Appendix H

Evidence Table per FDA Draft Guidance Document

Pressure Ulcers

Evidence Table - RCTS of pressure ulcers (additional data on 20 selected studies)

Author Year Country	Population	# Patients (# ulcers)	Ulcer duration	Provider / Treatment duration / Method of wound size assessment	FDA Draft Guidance Document Recommendations						1° Outcome	2° Outcome
					Partial wound closure	Complete wound closure	3 months post-wound closure assessment	Wound size pre- & post-debridement	Antimicrobial treatment			
									Systemic versus topical	Pre- versus during study		
Bale, 1998 UK	**Age (years)** 78 Range (20-99) **% male** 38 **Setting** University Wound Healing Research Unit	50 (50)	5 days– 4 years	Dressing applied by patient/ 4 weeks or until wound had debrided/ Not specified	N	Y[1]	ND	ND	ND	ND	Successful debridement defined as 80% red granulation tissue	
Bale, 1997 UK	**Age (years)** 74 **% male** 45 **Setting** Hospitals (5 centers)	60 (60)	ND	Not specified/ Up to 30 days/ Digitalized photography	N	Y[1]	ND	ND	ND	ND	Compare the performance of the 2 dressings in ease of application; initial adhesion; absorbency of exudates; wear time and ease of removal	

[1] Unclear whether complete or partial wound closure.
Abbreviations: Y = yes, N = no; ND = no data

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									Systemic versus topical	Pre- versus during study		
Belmin, 2002 France	**Age (years)** 83 (≥ 65) **% male** 30 **Setting** Hospital	110 (110)	ND	Dressing changed by nurses/ 8 weeks / Computerized planimetry	N	Y	ND	ND	ND	ND	Mean surface area reduction of ulcer	
Burgos, 2000 Spain	**Age (years)** 80.1 Range 55-96 **% male** 46 **Setting** Hospital	37	1-7 months	Not specified/ Up to 12 weeks/ Photographic imaging	N	Y	ND	ND	Systemic if there is infection	During study if infection	Reduction of ulcer area	
Burgos, 2000 Spain	**Age (years)** 78.8 Range 55-106 **% male** 35 **Setting** Hospital	92 (29 drop outs)	1-11 months	Not specified/ Up to 8 weeks/ Not specified	N	Y	ND	ND	Systemic if there is an infection	During study if infection	Measurement of the ulcer area	

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Dehlin, 2003 Denmark, Sweden	**Age (years)** 84 Range 65-105 **% male** 35 **Setting** Geriatric Centers In- and Outpatient	164	2 weeks - 6 months	Nurses/ Up to 11 weeks/ Mechanical planimetry	N	Y	ND	ND	ND	ND	Ulcer area measurement	
Graumlich, 2003 USA	**Age (years)** Median 83.1 **% male** 37 **Setting** Nursing homes	65 (65)	Median (weeks) 4	Nurses/ Up to 8 weeks/ Photographic imaging	N	Y	ND	ND	ND	ND	Proportion of pressure ulcers completely healed (epithelial tissue covering 100% of study ulcer) within 8 weeks of randomization	Time to ulcer healing, area healed per day, and linear healing of the wound edge
Kloth, 2002 USA	**Age (years)** 78 **% male** 37 **Setting** VA Medical Center and Long-term care facilities	40 (43)	Mean (days) Tx:151 C:116	Not specified/ Up to 11 weeks/ Digitalized imaging	N	Y	ND	ND	ND	ND	Complete wound healing	

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Matzen, 1999 Denmark	**Age (years)** 83 Range 32-97 **% male** 16 **Setting** outpatient	32 (32)	ND	Not specified/ Up to 12 weeks/ Not specified	N	Y	ND	ND	ND	ND	Wound volume	
Price, 2000 UK	**Age (years)** 73 **% male** 36 **Setting** Hospitals, Nursing homes, ambulatory	50	ND	Not specified/ Up to 6 weeks/ Photographic imaging	N	Y	ND	ND	ND	ND	Wound dimension as a variable in Time of healing to a percentage of original area	Subjective rating of wound pain
Pullen, 2002 Germany	**Age (years)** 79 Range 55-94 **% male** ND **Setting** 17 hospitals	135 (135)	ND	Not specified/ Up to 4 weeks/ Not specified	N	Y	ND	ND	ND	ND	% change in the yellow or black wound surface	Wound environment, margins, depth, pocketing, area and healing

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Rhodes, 2001 USA	**Age (years)** 77 **% male** ND **Setting** VA nursing homes	47	ND	Not specified/ (?up to 90 days)/ Photographic imaging	N	Y	ND	ND	Topical antibiotics is the treatment	See comment in topical antibiotics	Ulcer size, complete healing defined as total closure without evidence of residual exudate or inflammation	Appearance of granulation tissue; reduction in wound exudate
Robson 2000 USA	**Age (years)** 50 Range 28-70 **% male** ND **Setting** Hospitalized	61	≥ 8 weeks	Not specified/ 35 days/ Mechanical planimetry	N	Y	ND	ND	ND	ND	Wound volume decrease over time	% wound closure on day 36; wound cytokine levels and mRNA levels
Rosenthal 2003 USA	**Age (years)** 70 **% male** ND **Setting** Hospitalized/Inpatient/Nursing Homes	207	ND	Not specified/ 4 weeks; trial to compare 3 different support surfaces (seats)/ Not specified	N	Y	ND	ND	ND	ND	Number of subjects who totally healed, time to total healing, and pressure ulcer status score after 4 weeks of treatment	

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Seeley, 1999 USA	**Age (years)** 76 **% male** 46 **Setting** Diabetic foot and wound Cente	39 (39)	Median (weeks) Tx: 9 C: 10	Not specified/ Up to 8 weeks/ Photographic imaging	N	Y	ND	ND	ND	ND	Ease of use and ulcer area	
Sopata, 2002 Poland	**Age (years)** 58.6 Range 24-88 **% male** 48 **Setting** Palliative Care Department	34 (38)	Mean (weeks) ~2.5	Not specified/ Up to 8 weeks/ Photographic imaging	N	Y	ND	ND	ND	ND	Efficacy of wound healing; Treatment times; rate of healing	
Thomas, 1998 USA	**Age (years)** 76 Range 35-97 **% male** 53 **Setting** Nursing facilities	30 (30)	ND	Dressing changed by patient/ 10 weeks observation period / Photographic imaging	N	Y	ND	ND	ND	ND	Completely healed or not healed	

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Thomas, 1997 UK; Ref ID: 1849	**Age (years)** 79 **% male** 31 **Setting** Community setting	100 pts in study sample; 49 with pressure ulcer	ND	Not specified/ ?7 days/ Photographic imaging	N	Y[1]	ND	ND	ND	ND	Dressing's ability to resist wrinkling, ability to prevent maceration	
Thomas, 1997 UK; Ref ID: 1841	**Age (years)** 79 **% male** 31 **Setting** Community setting	99	ND	Not specified/ 6 weeks/ Photographic imaging	N	Y	ND	ND	ND	ND	Treatment duration; efficacy of complete wound healing; average time to complete healing; mean percent change in wound healing (partial)	Dressing leakage; odor production
Whitney, 2001 USA	**Age (years)** 58 **% male** 62 **Setting** Outpatient	29	ND	Both patients and care providers/ Up to 8 weeks/ Photographic imaging	N	Y	ND	ND	ND	ND	Linear rate of healing; effect of noncontact normothermic wound Rx on periwound temperatures	

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