Appendix B. Evidence Table – Diabetic Ulcers

Background Care in RCTS of Diabetic 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					
Abidia 2003 UK	**Age (years)** 71 **% male** 50 **Setting** Outpatient	16 (16)	Clinical for ulcer evaluation Lab (ABI, diagnostic angiography) to diagnose occlusive arterial disease Clinical to diagnose infection	ND	To compare hyperbaric oxygen to control in treatment of diabetic lower-extremity ulcers	**Tx** Off-loading Aggressive debridement Dressing for moist wound environment Antibiotics if infected **Controls** Same as Tx	X[1]			S		X	X
Agrawal 2003 India	**Age (years)** 57 **% male** ND **Setting** Outpatient	32	ADA criteria to diagnose DM Clinical for Wagner classification Clinical to exclude active infection Clinical +Lab to diagnose neuropathy Clinical +Lab to diagnose peripheral vascular disease	> 3 mo	To establish the usefulness of GM-CSF in treatment of chronic DM 2 foot ulcers	**Tx** Frequent dressing Off-loading **Controls** Same as Tx				N			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Alvarez 2003 USA	**Age (years)** 57 Range 38-78 **% male** 50 **Setting** Outpatient	20	Clinical for ulcer evaluation Clinical +Lab (ABI) to exclude ischemia Clinical to exclude infection, osteomyelitis, cellulitis	ND	To compare efficacy of noncontact normothermic wound therapy vs. standard care	**Tx** Aggressive, sharp debridement NNWT (intervenion) bandaged w/ rolled bulky gauze Covered w/ an elastic rib-knit stockinet Therapeutic sandals w/ customized plastizote inserts and crutches or wheel chair **Controls** Aggressive, sharp debridement Rinsed w/ normal saline Moist to moist saline gauze followed by dry gauze sponges, bandaged w/ rolled bulky gauze (changed once daily) Covered w/ an elastic rib-knit stockinet Therapeutic sandals w/ customized plastizote inserts and crutches or wheel chair	X		X	S	X		X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Armstrong 2000 USA	**Age (years)** 50 **% male** 83 **Setting** Hospital followed by outpatient period	97 (97)	WHO criteria to diagnose DM Clinical + Lab (biothesiometer) to assess vibration perception Clinical +Lab ($TcPO_2$) to assess tissue perfusion Clinical for ulcer evaluation and assess edema	ND	To compare difference in wound healing with or without use of a foot-level mechanical compression device	**Tx** Thorough sharp debridement w/scalpel blade Cleanse wound twice daily w/sterile isotonic NaCl solution, blot dry w/disposable gloves Moist gauze dressing (twice daily by patients themselves) Pulsatile pneumatic foot compression system (intervention) Post-hospital, all pts off-loaded in removable cast walker **Controls** Thorough sharp debridement w/scalpel blade Cleanse wound twice daily w/sterile isotonic NaCl solution, blot dry w/disposable gloves Moist gauze dressing (twice daily by the patient) PLACEBO Post-hospital, all pts off-loaded in removable cast walker	X		X	S	X		X
Baker 1997 USA	**Age (years)** 53 **% male** 69 **Setting** Outpatients	80 (114)	Clinical to evaluate ulcers	6-640 d	To evaluate the effects of two stimulation waveforms on healing rates in patients w/ DM and open ulcers	**Tx** Dressing (changed by nurses) **Controls** Same as Tx				N			

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Caravaggi 2003 Italy	**Age (years)** ND **% male** ND **Setting** Hospital	79 (79)	Clinical for Wagner's classification Lab (ABI, $TcPO_2$) to exclude severe ischemia Clinical to exclude infection X-rays to exclude osteomyelitis	4 mo	To assess the efficacy of autologous fibroblasts and keratinocyes vs. non-adherent paraffin gauze	**Tx** Aggressive extensive debridement Cleansing Non-adherent paraffin gauze dressing covered by sterile cotton pads and gauze If infection, appropriate antibiotic treatment Non-removable fiber-glass off-loading cast **Controls** Same as Tx	X[1]		X	P		X	X
Caravaggi 2000 Italy	**Age (years)** 60 **% male** 68 **Setting** Outpatient	50	Clinical for ulcer evaluation Lab (Semmes-Weinstein 5.07 monofilament, biothesiometer) to diagnose loss of pressure sensation and vibration perception Lab (ABI $TcPO_2$), to assess ischemia Clinical +X-rays to exclude osteomyelitis	ND	To evaluate and compare non-removable rigidity-differentiated fiberglass off-bearing casts vs. therapeutic shoes	**Tx** Surgical debridement when necessary Paraffin gauze dressing (changed every 2 days by patients themselves) Non-removable rigidity-differentiated w/ fiberglass bandages off-bearing cast (intervention) **Controls** Surgical debridement when necessary Paraffin gauze dressing (changed every 2 days by patients themselves) Cloth shoe w/ rigid rocker-bottom sole w/ unloading sole	X			P			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Chin 2003 USA	**Age (years)** 62 **% male** 86 **Setting** Outpatient	7 (7)	Clinical for ulcer evaluation Lab (bacterial counts from punch tissue biopsy) to assess potential infection Lab (ABI, $TcPO_2$) to exclude ischemia	4 wk – 2 years	Safety and efficacy of topical doxycycline	**Tx** Moist to dry saline gauze dressings, hydrogel, cover w/ dry gauze pads, secure them w/soft wraps (changed twice daily by patients themselves) Offloading shoes fitted **Controls** Same as Tx				S			X
de Lalla 2001 Italy	**Age (years)** 58 Range (42-85) **% male** 75 **Setting** Hospital Diabetes Center	40	Clinical for ulcer evaluation Clinical + Lab (blood cultures, White Cell Count) to diagnose severe limb-threatening foot infection Lab (ABI) to exclude critical leg ischemia and determine potential vasculopathy Lab (vibration perception) to determine potential neuropathy Clinical + Lab when required (X-rays, scintigraphy) to diagnose osteomyelitis	ND	Determine effectiveness of G-CSF in (i) healing ulcers (ii) eradication of pathogens in patients with severe infected diabetic foot ulcers	**Tx** Careful debridement of soft tissues and bone, surgical debridement when necessary Cleaning with sterile water, disinfection with povidone iodine Occlusive dressings Systemic Antibiotic **Controls** Same as Tx	X		X	N		X	

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Donaghue 1998 USA	**Age (years)** 60 Range 30-81 **% male** 72 **Setting** ND	75 (75)	Clinical for ulcer evaluation Clinical or Lab (non-invasive tests) to determine adequate blood flow Clinical or X-rays to exclude osteomyelitis	ND	Collagen-alginate versus saline-moistened gauze dressings	**Tx** Healing sandals Self-adhesive felted foam dressing (changed by the patient) Collagen-alginate dressing **Controls** Healing sandals Self-adhesive felted foam dressing (changed patients themselves) Saline moistened gauze				H			X
Eginton 2003 USA	**Age (years)** ND **% male** ND **Setting** ND	6 (7)	Clinical for ulcer evaluation Clinical(?) to exclude osteomyelitis, cellulites, significant necrotic tissue in wound Clinical or Lab (toe pressure) to determine adequate perfusion	ND	Vacuum assisted closure dressing vs. moist gauze dressing	**Tx** Sharp debridement Vacuum assisted closure dressing (changed daily) **Controls** Sharp debridement Gauze dressing w/ hydrocolloid wound gel (changed daily)	X			H			

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Gough 1997 UK	**Age (years)** 66 Range 30-80 **% male** 73 **Setting** Hospital	40 (40)	Clinical for ulcer evaluation Lab (Doppler US) to diagnose vein disease Lab (Sonogram and transcutaneous O_2 pressure of the dorsum, ABI arteriography) to diagnose arterial disease Clinical + Lab (cultures) to diagnose infection	Mean (days) Tx: 21 C: 39.5	Effect of G-CSF on foot cellulitis	**Tx** Foam dressing Antibiotics:4 (ceftazidime, amoxicillin, flucloxacillin, metronizadole) or iv vancimycin (penicillin hypersensitivity or MRSA) or according to microbiological cultures **Controls** Same as Tx				H		X	
Hanft 2002 USA	**Age (years)** 56 **% male** 93 **Setting** Ambulatory	28	Clinical for ulcer evaluation (especially to exclude infection, cellulites, gangrene, osteomyelitis and tunnels or sinus tracts that cannot be completely debrided) Clinical and lab (ABI) to exclude inadequate circulation	>6 wk	To assess the safety and effectiveness of dermagraft product in the treatment of plantar diabetic foot ulcers as compared w/ conventional therapy alone	**Tx** Shoe gear w/ custom-molded inserts Orthotic device prescribed Sharp debridement Dressed w/ non adherent interface, saline-moistened gauze, dry gauze and adhesive tape **Controls** Same as Tx	X			S			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Jensen 1998 USA	**Age (years)** ND **% male** ND **Setting** Outpatient	31 (31)	Clinical for ulcer evaluation Clinical to exclude infection, vascular disease	Average (mo) Tx: 8.9 C: 3	To compare 2 moist healing protocols on diabetic foot ulcerations	**Tx** Custom made healing sandals Sharp debridement Cleansing Hydrogel dressing (intervention), Gauze pad (changed daily) Wrapped w/ Klinge bandage and secured by tape **Controls** Custom made healing sandals Sharp debridement Cleansing Sterile saline dressing, gauze pad (changed daily) Wrapped w/ Klinge bandage and secured by tape	X		X	S	X		X
Kalani 2003 Sweden	**Age (years)** 73 **% male** 71 **Setting** Outpatient by Foot care Team	85	Clinical to determine ulcer staging Lab (toe/arm blood pressure index) to diagnose arterial disease Clinical (Hx) to exclude vascular reconstruction or angioplasty	>2 mo	To investigate Dalteparin Tx on chronic foot ulcer outcomes	**Tx** Non-weight bearing protective footwear, off-loading Revision of dead/infected tissues Topical Tx and dressings Antibiotics (as needed) **Controls** Same as Tx	X[1]			N		X	X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Kasten-bauer 2003 Austria	**Age (years)** 59 **% male** 76 **Setting** Hospitalized	37	Clinical for Wagner's classification Clinical to diagnose cellulitis Lab (10g-monofilament test) to diagnose neuropathy Clinical +Lab (Doppler U/S) + angiography as needed to diagnose arterial disease	ND	To re-evaluate the use of G-CSF Tx on infected foot ulcers	**Tx** Debridement Antibiotics (i.v and pos after inflammation was visibly improved if needed) Bed-rest **Controls** Same as Tx	X[1]					X	X
Kessler 2003 Italy	**Age (years)** 54 **% male** 61 **Setting** Hospital followed by outpatient period	27	Clinical for Wagner grading Clinical to exclude infection Clinical + Lab (doppler, $TcPO_2$) to exclude severe ischemia Clinical to diagnose neuropathy	≥ 3 mo	To study the effect of systemic Hyperbaric oxygenation on non-ischemic chronic diabetic foot ulcers	**Tx** Orthopedic device to remove mechanical stress and pressure off ulcer (Barouk shoes) Antibiotics (if positive culture) **Controls** Same as Tx						X	X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Koblik 2001 Italy	**Age (years)** 54 **% male** 61 **Setting** Hospital	18	Clinical for ulcer evaluation (especially to exclude gangrene) Lab (laser doppler for skin capillary flow at rest, after transitory artery occlusion) for capillary flow assessment Lab (nerve conduction test) for neuropathy assessment	ND	To assess the efficacy of insulin plus Sulodexide on diabetic ulcers and its influence on foot skin microcirculation and diabetic neuropathy	**Tx** Weight alleviation Local dressings (changed daily) Antibiotics if necessary **Controls** Same as Tx				N		X	X
Lalau 2002 France	**Age (years)** 62 **% male** 58 **Setting** Endocrinology, Rehabilitation, and Plastic Surgery Centers	77	Clinical for ulcer evaluation Clinical to exclude infection Lab ($TcPO_2$) to exclude severe ischemia	Mean (mo) Tx: 4.9 C: 9.1	Calcium alginate dressing versus Vaseline gauze dressing	**Tx** Pressure relieving methods Mechanical debridement as necessary Saline solution Alginate dressing (intervention) and sterile dressing (changed by nurses daily) **Controls** Pressure relieving methods Mechanical debridement as necessary Saline solution Vaseline gauze dressing and sterile dressing (changed by nurses daily)		X	X	V			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Lipkin 2003 USA	**Age (years)** 58 **% male** 80 **Setting** Outpatient	40 (40)	Clinical (The University of Texas Health Services Classification) for wounds Clinical +X-rays +MRI (if indicated) to exclude osteomyelitis Lab (ABI) to exclude ischemia Lab (10 g monofilament pressure test) to diagnose absence of protective sensation	12 mo	Effectiveness and safety of bilayered cellular matrix plus standard care vs. standard care alone	**Tx** Sharp wound debridement as necessary Covering w/moist saline gauze and layer of transparent adhesive dressing, and gauze wrap (changed twice daily) Pressure relief walkers **Controls** Same as Tx	X			S			X
Marston 2003 USA	**Age (years)** 56 Range 27-83 **% male** 74 **Setting** Ambulatory	245	Clinical for ulcer evaluation (especially to exclude gangrene, Charcot's deformity, infection) Lab (ABI Doppler) to ensure adequate circulation	41-67 wk	Efficacy and safety of Dermagraft	**Tx** Sharp debridement Dressing: non-adherent interface, saline-moistened gauze to fill the ulcer, dry gauze, and adhesive fixation sheets Off-weight bearing instructions, pressure reducing footwear **Controls** Same as Tx	X			S			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Martinez de Jesus 1997 Mexico	**Age (years)** 60 **% male** 42 **Setting** Hospital	140	Clinical for Wagner classification Clinical + Lab (electromyographic sensory testing, nerve conduction, autonimic studies) for neuropathic assessment	Median (wk) 8	Efficacy of topical ketanserin	**Tx** Surgical debridement and lavage Ketanserin (intervention) covered by dry gauze dressing (changed daily by hospital staff) Systemic antibiotics (when indicated) Weight avoidance **Controls** Surgical debridement & lavage Normal saline covered by dry gauze dressing (changed daily by hospital staff) Systemic antibiotics (when indicated) Weight avoidance	X			S		X	X
McCallon, 2000 USA	**Age (years)** 55.4 Range 18-75 **% male** ND **Setting** Hospital	10	Clinical for ulcer evaluation Clinical (?) to exclude venous disease, infection	>1 mo	Whether VAC facilitates healing quicker than saline gauze dressings	**Tx** Surgical debridement VAC (intervention) +dressing (changed twice a day by plastic residents) Bed-rest or strict non-weight bearing status **Controls** Surgical debridement Sterile saline moistened dressings (changed twice a day by plastic residents) Bed-rest or strict non-weight bearing status	X			S			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
McCulloch 2002 USA	**Age (years)** 54 **% male** ND **Setting** Hospital	36	Clinical for ulcer evaluation Clinical (?) to exclude arterial insufficiency, infection	ND	To determine if the healing rate of non infected neuropathic foot ulcers could be accelerated by adding controlled warmth	**Tx** Cleansed w/ saline Dressed by the appropriate moisture retentive dressing (calcium alginate combined w/ semipermeable foams, or semipermeable foams alone) (changed daily by the patient) Off-loading device applied **Controls** Same as Tx			X	H			X
Mueller, 2003 USA	**Age (years)** 56 **% male** 77 **Setting** Hospital	64 (64)	Clinical for ulcer evaluation Clinical to exclude ischemia Lab (Semmes Weinstein monofilament) to diagnose loss of protective sensation	ND	To compare Achilles tendon lengthening + total contact cast vs. total contact cast alone on neuropathic plantar ulcers	**Tx** Sharp debridement Dry gauze dressing Total contact cast Padded diabetic pressure-relief walking boot changed to extra-depth shoes w/ custom-molded inserts **Controls** Same as Tx	X			D			X
Pai, 2001 India	**Age (years)** Median 58 **% male** 67 **Setting** Hospitalized	70 (70)	Clinical for Meggitts ulcer classification Clinical to assess vascular status Clinical to examine for neuropathic changes	ND	Efficacy of topical phenytoin on healing of diabetic ulcers (vs. placebo)	**Tx** Surgical debridement Gentle saline cleaning Sterile dry dressing cover (changed daily) **Controls** Same as Tx	X		X	D			

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Pham 1999 USA	**Age (years)** Median 57 IQR 52-62 **% male** 85 **Setting** Deaconess-Joslin Foot Center	33 (33)	Clinical for ulcer evaluation Clinical +radiographic to exclude Charcot's disease Lab to diagnose DM status Lab (Doppler, ABI) to exclude clinically significant ischemia Clinical to exclude infection	>1 wk	Determine efficacy of human skin equivalent in healing diabetic foot ulcers	**Tx** Aggressive debridement Irrigation Layer of saline-moistened contact material (Tepagore) secured by hypoallergenic tape, layer of dry gauze, layer of petrolatum gauze (changed twice daily by the patient) Conforming gauze bandage (Kling) **Controls** Same as Tx	X[1]		X	H	X		
Piaggesi 2001 Italy	**Age (years)** 62 **% male** ND **Setting** Ambulatory	20	Clinical +Lab (ABI) to exclude ischemia Clinical for ulcer evaluation	≥ 3 wk	Assess efficacy of Sodium carboxyl-methyl-cellulose dressings vs. saline-moistened gauze	**Tx** Aggressive surgical debridement Cellulose (hydro-fibres) dressing, several layer of gauze (changed every second, third day by nurses) Post-operative shoes for pressure relief **Controls** Aggressive surgical debridement Saline-moistened dressing, several layer of gauze (changed daily by nurses) Post-operative shoes for pressure relief	X			S			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Piaggesi 1998 Italy	Age (years) 64 % male ND Setting Ambulatory		41	Clinical for Wagner's classification Clinical +Lab (MNSI) to diagnose neuropathy Clinical +Lab (ABI) to exclude ischemia Clinical +X-rays to exclude osteomyelitis		ND	Surgical excisionand closure of diabetic ulcers vs. conventional treatment	Tx Shoes for pressure relief Controls Debridement Irrigation with povidone iodine 50% + saline 50%) Saline-moistened sterile gauze Shoes for pressure relief w/ custom made orthosis + crutches
X[1]			X			S		X
Pollack 1997 USA	Age (years) 55 % male 72 Setting Ambulatory	281	Lab (glycosylated Hb A1c) to diagnose DM status Clinical +Lab (ABI) to exclude ischemia Clinical for ulcer evaluation (especially to exclude the presence of necrotic debris) Clinical +X-rays to exclude osteomyelitis	>2 wk	To determine the effectiveness of a human dermal replacement: Dermagraft	Tx Sharp debridement w/ removal of all necrotic tissue and callus down to a bleeding bed Moist dressings: a non-adherent interface to which a saline-moistened gauze was added to fill in the remaining volume of ulcers before it was covered by an adhesive covering Therapeutic shoes along w/ custom-molded insert and crutches or wheelchair Controls Same as Tx	X	S	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					
Puttirut-vong 2004 Thailand	**Age (years)** 52.6 **% male** ND **Setting** ND	80	Clinical for ulcer evaluation Clinical +Lab to assess infection	ND	To compare results of skin graft healing in diabetic ulcers between the meshed skin graft method and split thickness skin graft method	**Tx** Debridement Wet-to-dry dressing **Controls** Same as Tx	X[1]			S			
Razzak 1997 Saudi Arabia	**Age (years)** 60 Range 47-80 **% male** 79 **Setting** Riyadh Central Hospital	24	Clinical for ulcer evaluation and to exclude potential amputation Clinical +Lab (tissue cultures) +X-rays to exclude osteomyelitis	ND	To determine the effectiveness of adding insulin to the standard treatment regimen in healing diabetic foot ulcers and infections	**Tx** Debridement Povidone solution (0.05 %) Saline-soaked dressing impregnated w/ insulin (changed daily) Antibiotics (keflex 500 mg every 6 hr on admission) **Controls** Povidone solution (0.05 %) Saline-soaked dressing (changed daily) Antibiotics (keflex 500 mg every 6 hr on admission)	X		X	S		X	

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Robson 2002 USA	Age (years) 56 % male 80 Setting 15 centers, (ambulatory)	177	Clinical for ulcer evaluation Clinical to exclude exposure of bone or tendon Lab (ABI or transcutaneous oxygen pressure) to ensure adequate circulation Clinical + X-rays to exclude osteomyelitis	≥8 wk	To Determine the safety and efficacy of TGF-β2 for healing of chronic diabetic foot ulcers	Tx Sharp debridement Coverage with non-adherent dressing (twice weekly by the patient or a caregiver) Weight off-loading of affected foot Controls Same as Tx	X		N	X
Saap 2002 USA	Age (years) Range 18-80 % male ND Setting Ambulatory	143	Clinical for ulcer evaluation Clinical (?) to exclude infection Clinical (?) to exclude Charcot's disease Lab (Doppler, ABI) to assess arterial status	≥ 2 wk	To describe a scoring system to assess whether debridement has been performed adequately (Based on RCT for Bioengineered skin construct as intervention)	Tx Debridement (not for all) Off-loading Controls Debridement (not for all) Moist saline gauze dressing (change twice daily) Off-loading				X[1]
X[1]			S				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					
Sams 2002 USA	**Age (years)** 53.6 Range 25-67 **% male** 76 **Setting** Dermatologic al clinic	17	Clinical for ulcer evaluation Lab: standard monofilament test (for neuropathy) Clinical, Lab (Doppler U/S, ABI) to exclude significant ischemia Clinical to exclude infection, cellulitis, or Charcot foot	>2 wk	To compare Graftskin + standardized wound care to standardized wound care alone to diabetic neuropathic foot ulcers	**Tx** Weight off-loading, custom made tridensity pressure-relieving footwear Aggressive surgical debridement Saline moistened woven gauze dressing (changed twice daily by the patient) **Controls** Same as Tx	X			S			X
Smiel 1999 USA	**Age (years)** Range 23-93 **% male** 70 **Setting** Outpatient clinic (multiple centers)	922	Clinical to exclude infection Clinical for ulcer evaluation	≥ 8 wk	To examine the efficacy and safety of becaplermin (rhu PDGF-BB) on diabetic ulcers	**Tx** Off-loading Sharply debrided to remove all nonviable tissue, fibrin and callus Saline moistened gauze (changed twice daily) **Controls** Same as Tx	X			S			X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Szor 2002 USA	**Age (years)** 60.8 **% male** 71 **Setting** Wound Care Center	56	Clinical for ulcer evaluation	Mean (mo) Tx: 5.7 C: 4.5	To compare static magnetic field therapy in addition to standard care vs. standard care on diabetic ulcers	**Tx** Off-loading Sharp debridement Dressing (changed twice daily by the patient) Antibiotics (when needed) **Controls** Same as Tx	X			N		X	X
Tankova 2002 Bulgaria	**Age (years)** 55.7 **% male** 63 **Setting** Ambulatory and hospitalized	59 (71)	Clinical for ulcer evaluation and classification (Wagner's) Clinical +Lab to diagnose infection Clinical +Lab (10 g monofilament) to diagnose loss of sensation Clinical +Lab (Doppler, ABI) to assess arterial status	Mean (mo) 6.7	To evaluate the effect of zinc hyaluronate (vs. standard methods) on neuropathic and neuroischemic diabetic foot ulcers	**Tx** Debridement Local antiseptics Antibiotics if necessary Immobilization **Controls** Same as Tx	X[1]		X			X	X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Tsang 2003 Hong Kong	**Age (years)** 64 **% Male** 47.5 **Setting** Ambulatory	61 (61)	Clinical for Wagner classification Lab (ABI) to ensure adequate perfusion Lab (10 g monofilament test, pin prick tests) for vibration perception assessment Clinical + Lab (wound swabs) to diagnose infection	Mean (wk) Tx1: 8.24 Tx2: 11.48 C: 12	Whether local application of high concentration of hEGF is effective	**Tx** Debridement, reduction of callus Cream covered w/sterile gauze (saline dressing) (changed by nurses) Antibiotics (if positive cultures) **Contols** Same as Tx	X[1]			S, O		X	
Veves 2002 USA	**Age (years)** 58.5 Range 23-85 **% male** 74 **Setting** Ambulatory	276	Clinical for Wagner classification Clinical to diagnose infection Lab (oscillometry) to assess vascular status	≥ 30 days	Evaluate Promogran vs. normal saline-moistened gauze	**Tx:** When appropriate, only surgical debridement Wound was cleaned and irrigated w/isotonic NaCl Collagen dressing (intervention) applied covered w/gauze (changed at least every 2-3days by the patient or a health care provider) Bandage and tape Off-loading **Controls:** When appropriate, only surgical debridement Wound was cleaned and irrigated w/isotonic NaCl Isotonic NaCl solution-moistened gauze applied, covered w/gauze (changed at least every 2-3days by the patient or a health care provider) Bandage and tape	X		X	S	X		X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Veves 2001 USA	**Age (years)** 57 **% male** 78 **Setting** Ambulatory	208	Clinical for ulcer evaluation Clinical + radiographic to exclude Charcot's disease Clinical +Lab (ABI) to exclude lower extremity ischemia Clinical to exclude infection	11 mo	Efficacy of Graftskin vs. saline-moistened gauze	**Tx** Extensive and aggressive surgical debridement Irrigation w/ saline Layer of Tegapore secured by tape, layer of dry gauze, layer of petrolatum gauze (changed twice daily by the patient) Kling (bandage?) Use of crutches or a wheelchair plus customized tridensity sandals **Controls** Extensive and aggressive surgical debridement Irrigation w/ saline Layer of saline moistened Tegapore secured by hypoallergenic tape, layer of dry gauze, layer of petrolatum gauze (changed twice daily by the patient) Kling bandage Adequate foot off-loading	X		X	H	X		X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Zimny 2003 Germany	**Age (years)** 62.1 **% male** 56 **Setting** Outpatient	54 (54)	Clinical for ulcer evaluation (Wagner classification) Clinical +Lab (Doppler ABI, $TcPO_2$) to exclude ischemia Clinical (Rydell-Seiffer tuning fork) to assess vibration perception Clinical +Lab (cultures) to diagnose infection Clinical +X-rays to exclude osteomyelitis	ND	To evaluate the effects of felted foam on wound healing in diabetic foot ulcers	**Tx:** Thorough debridement Saline-soaked sponge (changed every day) compress fixed w/ Peha-haft Antibiotics when appropriate Felted foam dressing secured by gauze (changed every third day) **Controls:** Repeated debridement when necessary Saline-soaked sponge (changed every day), compress fixed w/ Peha-haft Antibiotics when appropriate Pressure-relief half shoe	X[1]			S		X	X
Zimny 2002 Germany	**Age (years)** 61 **% male** 54 **Setting** Outpatient	61	Clinical for ulcer evaluation Clinical +Lab (Doppler ABI, $TcPO_2$) to exclude ischemia Clinical (Rydell-Seiffer tuning fork) to assess vibration perception Clinical +X-rays to exclude osteomyelitis	ND	To evaluate the effects of felted foam padding vs. conventional pressure relief half-shoe	**Tx:** Repeated debridement using a scalpel when necessary Gauze, saline-soaked sponge (changed every day) compress fixed w/ Peha-haft Antibiotics when appropriate Felted foam dressing (changed every third day) Post-operative shoes **Controls:** Repeated debridement when necessary Gauze, saline-soaked sponge (changed every day), compress fixed w/ Peha-haft Antibiotics when appropriate Post-operative shoes	X			S		X	X

[1] Unclear whether surgical or nonsurgical debridement.

Abbreviations: ABI, ankle/brachial index; mo, month(s); US, ultrasound; wk, week(s); y, year(s).
Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified