Appendix C. Evidence Table – Pressure Ulcers

Background Care in RCTS of Pressure 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					
Adegoke 2001 Nigeria	**Age (years)** 43.8 Range (21-60) **% male** ND **Setting** Hospital	7	Clinical for ulcer staging	Mean (wk) Tx: 12 C: 8	To compare interrupted direct current and routine care with routine care alone	**Tx** Cleaning Sterilized gauze soaked in 0.9% saline **Controls** Same as Tx			X	S			

[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)** 76 Range 21-101 **% male** 42 **Setting** Nursing home residents	26 (26)	Clinical for ulcer evaluation Clinical +Lab (ABI) to exclude ischemia Clinical to exclude infection, osteomyelitis, cellulitis	ND	To compare the ability of an enzymatic formulation ointment (collagenase) vs. a formulation of papain and urea to effectively remove devitalized tissue and promote granulation in pressure ulcers requiring debridement	**Tx 1** Cleansed w/ normal saline Collagenase ointment Non-adherent primary dressing and moist-to-moist saline gauze (changed once daily or according to needs) Support surfaces (dynamic air mattress replacement systems, low air loss beds, air-fluidized beds, alternating pressure mattress overlays, wheel chair cushions) or repositioning every 2 hours for patients confined to bed **Tx 2** Cleansed w/ normal saline Papain-urea ointment Non-adherent primary dressing and moist-to-moist saline gauze (changed once daily or according to needs) Support surfaces (dynamic air mattress replacement systems, low air loss beds, air-fluidized beds, alternating pressure mattress overlays, wheel chair cushions) or repositioning every 2 hours for patients confined to bed		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

Author Year Country	Population	# Patients (# ulcers)	Dx method	Ulcer duration	Trial objective	Background care	Debridement		Cleansing	Dressing	Compression	Antibiotics	Off-loading
							Surgical	Non-surgical					
Bale 1998 UK	**Age (years)** 78 Range (20-99) **% male** 38 **Setting** University Wound Healing Research Unit	50 (50)	Clinical for ulcer evaluation	5 days – 4 y	To compare a new hydrogel product (Sterigel) vs. the established hydrogel on necrotic pressure sores	**Tx** Amorphpus hydrogel, low-adherent dressing, and semipermeable film (changed daily by nurses) **Controls** Same as Tx				H			
Bale 1997 UK	**Age (years)** 74 **% male** 45 **Setting** Hospitals (5 centers)	60 (60)	Clinical for ulcer evaluation	ND	To compare polyurethane foam vs. the established hydrocolloid dressing on necrotic pressure sores	**Tx** Polyurethane foam dressing **Controls** Hydrocolloid dressing				H			
Belmin 2002 France	**Age (years)** 83 (≥ 65) **% male** 30 **Setting** Hospital	110 (110)	Clinical for Yarkony's ulcer classification Clinical to exclude infection	ND	To compare the efficacy of a sequential strategy combining calcium alginate and hydrocolloid dressings and a non-sequential strategy w/ hydrocolloids alone	**Tx** Ulcers cleansed w/sterile saline and dried Dressed w/ calcium alginate then hydrocolloid dressing (changed daily by nurses) **Controls** Ulcers cleansed w/sterile saline and dried Dressed w/ hydrocolloid dressing (changed daily by nurses)			X	H			

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Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

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							Surgical	Non-surgical					
Burgos 2000 Spain	**Age (years)** 80.1 Range 55-96 **% male** 46 **Setting** Hospital	37	Clinical + Lab (cultures) to diagnose infection Clinical for ulcer evaluation (Arnell scale score)	1-7 mo	Efficacy and tolerability and cost of collagenase ointment vs. hydrocolloid occlusive dressing	**Tx** Ulcers cleansed w/saline Collagenase ointment applied If infection, systemic antimicrobial treatment initiated **Controls** Ulcers cleansed w/saline Hydrocolloid dressing If infection, systemic antimicrobial treatment initiated			X	H		X	
Burgos 2000 Spain	**Age (years)** 78.8 Range 55-106 **% male** 35 **Setting** Hospital	37	Clinical (according to American Pressure Advisory Panel) for ulcer staging Clinical +Lab (cultures) to diagnose infection Clinical for ulcer evaluation (Arnell scale score)	1-11 mo	To demonstrate equivalence between collagenase ointment at 24 and 48 h intervals	**Tx** Ulcers cleansed w/saline Collagenase applied, covered w/ paraffin gauze and a conventional dressing (changed every 3 days by nurses) If infection, systemic antimicrobial treatment initiated **Controls** Same as Tx			X	P		X	

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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					
Burke 1998 USA	**Age (years)** ND **% male** ND **Setting** VA Hospital (inpatient)	18 (42)	Clinical for ulcer staging	ND	To evaluate the effects of hydrotherapy on pressure ulcer healing	**Tx** Sharp debridement Irrigation with saline Sterile cotton pads soaked in normal saline (changed twice a day) Air mattresses, turning onto alternating sides, transportation w/ prone cart, Roho cushions, heel cushions, wheel-chairs **Controls** Same as Tx	X		X	S			X
Dehlin, 2003 Denmark, Sweden	**Age (years)** 84 Range 65-105 **% male** 35 **Setting** Geriatric Centers In- and Outpatient	164	Clinical (Shea score) for ulcer staging	2 wk - 6 mo	Efficacy of monochromatic phototherapy	**Tx** Hydrocellular /hydrocolloid bandages and emollient or moisturizing cream around the ulcer Regular turning schedule, pressure reducing mattress, and a pressure reducing cushion for wheelchair bound patients **Controls** Same as Tx				H			

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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					
Ford 2002 USA	**Age (years)** 48 Range 18-80 **% male** ND **Setting** Plastic Surgery Clinic (ambulatory)	28 (41)	Clinical +Lab (biopsy, MRI) to diagnose osteomyelitis Clinical for ulcer evaluation	≥4 wk	To compare VAC (Vacuum assisted closure) dressings vs. the Healthpoint System (3 gel products for different types/stages of wounds)	**Tx** Surgical debridement as necessary VAC (Vacuum assisted closure) dressings (intervention) (changed 3 times per wk) Antibiotics for osteomyelitis (6 wk) Pressure reduction with beds and positioning **Controls** Surgical debridement as necessary Iodosorb or Iodoflex or Panafil dressing (changed twice daily) Antibiotics for osteomyelitis (6 wk) Pressure reduction with beds and positioning	X			O		X	
Graumlich 2003 USA	**Age (years)** Median 83.1 **% male** 37 **Setting** Nursing homes	65 (65)	Clinical (according to National Pressure Advisory Panel) for ulcer staging Primary physician's diagnosis of osteomyelitis, cellulites (to exclude)	Median 4 wk	Collagen vs. hydrocolloid on pressure ulcer (stage II, III) healing	**Tx** Irrigation w/sterile saline Sprinkle sterile collagen particles in a thin continuous layer and cover w/dry gauze (intervention) **Controls** Irrigation w/sterile saline Apply hydrocolloid and rim the perimeter with tape (changed every 4th day by nurses)			X	H			

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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					
Hirshberg 2001 USA	**Age (years)** 43.8 **% male** 57 **Setting** University Wound Care Center	14	Biopsy (to exclude infection or malignancy) Clinical and X-ray and/or bone tissue (to exclude osteomyelitis) Clinical for ulcer evaluation	≥ 4 wk	To determine safety, tolerability and efficacy of TGF-B3 on chronic, pressure ulcers	**Tx** Off-loading using low-air-loss surfaces Adequate debridement of nonviable tissue Gentle cleansing of wound bed w/ saline Loosely packed w/saline moistened gauze **Controls** Same as Tx	X[1]		X	S			X
Joseph 2000 USA	**Age (years)** 53 **% male** 50 **Setting** Hospital, nursing home, at home	ND (28)	Clinical +lab (blood tests, biopsies) to exclude infection Clinical for ulcer evaluation	ND	To test the ability of vacuum-assisted closure to traditional saline-wet-to-moist dressing	**Tx** Pressure relieving surface Sharp debridement Open-cell foam dressing + sub-atmospheric pressure (intervention) (changed every 48h by residents) **Controls** Pressure relieving surface Sharp debridement Saline-wet-to-moist dressing	X			S			X

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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					
Kloth 2002 USA	**Age (years)** 78 **% male** 37 **Setting** VA Medical Center and Long-term care facilities	40 (43)	Clinical for ulcer staging Clinical to exclude infection	Mean (days) Tx:151 C:116	To determine the effect of normothermic non-contact wound therapy vs. standard care	**Tx** Saline irrigation Non-contact dressing (NNWT plus sterile dressing) (intervention) **Controls** Saline irrigation Non-contact moisture-retentive dressing (hydrofibers, alginates, hydrogels, hydrocolloids, saline-moistened gauze, or saline-impregnated gauze)			X	S, H			
Kallianinen 2000 USA	**Age (years)** 47 **% male** 68 **Setting** Outpatient	28 (28)	Clinical for ulcer staging Lab (quantitative bacterial cultures) to exclude infection	> 4 wk	Pre-treatment with rhPDGF-BB vs. placebo followed by salvage surgical repair	**Tx** Off-loading Debridement Antibiotic (if positive culture) **Controls** Same as Tx	X[1]					X	
Ljungberg 1998 USA	**Age (years)** Range 23-73 **% male** 100 **Setting** VA hospital	23 (30)	Clinical for Eltorai grading Lab (quantitative bacterial cultures) to exclude infection Clinical to exclude osteomyelitis	0.5–12 mo	Dextranomer paste vs. saline dressings	**Tx** Saline irrigation Debridement, Dextranomer paste dressing (intervention) (at least twice a day by nurses) **Controls** Saline irrigation Debridement, Saline-soaked dressing, dry sterile dressing (at least twice a day by nurses)	X		X	S			

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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					
Lucas 2000 The Netherlands	**Age (years)** Median 88 **% male** 13 **Setting** Nursing homes	16 (16)	Clinical for ulcer staging Clinical for ulcer evaluation (Norton score)	1-10 wk	Low level laser and consensus Tx vs. consensus Tx alone	**Tx** Patient rotation Cleansing Moist dressing (5 times a wk) **Controls** Same as Tx			X	S			X
Matzen 1999 Denmark	**Age (years)** 83 Range 32-97 **% male** 16 **Setting** outpatient	32 (32)	Clinical for ulcer staging	ND	Compare effects of amorphous hydrocolloid vs. conventional Tx	**Tx** Surgical debridement Amorphous hydrocolloid dressing (intervention), transparent dressing (changed daily) **Controls** Surgical debridement Saline-gauze compress, transparent dressing (changed daily)	X			S			
Motta 1999 USA	**Age (years)** Range 34-76 **% male** 50 **Setting** Home healthcare	10 (10)	Clinical for ulcer staging	Mean (days) 49.8	Evaluate clinical efficacy of new hydrogel dressing vs. hydrocolloid dressing	**Tx** Light debridement Sterile saline irrigation Hydrogel dressing **Controls** Light debridement Sterile saline irrigation Hydrocolloid dressing		X	X	H			

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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					
Price 2000 UK	**Age (years)** 73 **% male** 36 **Setting** Hospitals, Nursing homes, ambulatory	50	Clinical for ulcer staging	ND	To determine the effectiveness of heat therapy in wound healing	**Tx** Semi-occlusive film attached to open-cell pad Pressure relief Use of cushion or mattress (not for all) **Controls** Alginate dressings Pressure relief Use of cushion or mattress (not for all)				H			X
Pullen 2002 Germany	**Age (years)** 79 Range 55-94 **% male** ND **Setting** 17 hospitals	135 (135)	Clinical for ulcer staging (Seiler)	ND	To test the hypothesis that collagenase debrides necrotic pressure ulcers more effectively than fibrinolysin /deoxyribonuclease	**Tx** Arm 1 Collagenase ointment covered w/ gauze Arm 2 fibrinolysin /deoxyribonuclease ointment covered w/ gauze		X		D			

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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					
Rhodes 2001 USA	**Age (years)** 77 **% male** ND **Setting** VA nursing homes	47	Clinical for ulcer staging (AHCPR Pressure Ulcer Guideline Panel) Clinical to exclude infection	ND	Compare effectiveness of topical phenytoin to topical triple antibiotic ointment, and collagen dressings (Duoderm)	**Tx:** Surgical debridement as necessary Cleansing with NaCl 0.9% and hydrogen peroxide, and dried Arm 1: bandaged with gauze soaked in phenytoin solution (0.9% NaCl) and then dry gauze Arm 2: bandaged with Duoderm collagen dressing (changed once a wk) Arm 3: topical triple antibiotic ointment followed by sterile gauze dressing (changed daily)	X		X	H, O			
Robson 2000 USA	**Age (years)** 50 Range 28-70 **% male** ND **Setting** Hospitalized	61	Clinical for ulcer staging	≥ 8 weeks	To determine safety and efficacy of sequential cytokine therapy	**Tx** Pressure relief devices, and fixed turning schedule Sharp debridement Non-adherent dressing and dry gauze **Controls** Same as Tx	X			D			

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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					
Rosenthal 2003 USA	**Age (years)** 70 **% male** ND **Setting** Hospitalized/ Inpatient/ Nursing Homes	207	Clinical for ulcer staging Clinical +X-rays or bone scan to exclude osteomyelitis	ND	Comparing a generic total contact seat vs. a low air loss bed, and a pressure-reducing foam bed overlay	**Tx** Debridement if clinically indicated Dressing Arm 1: generic total contact seat Arm 2: low air loss bed Arm 3: pressure-reducing foam bed overlay	X[1]			N			X
Seaborne 1996 Canada	**Age (years)** 79.9 Range 60-101 **% male** 100 **Setting** Hospital inpatients	20	Lab (swab cultures) to exclude infection Clinical for ulcer evaluation	0.5-52 wk	To evaluate the effectiveness of pulsed electromagnetic energy on pressure sores (electrostatic vs. electromagnetic field)	**Tx** Arm1 Turning regime Dry dressing Arm 2: Same as Arm 1				D			X
Seeley 1999 USA	**Age (years)** 76 **% male** 46 **Setting** Diabetic foot and wound Center	39 (39)	Clinical for ulcer staging (AHCPR Pressure Ulcer Guideline Panel) Clinical to exclude infection	Median (wk) Tx: 9 C: 10	To evaluate the adhesive hydrocellular and hydrocolloid dressings on pressure sores	**Tx** Cleansed w/ dermal wound cleanser Adhesive hydrocellural (intervention) (changes according to clinical investigator's opinion) **Controls** Cleansed w/ dermal wound cleanser Hydrocolloid dressing (changes according to clinical investigator's opinion)			X	H			

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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					
Sopata 2002 Poland	**Age (years)** 58.6 Range 24-88 **% male** 48 **Setting** Palliative Care Department	34 (38)	Clinical for ulcer evaluation Lab (swab cultures +dilution method for quantitative study) to diagnose bacteriological status	Mean (wk) ~2.5	To identify the quantitative and qualitative bacteriological status of pressure ulcers in patients w/ advanced cancer	**Tx** Polyurethane foam dressing (changed according to clinical need) **Controls** Hydrogel dressing (changed according to clinical need)				H			
Thomas 1998 USA	**Age (years)** 76 Range 35-97 **% male** 53 **Setting** Nursing facilities	30 (30)	Clinical for ulcer evaluation and staging Clinical +Lab to exclude infection	ND	To compare acemannan hydrogel dressing vs. standard moist saline gauze dressing on pressure ulcers	**Tx** Cleansed w/ saline and mechanical wiping w/ gauze 1/8 inch layer acemannan hydrogel (changed daily by the patient) **Controls** Cleansed w/ saline and mechanical wiping w/ gauze Sterile non-woven saline soaked gauze (changed daily by the patient)			X	S			

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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					
Thomas 1997 UK	**Age (years)** 79 **% male** 31 **Setting** Community setting	99	Clinical for ulcer evaluation and staging (Stirling)	ND	To compare two adhesive primary wound dressings in the management of pressure sores	**Tx** Cleansed w/ saline solution of sodium chloride 0.9% Hydropolymer dressing (changed at least weekly nurses) Pressure relieving devices **Controls** Cleansed w/ saline solution of sodium chloride 0.9% Hydrocolloid dressing (changed at least weekly nurses) Pressure relieving devices			X	H			X
Thomas 1997 UK	**Age (years)** ND **% male** ND **Setting** Community setting	49 (49)	Clinical for ulcer evaluation and staging (Stirling)	ND	To compare Duoderm Extra Thin dressing vs. Tegaderm dressing in the management of pressure sores	**Tx** Amorphous hydrogel or alginate sheet as primary dressing covered by Duoderm Extra Thin as secondary dressing (changed at least weekly by investigators) **Controls** Amorphous hydrogel or alginate sheet as primary dressing covered by Tegaderm as secondary dressing (changed at least weekly by investigators)				H			

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Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified

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							Surgical	Non-surgical					
Wanner 2003 Switzerland	**Age (years)** 51 Range 25-77 **% male** 75 **Setting** Palliative Care Department	22 (22)	Clinical for ulcer evaluation	ND	To compare vacuum assisted vs. tranditional method on pressure ulcers	**Tx** Surgical debridement Vacuum dressing: polyvinyl foam, transparent polyurethane dressing (change 2-7 days) Prone position, use of sand beds or air mattresses **Controls** Surgical debridement Wet-to-dry /wet-to-wet dressing: gauze soaked w/ Ringer's solution (change 1-3 times/day to keep the wound moist) Prone position, use of sand beds or air mattresses	X			S			
Whitney 2001 USA	**Age (years)** 58 **% male** 62 **Setting** Outpatient	29	Clinical for ulcer staging (National Pressure Ulcer Advisory Panel) Clinical evaluation of ulcer (Pressure Sore Status Tool) Clinical (?) to exclude infection	ND	To test non contact normothermic wound Tx vs. moisture retentive dressing	**Tx** Dressing w/ open cell foam border and a non-contact transparent film cover (changed at least once per day) Dry pressure pad for mattress, air pressure pad for mattress, air overlay or alternating pressure mattress (not for all) **Controls** Moisture retentive dressing (in non-infected wounds) (changed at least once per day) Dry pressure pad for mattress, air pressure pad for mattress, air overlay or alternating pressure mattress (not for all)				S			

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							Surgical	Non-surgical					
Zur Nieden 1999 Germany	**Age (years)** 82 > 64 **% male** 15 **Setting** Nursing homes (inpatient)	13	Clinical for ulcer staging (Shea) Clinical +Lab (ABI) to exclude severe microangiopathy, peripheral vascular disease (Fontaine Stage III and IV)	>4 mo	To test the efficacy of ornithine oxoglutate on decubital ulcers	**Tx** Enzymatic or surgical debridement Physiological saline dressing Change position every 2-3 hours **Controls** Same as Tx	X		X	S			X

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Dressing: O= ointment/cream; D= dry gauze; S= saline we-to-dry; P= paraffin gauze; V= Vaseline gauze; H= hydrocolloid; N= not clearly specified