

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			

¹Unclear 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

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							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

¹Unclear whether surgical or nonsurgical debridement

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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 Amorphus 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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							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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							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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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 4 th day by nurses)			X	H			

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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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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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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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							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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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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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 hydrocellular (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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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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							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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							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. traditional 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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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 oxoglutarate 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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