 24 **Setting** ND	63	Clinical exam, ankle brachial pressure index ≥ 0.8 by Doppler	Tx: 36.91 mo (3 wk-40 y) Ctrl: 39.19 mo (2 mo-3 y)	Polyurethane foam dressing compared to calcium alginate dressing	**Tx** Saline irrigation, dressings changed as needed, long stretch compression bandage **Controls** Same as Tx			X	H	X		
Falanga 2000 USA	**Age** ND **% male** ND **Setting** Ambulatory	240	Clinical diagnosis, Venous Insufficiency- (+) venous reflux text, arterial insufficiency (ABCI < 0.65 excluded)	≥ 1mo	Efficacy of Graftskin with compression vs compression with Unna boot	**Tx** Multilayer compression tx of nonadherent primary dressing overlaid with a gauze pressure bolster, zinc oxide-impregnated paste bandage, Unna boot, and elastic wrap, interval between dressing changes unknown **Controls** Same as Tx				U	X		

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Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Falanga 1999 USA	**Age** 58 **% male** 62 **Setting** Outpatient	129	Clinical diagnosis, Venous Insufficiency- (+) venous reflux text, arterial insufficiency (ABCI < 0.5 excluded)	≥ 2 mo	Efficacy of Pentoxifylline (400 or 800 mg 3x daily)	**Tx** Unna boot with zinc-impregnated dressing & elastic bandage, interval between dressing changes unknown **Controls** Same as Tx				U	X		
Falanga 1999 USA	**Age** 58 **% male** 61 **Setting** Ambulatory	120	NOTE: THIS Study is a subgroup analysis of **Falanga 2000**, see article for information	> 1 y	Efficacy of Graftskin on subgroup of N=120 patients with hard to heal ulcers (> 1 y)	**Tx** see Falanga 2000				U	X		
Falanga 1998 USA	**Age** 60 **% male** 53 **Setting** Ambulatory	275	(1) Clinical Signs and Symptoms, (2) absence of significant arterial insufficiency (ABCI > 0.65) (3) evidence of venous insufficiency by air plethysmography or photoplethysomography	~ 70% > 6 mo	To test the safety, efficacy, and immunological impact of cultured allogeneic human skin equivalent in treatment of venous ulcers	**Tx** Nonadherent primary dressing, gauze bolster, Unna Boot, and self-adherent elastic wrap, systemic antibiotics as needed, weekly dressing changes **Controls** Same as Tx				U	X	X	

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author	Population	Dx method	Trial objective	Background c
Franek 2000 Poland	Age 67 % male 21.5 Setting Hospitalized	65 Clinical exam,Doppler	≥ 2 mo High Voltage Stimulation vs various topical medications	compress bandaging dressing
Tx2 Potassium permanganate bath, wet dressing of rivanol & copper sulphate, compression bandage		X	C,W	

Franek 2002 Poland	Age 66 % male 26 Setting Hospitalized	65	Symptomsofchronic venous insufficiency, including edema, hyperpigmenta-tion, and lipodermato-sclerosis. Doppler	≥ 1 wk, average 40 mo	To evaluate the impact of laser stimulation on venous ulcer healing	Tx Single layer elastic compression dressings – changed every few days, potassium permanganate, wet dressings of 0.1 % copper sulfate, compression, topical antibiotics Controls Same as Tx	X	C,W
Franks 1999 Moffatt 1999 UK	Age 67 % male 45 Setting Outpatient	232	Clinical & Lab: ABPI	7.5 wk	Compare 4-layer bandage Velband to new 4-layer bandage Profore	Tx Nonadherent dressing changed at least weekly Controls Same as Tx		

Author	Population		Dx method		Trial objective	Background care			D
Fumal 2002 Belgium	Age 55 % male ND Setting ND	51	Leg Ulcers.Excluded patients with diabetes, arterial occlusion. "All lesions were developed on moderate grade lipodermatosclerosis." Does not specifically state ulcers are venous.	ND	To comparebeneficial and toxic effects of various antimicrobials on wound healing: Silver Sulfadiazine, Chlorhexidine Digluconate, and Povidine-iodine (PVP-I)	Tx Hydrocolloid dressing changed 3 per week		X	
Controls Hydrocolloid dressing					H				
Gherardini 1998 USA	Age 59 % male 36 Setting French centers	66	ND	ND	Effectoftransdermal calcitonin gene-related peptide and vasoactive intestinal polypeptide and electric stimulation on venous ulcers	Tx Irrigated with saline, non-adherent dressing, compression, interval between dressing changes unknown Controls Same as Tx	X	N	
Gould 1998 UK	Age 44-87 % male ND Setting Outpatient	39	Doppler, ABI>0.8	≥ 2 mo	Long stretch bandage compared to short stretch bandage on venous ulcer healing	Tx Potassium permanganate soak, medicated paste bandage, long stretch bandage, layer of stockinet, weekly dressing changes Controls Same as Tx	X	U	

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Guilhou 1997 France	**Age** 18-85 y **% male** 31 **Setting** Inpatient	107	ABI>0.8 (to exclude arterial disease)	≥ 3 mo	To assess efficacy of flavonoidic fraction tb in addition to conventional therapy in healing of venous ulceration	**Tx** Cleaning, topical antiseptic, compress or dressing compression therapy (~15 mmHg), dressing changed at least @ 2 weeks Venous drainage Skin care of peri-ulcerous area **Controls** Same as Tx			X		X		
Gupta 1998 Canada	**Age** 37-76 y **% male** 56 **Setting** Outpatient	9 (12)	Clinical (stasis changes, normal arterial foot pulses)	Mean (wk) Tx: 105.8 Ctrl: 36	To evaluate the efficacy of low energy photon therapy in the treatment of venous leg ulcers	**Tx** Cleaned w/saline, dry dressing changed weekly, moisturizer to the periphery **Controls** Same as Tx			X	D			

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Author	Population		Dx method	Trial objective		Background care	
Hansson 1998 Sweden	Age 72 % male ND Setting Outpatient clinic	158	Clinical to exclude infection Lab (ABI) to exclude arterial disease	ND	To examinecadexomer iodine paste in non-infected venous ulcers compared w/ hydrocolloid dressing (paraffin gauze was chosen as control)	Tx 1 Cadexomer iodine paste, short stretch bandage, dressings changed 2.7 @ week	
Tx 2 Sterile hydrocolloid dressing of gelatin, pectin, sodium carboxy-methylcellulose, short stretch bandage, dressings changed 2.8 @ week				X			
Controls Paraffin gauze, short stretch bandage, dressings changed 3.3 @ week			V			X	
Koksal 2003 Turkey	Age 50 % male 38 Setting Outpatient	60	Clinical exam	ND	Hydrocolloiddressing & medical compression stocking versus Unna's boot	Tx Saline, debridement, dressing, compression for both tx, dressing changed every 3-7 days Control NA	X
Kumar 2002 UK	Age Tx: 65 Ctrl: 72 % male 31.9 Setting Outpatient	41 (48)	ABPI > 0.7	< 3 mo (N=32) > 3 mo (N=15)	Intermittent pneumatic compression	Tx Weekly 4-layer compression bandaging Control Same as Tx	

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Lagan 2002 N Ireland	**Age** 69.9 **% male** 33 **Setting** Outpatient leg ulcer clinic	15 (16)	ND	11 wk	Low-intensity laser Tx/phototx on wound surface area & pain levels	**Tx** Cleansing, debridement w/dressing changed weekly, and/or compression bandage **Control** Same as Tx	X		X	N	X		
Limova 2003 USA	**Age** 74 **% male** 16 **Setting** Outpatient	19	Clinical exam	≥ 1 mo	2 different calcium alginate dressings	**Tx** Surgical debridement not requiring anesthesia, hydrocolloid dressings changed weekly, compression **Control** NA	X			H	X		
Limova 2002 USA	**Age** 64 **% male** 68 **Setting** Outpatient	31	Clinical exam, photoplethysmography	≥ 1 mo	2 different hydrocolloid dressings	**Tx** Debridement, dressings changed at least weekly or as needed, compression for both tx **Control** NA	X[1]			H	X		
Lindgren 1998 Sweden	**Age** Median 76 (56-89) **% male** 33 **Setting** Outpatient	27	Clinical exam	ND	Cryopreserved cultured allogeneic keratinocytes versus compression	**Tx** Debridement by CO_2 laser, antibiotics as needed, cleansing, compression, hydrocolloid dressings in some cases, off-loading 1st 24 hr **Control** Same as Tx	X		X	H	X	X	X

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Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Ljungberg 1998 ND	**Age** 51-78 **% male** 34 **Setting** Hospital	29 (32)	Clinical exam including grading for venous or mixed venous/arterial leg ulcers	2 mo-10 y	Dextranomer paste versus dextranomer beads	**Tx** Debridement as needed, irrigation, dressing changed daily or as needed **Control** Same as Tx	X		X	C			
Lyon 1998 USA	**Age** 60 **% male** 65 **Setting** Outpatient	164	Air plethysmography, photoplethysmography, or color duplex US	ND "Chronic"	Oral thromboxane A_2 antagonist Ifetroban versus standard tx	**Tx** Cleansing, hydrocolloid dressings w/optional underlay of alginate, dressings changed weekly, Unna's boot wrap, compression **Control** Same as Tx			X	H	X		
Marques da Costa 1997 Portugal	**Age** 64.5 **% male** 75, then 55 **Setting** Vascular surgery consult	40	"Clinical diagnosis"	> 6 wk	Efficacy safety and tolerabily of single dose GM-CSF	**Tx** Dressing containing iodine ointment, dressing changed ever other day **Control** Same as Tx				D			
Meyer 2002 UK	**Age** ND **% male** ND **Setting** Outpatient	112	Lab: APBI	ND	Compare efficacy of Tensopress and Elastocrepe bandages	**Tx** Gentle cleansing w/saline soaked cotton, 3-layered bandaging, Viscopaste dressing changed at each visit – 2 wks maximum **Control** Same as Tx			X	S	X		

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Meyer 2003 UK	**Age** 66 median **% male** 56 **Setting** Outpatient	133	Lab: ABPI	14.8-19.8 mo	Compare 3 to 4 layer bandage regimens	**Tx** Cleansing w/saline soaked cotton, paste & compression bandages, dressing changed initially weekly-later @ 2 weeks **Control** Same as Tx			X	S	X		
Moffatt 2003 UK	**Age** 71 **% male** 23 **Setting** ND	112	Lab: ABPI	6 wk	Compare 2 systems of high compression elastic bandages	**Tx** Washing w/emollient, debridement, hypoallergenic creams, nonadherent dressing changed at least weekly, compression bandages **Control** Same as Tx	X[1]		X	N	X		
Moody 1999 UK	**Age** 73 **% male** 27 **Setting** Outpatient	52	Lab: ABPI	ND	To compare Rosidal K short-stretch compression bandage vs SurePress long-stretch bandage	**Tx** Water cleansing & emollient, irrigate w/saline spray, low-adherent contact dressing & undercoat padding, dressing changes as needed **Control** Same as Tx			X	D, H	X		

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Navratilova 2004 Czech	**Age** 62 **% male** 36 **Setting** Hospital	50	Lab: Doppler US, ankle index, routine lab tests	Tx1: 30.7 mo (3-204) Tx2: 16.7 mo (3-111)	Compare effect of cryo-preserved lyophilized cultured epidermal allografts	**Tx1** Mechanical & enzymatic debridement, silicone dressings including alginates, active charcoal & silver, hydrocolloids, hydrogels, antibiotics as needed, off-loading after graft **Control** Same as Tx		X		H		X	X
Neander 2003 Germany	**Age** 70 **% male** 32 **Setting** Dermatology clinics	227	Clinical	> 2 y	Protect wound edges w/Cavilon No Sting Barrier Film vs water	**Tx** Hydrocolloid dressings, dressings changed every 2 or 3 days **Control** Same as Tx				H			
Nikolovska 2002 Macedonia	**Age** 61 **% male** 54 **Setting** Outpatient/ inpatient	80	Clijnical (hyperpigmentation, lipo-dermatosclerosis, varicosity, edema) & lab (ABI, photoplethysmography)	24/80 < 6 mo 16/80 > 6 mo	Efficacy of pentoxifylline in pts unable to tolerate compression	**Tx** Hydrocolloid dressing, no compression, dressing changed weekly 1st 4 wks **Control** Same as Tx				H			

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Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author	Population			Dx method		Trial objective	Background							
O'Brien 2003 Ireland	Age 71 % male 34 Setting Outpatient		200	Clinical& Lab (ABPI)	9-11 wk	Compare cost-effectiveness of 4-layer bandages vs alternate dressings	Tx Desloughing agents as needed, dressings changes mean 11.4 times over 24 wks, compression bandage							
Control Topical dressings: hydrocolloids, alginates, paraffin & iodine							H,P							
Omar 2004 UK	Age 60 % male 55 Setting Outpatient		18	Clinical (duplexfinding of venous dysfunction) & lab (ABI)	Tx: 118 wk Ctrl: 120 wk	Compare efficacy of Dermagraft w/4-layer compression bandaging	Tx Cleansing, de-sloughing materials or surgical curettage after topical anesthetics	X	X					
Control Same as Tx, also dressing (Dermanet) changed weekly		X		X		X	V		X					
Partsch 2001 Austria, The Netherlands	Age Tx1: 69 Tx2: 71 % male 37.5 Setting Outpatient		112	Doppler or Hx of CVT and appearance of post-thrombotic limb	Median Tx1: 5 wk Tx2: 4 wk (1-1040)	4 layer versus short-stretch compression bandages	Tx1 Minimum weekly follow-up bandaging & cleansing with saline or water & dressing changed weekly Tx2 Same as Tx1	X						
Peschen 1997 Germany	Age 68 % male 42 Setting ndard deviatiOutpatient		24	Clinical& Lab: e noted. Doppler sonography, light reflection rheography, APBI	5 mo	Examine the effect of 30 kHz low dose US in addition to convention tx	Tx Cleansing, hydrocolloid dressings, compression, dressing changed 3@ week Control	X						

						Same as Tx	

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Robinson 1998 USA	**Age** 62 (39-80) **% male** 84.6 **Setting** Inpatient	13 (27 venous ulcers, 9 arterial/venous ulcers)	Complete venous duplex exam	67 mo (1-168)	Daily warm-up active wound tx with overnight collagen-alginate dressing versus continuous collagen-alginate dressing.	**Tx** Cleansing compression with elastic wraps, collagen-alginate dressing applied w/daily changes, leg-elevation, nutrition **Control** Same as Tx, saline dressing changed twice @ day, when no significant exudate, collagen-alginate dressing applied w/daily changes			X	H	X		X
Robson 2001 USA	**Age** 60 **% male** 65 **Setting** Ambulatory	94	Venous ulcers, patients with venous insufficiency, excluded patients with significant arterial insufficiency	> 3 mo, mean 1 y	To compare the effectiveness of topical Repifermin (recombinant human KGF-2-fibroblast growth factor 10) to placebo	**Tx** Nonadherent dressing, self-adherent elastic wrap, compression, dressing changes 2 @ week **Control** Same as Tx				C	X		
Romanelli 1997 Italy	**Age** ND **% male** ND **Setting** ND	32	Lab: Doppler, duplex color flow, ABPI	41 d	Debridement of hydrogel containing propylene glycol, pectin & water vs ointment containing fibronolysin & deoxyribonuclease	**Tx** Treatments covered w/polyurethane transparent film, elastic compression bandage, irrigation w/saline solution, dressing changed daily **Control** Same as Tx		X		H	X		

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Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Roztocil 2003 Czech and Slovak Republics	**Age** 64 **% male** Tx: 23 Ctrl: 23 **Setting** Ambulatory	150	Ankle/arm pressure index > 0.9 by Doppler	≥ 3 mo	Supplement tx of Daflon with compression and standard local tx	**Tx** Compression elastic bandage, chloraminum, saline & silver nitrate solution, antibiotics as needed, interval of dressing changes unknown **Control** Same as Tx				U	X	X	
Schulze 2001 UK, Germany	**Age** 73 (28-97) **% male** 34 **Setting** 38% Hospitalized 16% Outpatient 46% Alternative/community	113	Ankle brachial pressure index ≥ 0.8 by Doppler US or color Duplex sonography	44 (0.5 – 744)	Hydropolymer dressing versus alginate dressing with secondary dressing of film or sterile swab	**Tx1** Dressings changed as needed for maximum 7 d, short-stretch compression bandage **Tx2** Same as Tx1 **Tx3** Same as Tx				H	X		
Scondotto 1999 Italy	**Age** 72 **% male** 34 **Setting** Outpatient	94	Clinical + Lab (echo Doppler)	0-6 mo (N=62) 7-12 (N=22) >12 (N=10)	To examine the efficacy of sulodexide on venous ulcers	**Tx** Cleansing by normal saline, compression w/short extensibility removable bandages, **Control** Same as Tx			X		X		

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Scriven 1998 UK	**Age** 72 y **% male** ND **Setting** Leg ulcer clinic (outpatient)	53	Lab (Colour Duplex scanning) to diagnose vein insufficiency Lab (ABI) to exclude arterial disease	≥ 1 mo	To examine the safety and efficacy of 4-layer and short stretch compression bandages	**Tx** Non-adherent dressing followed by a layer of sterile gauze, four layer bandage which was changed weekly **Control** Same as Tx				D	X		
Stacey 2000 Australia	**Age** 26-92 y **% male** 42 **Setting** Leg ulcer clinic	86	Lab: Doppler, venous refilling time by photoplethysmography, blood tests	0.75-360 mo median: 3 mo	To assess the effect of topical autologous platelet lysate vs placebo	**Tx** Plain unbleached gauze soaked with platelet lysate or placebo, covered by Viscopaste bandage followed by 2 Comprilan bandages Tubi-grip stockinette, dressing changed 2 @ week **Control** Same as Tx				S	X		

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author	Population		Dx method		Trial objective		Backgrou care	
Stacey 1997 Australia	Age 31-92 y % male 41 Setting Leg ulcer clinic	133	Lab (ABI) to exclude arterial disease Lab (venous refilling time on photoplethysmography to diagnose venous disease Clinical exam	0.25-504 mo	To assess the effect of different dressing on venous ulcers	All Tx groups Cleansing, debridement as needed, 2 Elastocrepe bandages and Tubigrip stockinet, dressings changed 2-3 @ week if needed, reduced to weekly Tx 1: Zinc oxide impregnated paste bandage Tx 2: Zinc oxide impregnated stockinet Tx 3: Calcium alginate fiber dressing	X[1]	X
Tausche 2003 Germany, Switzerland	Age 70 % Male 42 Setting Hospital		77	CEAPsystem:clinical signs, etiology, anatomic distribution, pathophysiol function Lab: ankle & great toe pressure	68-74 mo	Compare efficacy of autologous epidermal equivalent tissue engineered from keratinocytes w/split thickness skin allograft	T “standard c and compr C Same as T	
Taylor 1998 UK	Age 75 % male 37 Setting Outpatient	30	Clinical & Lab: ABPI	< 6 mo (N=16) >6 mo (N=14)	Compare 4-layer high compression bandaging (Charing Cross) to conservative tx	Tx Dressings changed 2 @ week if needed		
Controls Cleansing agents, topical treatments, bandages, skin treatments, compression, dressing changed weekly		X		N		X		

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Thomas 1997 UK	**Age** 74 **% male** 29 **Setting** Community setting	100	Clinical exam, Hx, ABPI > 0.8	< 1 mo (N=5) > 1 mo (N=95)	Hydropolymer vs hydrocolloid dressings	**Tx** Compression with Type 3C bandage over layer of orthopedic wadding, cleansing with saline as needed, dressing changed as needed or weekly **Control** Same as Tx			X	H	X		
Ukat 2003 Germany	**Age** 67 **% male** < 40 **Setting** Inpatient/ outpatient	89	Lab: APBI, Doppler	> 6 mo (>50%)	Efficacy of short-stretch bandage vs Profore	**Tx** Cleansing, hydrocellular dressing, bandage, dressing changed weekly or more frequently if needed **Control** Same as Tx			X	H	X		
Vin 2002 France	**Age** 73 **% male** 36 **Setting** Outpatient	73	Lab: APBI, Doppler US, Duplex scan	8.5-9.9 mo	Compare Promogran + compression vs non-adherent dressing + compression	**Tx** Clean w/warm sterile normal saline, petrolatum-impregnated dressing, dressing changed 2 @ week **Control** Same as Tx			X	V			

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Wayman 2001 UK	**Age** 56 **% male** 42 **Setting** Outpatient	12	Clinical	4-5 mo	Compare cost and efficacy of fly larvae for debridement	**Tx** Containment dressing of nylon mesh across adhesive hydrocolloid border, changed @ 72 hr **Controls** Hydrogel dressing changed @ 72 hr		X		H			
Wieman 2003 USA Study 1	**Age** 63 **% male** 69.4 **Setting** Outpatient	71	Etiology to be verified, Doppler or Duplex scan, ABI ≥ 0.8	≥ 4 wk ≤ 3 yr	Efficacy & safety of becaplermin gel, 100 µ/g @ day, vs placebo	**Study 1** **Tx** Sharp debridement, cleansing, nonadherent dressing (Telfa or Adaptic) with or w/o gauze, knee-high compression stocking, antibiotics as needed **Control** Same as Tx	X			D, H	X	X	

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-Surgical					
Wieman 2003 USA Study 2	**Age** 62 **% male** 54 **Setting** Outpatient	64	Etiology to be verified, Doppler or Duplex scan, ABI ≥ 0.8	≥ 4 wk ≤ 3 yr	Efficacy & safety of becaplermin gel, 100 µ/g 2 @ wk, vs placebo	**Study 2** **Tx** Sharp debridement, cleansing, nonadherent dressing with or w/o gauze, multilayer bandage, multiplayer compression system, or dry boot, antibiotics as needed, interval between dressing changes unknown **Control** Same as Tx	X			D, H, U	X	X	
Wilkinson 1997 UK	**Age** ND **% male** ND **Setting** "Majority…in primary care"	29 (35)	Uncomplicated chronic venous ulcers on lower leg, ABPI > 0.8	ND	Four-layered compression bandage versus Charing Cross compression system	**Tx1** Knitted viscose primary dressing (Tricotex), cleansing solution and emollients, bandages changed weekly **Tx2** Same as Tx1			X	D	X		

Mean and standard deviation unless otherwise noted.

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).

Dressing: C= ointment/cream; D= dry gauze; H= hydrocolloid; N= not clearly specified; P= paraffin gauze; S= saline wet-to-dry; U= Unna boot; V= Vaseline gauze; W= wet dressing