Recommendation 4.0 Evidence Profile

Recommendation question 4: Should the use of prophylactic dressings be recommended or not for the prevention of pressure injuries?

Recommendation 4.0: The expert panel suggests that nurses and health providers utilize multilayer foam silicone dressings as a prophylactic measure for individuals at risk of pressure injuries. These dressings should be applied to specific at-risk body locations, taking into account the potential for shearing, friction, and pressure.

Population: Persons at risk of developing pressure injuries (PI)
Intervention: Prophylactic dressing
Comparison: No prophylactic dressing
Outcomes: Incidence rate of pressure injury [critical] (any stage), Pressure injury precursor signs and symptoms [critical], Quality of life [critical], Pain [critical], Person/caregiver satisfaction [critical]
Setting: All health-care settings, including but not limited to: community care, outpatient care, and acute care.

Bibliography: 4, 16, 58, 59, 1064

COMPARISON: Silicone foam dressing vs no dressing

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Incidence rate of pressure injury, any stage (Assessed with observation. Follow-up: range 0-7 days)											
6[a]	SR for 6 RCT	Serious[b]	Not serious	Not serious	Serious[c]	Undetected	Total Participants n =1247 silicone dressing n=632 PI Events: 18/632 (3%) PI incidence: 29 per 1000 (19 to 48) -	no dressing n=615 PI Events: 72/615, (11.7%) PI Incidence: 117 per 1000 –	RR 0.25 (0.16 to 0.41) For every 100 people who receive intervention, 9 less people will have a pressure injury (ranges from 10 less to 7 less). Silicone dressings may reduce pressure ulcer incidence (any stage) when compared to no dressing.	⨁⨁◯◯ Low	4: Moore et al., 2018
Precursor signs and symptoms (measured as stage I PI incidence) (Assessed with observation. Follow-up: range 0-7 days)											
3[d]	SR for 3 RCTs	Very Serious[e]	Not Serious	Not Serious	Very Serious[f]	Undetected	Total Participants: n = 749 n=377 Stage I PIs: 8/377 (2%)	n=372 Stage I PIs: 35/372 (9%)	RR 0.27 (0.08 to 0.90) For every 100 people who receive intervention, 7 less people will have pressure injury (ranges from 8.3 less to 1 less). .	⨁◯◯◯ Very low	4: Moore et al., 2018

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Pain (follow-up time 8- 14 days)											
2	2 RCTs	Serious[g]	Not serious	Not serious	Serious[h]	Undetected	Participants: n=1299	Participants: n=756	Two patients in the intervention groups reported sacral pain. No patients in control group reported sacral pain Both RCTs demonstrated little to no effect on pain when silicone dressings were used compared to no dressing.	⨁⨁◯◯ Low	58 : Hahnel et al., 2020 16 : Beeckman et al, 2021
Quality of life (follow-up time 14 days)											
1	RCT Unpublished data	Not serious	Not serious	Serious[i]	Not serious	Undetected	Participants n=1087 PI events= 2.8% (sacral) and 1.4 % (heel)	Participant n= 546 PI events = 4.8% (sacral) and 1.9% (heel)	Null effect- quality of life increased as the trial progressed but were similar across groups	⨁⨁⨁◯ Moderate	16 : Beeckman et al, 2021 (HTA data)*
Patient satisfaction (follow-up 5 days)											
1	RCT	Serious[j]	Not serious	Not serious	Serious[k]	Undetected	Participants n = 102	Participants n = 102	The satisfaction rating of the dressing group was higher (78.43 %) than that of the control group (56.86%).	⨁⨁◯◯ Low	1064 : Liao, 2023

Note: Evidence for additional types of dressings reported in the literature are included below for transparency and for future consideration. However, this evidence is extremely limited in terms of certainty and outcomes reported, therefore the expert panel decided making a recommendation about these dressings was too speculative.

COMPARISON: Polyurethane foam dressing vs no dressing

Polyurethane foam dressing vs no dressing

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Incidence rate of pressure injury, any stage (Assessed with observation. Follow-up: mean 14.5 hours)											
1[l]	RCT (from SR)	Serious[m]	Not serious	Not serious	Very Serious[n]	Undetected	Total participants n=74 n=35 PI events : 20/35 (57%)	n=39 PI events: 17/39 (44%)	RR 1.31 (0.83 to 2.07) For every 100 people who receive intervention, 14 more people will have outcome (ranges from 47 more to 7 less). There was no clear difference in pressure ulcer incidence between thin polyurethane and no dressing.	⨁◯◯◯ Very Low	4: Moore et al., 2018
Pain											
1	RCT	Serious[o]	Not serious	Not serious	Very Serious[p]	Undetected	Total n=68 n=34 Patients with pain >3 on NRS: n=14, SD 41.2	n=34 Patients with pain >3 on NRS: n=17, SD 50	There were 3 less patients with pain scores >3 on NRS in the intervention group compared to the control group.	⨁◯◯◯ Very Low	59: Gazineo et al., 2020

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Precursor signs and symptoms (not measured)											
N/A											
Quality of life (not measured)											
N/A											
Patient satisfaction (not measured)											
N/A											

COMPARISON: Kang' huier dressing vs. no dressing

Kang' huier dressing vs. no dressing

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Incidence rate of pressure injury: (Assessed with observation. Follow-up mean: 14.5 hours)											
1[q]	RCT from SR	Very Serious[r]	Not Serious	Not Serious	Very Serious[s]	Undetected	Total participants : n=100 n=49 PI incidence : 2/49 (4%)	n=51 PI incidence : 5/51 (10%).	RR 0.42 (0.08 to 2.05) For every 100 people who receive intervention, 6 less people will have outcome (ranges from 9 less to 11 more). There was no clear difference in pressure ulcer incidence between thin Kang' huier dressing vs. no dressing	⊕◯◯◯ Very low	4: Moore et al., 2018

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Pain (not measured)											
N/A											
Precursor signs and symptoms (not measured)											
N/A											
Patient satisfaction (not measured)											
N/A											

COMPARISON: Adhesive foam dressing vs no dressing

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Incidence rate of pressure injury: (Assessed with observation. Follow-up mean: 14.5 hours)											
1[t]	SR for RCT	Very Serious[u]	Not serious	Not Serious	Very Serious[v]	Undetected	Total participants n= 78 n=39 PI incidence : 28/39 (72%)	 n=39 PI incidence : 17/39 (44%)	RR 1.65 (1.10 to 2.48) For every 100 people who receive intervention, 29 more people will have outcome (ranges from 4 more to 65 more). There was no clear difference in pressure ulcer incidence between adhesive foam compared to no dress	⊕◯◯◯ Very low	4: Moore et al., 2018

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Pain (not measured)											
N/A											
Precursor signs and symptoms (not measured)											
N/A											
Patient satisfaction (not measured)											
N/A											

COMPARISON: Pressure ulcer preventive dressing (PPD)

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Incidence rate of pressure injury, any stage (Assessed with observation. Follow-up: 3 weeks.)											
1[w]	RCT	Very Serious[x]	Not serious	Not Serious	Very Serious[y]	Undetected	Total Participants = 74 n=37 PI Incidence : 2/37 (5%)	n=37 PI Incidence: 11/37 (29%).	RR 0.18 (0.04 to 0.76) For every 100 people who receive intervention, 25 less people will have pressure injury (ranges from 29 less to 7 less) No clear difference in pressure ulcer incidence between PPD dressing and no dressing.	⨁⊖⊖⊖ Very low	4: Moore et al., 2018
Precursor signs and symptoms (not measured)											

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
N/A											
Pain (not measured)											
N/A											
Quality of life (not measured)											
N/A											
Patient satisfaction (not measured)											
N/A											

Individual study details: SILICONE foam dressing vs. no dressing

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: Incidence rate of pressure injury						
(Taken from review Moore et al., 2018) Forni et al., 1987 Kalowes et al., 2016 Qiuli B. et al., 2010 Saab et al., 2015 Santamaria et al., 2015 Walker et al, 2015	SR (6 RCTs)	Australia USA Italy China	In the intervention group a silicone dressing was compared to no dressing in the control group (all stages) Total Participants n =1247 n=632 PI Events: 18/632 (3%) PI incidence: 29 per 1000 (19 to 48) - silicone dressing	No dressing n=615 PI Events: 72/615, (11.7%) PI Incidence: 117 per 1000 – no dressing	RR 0.25 (0.16 to 0.41) Silicone dressings may reduce pressure ulcer incidence (any stage) when compared to no dressing. For every 100 people who receive intervention, 10 less people will have pressure injury (ranges from 10 less to 7 less).	Systematic review: LOW Individual studies: Serious
Outcome: Precursor signs and symptoms (measured as stage I PI incidence) (measure with incidence of stage 1 PI)						
(Taken from review Moore et al. 2018)	SR with 3 RCT	Italy, Australia	In the intervention group a silicone dressing was compared to no dressing in the control group (Stage 1)	No dressing	It is unclear whether silicone dressings reduced the incidence of stage 1	Systematic review:

Forni et al, 2018 Santamaria et al, 2015 Walker et al, 2015			Total n= 749 (3 RCTs) n=377 Silicone dressing 2/177 Silicone dressing 4/161 Silicone dressing 2/39 Total: 8/377 (2%)	n=372 No Dressing 11/182 No Dressing 23/152 No Dressing 1/38 Total: 35/372 (9%)	pressure ulcers (silicone compared to no dressing).	LOW Individual studies: Very Serious
Outcome: Pain (follow-up 8-14 days)						
Hahnel et al., 2020 Beeckman et al., 2021	RCT	Belgium	Experimental group 1 (Allevyn Brand), n=542 Experimental group 2 (Mepilex Brand), n= 545 Dressings applied to heels, sacrum and trochanters. Dressings were maintained on the treatable skin sites and were changed according to the manufacturer's instructions for use. The study nurse inspected the skin beneath the dressing daily, by lifting the dressing and reapplying (not replacing) it. Among the 1633 randomized patients, approximately 61.0% were > 80 years old (mean age 79.6 years, SD 12.2, range 28.3–103.7), and the majority were female (57.6%) and from non-ICU wards (87.5%). Patients who were underweight (BMI < 18.5 kg m2) accounted for 8.3% of the sample (n = 136), 29.7% were overweight (BMI 25.0– 30.0 kg m2) and 16.5% had obesity (BMI > 30 kg m2). The patient characteristics were equally distributed across the three groups.	n= 546 Standard hospital protocols for prevention of PI was used in the standard of care group (SOC) and treatment groups, with addition of the silicone foam dressings as the only variable in the treatment group.	Experimental group 1 (allevyn): 1 Experimental group 2 (mepilex): 0 Control group: 0	Serious
Outcome: Quality of life (follow-up 2 weeks)						
Beeckman et al., 2021	RCT	Belgium	Experimental group 1 (Allevyn brand), n=542 Experimental group 2 (Mepilex brand), n= 545 Dressings applied to heels, sacrum and trochanters. Dressings were maintained on the treatable skin sites and were changed according to the manufacturer's instructions for use. The study nurse inspected the skin beneath the dressing daily, by lifting the dressing and reapplying (not replacing) it. Among the 1633 randomized patients, approximately 61.0% were > 80 years old (mean age 79.6 years, SD 12.2, range 28.3–103.7), the majority were female (57.6%) and from non-ICU wards (87.5%). Patients who were underweight (BMI < 18.5 kg m2) accounted for 8.3% of the sample (n = 136), 29.7% were overweight (BMI 25.0– 30.0 kg m2) and 16.5% had obesity (BMI > 30 kg m2). The patient characteristics were equally distributed across the three groups. Netherlands value set:	n= 546 Standard hospital protocols for prevention of PIs were used in the SOC and treatment groups, with addition of the silicone foam dressings as the only variable in the treatment group. Netherlands value set: Baseline: 0.28 (0.28) Day 3: 0.29 (0.25) Day 14: 0.42 (0.27) Belgian value set: Baseline: 0.29 (0.28) Day 3: 0.29 (0.25) Day 14: 0.42 (0.27)	Intervention Group Mean (SD) Netherlands value set: Baseline: 0.29 (0.28) Day 3: 0.29 (0.25) Day 14: 0.40 (0.28) Belgian value set: Baseline: 0.28 (0.28) Day 3: 0.29 (0.25) Day 14: 0.40 (0.28) Control group Mean (SD) Netherlands value set: Baseline: 0.28 (0.28) Day 3: 0.29 (0.25) Day 14: 0.42 (0.27)	Low

			Baseline: 0.29 (0.28) Day 3: 0.29 (0.25) Day 14: 0.40 (0.28) Belgian value set: Baseline: 0.28 (0.28) Day 3: 0.29 (0.25) Day 14: 0.40 (0.28)		Belgian value set: Baseline: 0.29 (0.28) Day 3: 0.29 (0.25) Day 14: 0.42 (0.27)	
Outcome: Patient satisfaction (follow-up 5 days)						
Liao et al., 2023	RCT	China	n= 102 Patients undergoing ear dressing after the operation in the Affiliated Hospital of Southwest Medical University in Sichuan, China from January 2021 to September 2021 were recruited as research objects. The intervention group received predictive nursing: After the operation, a sterile gauze was used to cover the incision and separate it from the auricle, and then the auricle was surrounded by sterile adhesive foam dressing (Coloplast Seepage absorption adhesive dressing 10 × 10 cm produced by China Medical Products Co., LTD.) (Fig. 1). Finally, pressure dressing was applied, and other measures were the same as the control group.	N=102 The control group received routine nursing: After the operation, two sterile gauzes were used to surround the auricle, and the incision in the operative area was separated from the auricle. Then the medical bandage was used for pressure dressing. Dressing was changed on the next day after the operation in the same way. On the 5th day after operation, the medical bandage and gauze of pressure dressing were removed, and routine nursing measures were given, including condition observation, diet nursing, posture nursing and health education.	The two groups demonstrated significant difference in satisfaction (< 0.05): 56.86% of participants in the control group were satisfied, compared to 78.43% satisfied participants in the intervention group..	Serious

Individual Study Details: POLYURETHANE foam dressing vs. no dressing

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: Incidence rate of pressure injury						
(Taken from review Moore et al., 2018) Otero et al., 2017	RCT from SR	Spain	In the intervention group a thin polyurethane foam was used and compared to no dressing in the control group (all stages) Total Participants n=74 n=35 PI Incidence : 20/35 (57%)	No dressing n=39 PI Incidence : 17/39 (44%).	RR 1.31 (0.83 to 2.07) There was no clear difference in pressure ulcer incidence (thin polyurethane compared to no dressing).	Systematic review: LOW Individual studies: Very Serious
Outcome: Pain						
59: Gazineo et al., 2020	RCT	Italy	Patients in the intervention group received a single 12.9 × 12.9-cm 2 multilayered polyurethane foam dressing shaped for the sacrum area applied within 24 hours of hospital admission.	No dressing	3 less patients in pain in the intervention group compared to the control group.	Serious

			n=34 14 patients with pain >3 (NRS) SD 41.2	n=34 17 with pain >3(NRS) SD 50		

Individual study details: adhesive foam dressing vs. no dressing

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: Incidence rate of pressure injury						
(Taken from review Moore et al., 2018) Otero et al, 2017	RCT	Spain	In the intervention group an adhesive foam dressing was used and compared to no dressing. Total Participants n = 78 n=39 PI Incidence: 28/39 (72%)	No dressing n=39 PI Incidence: 17/39 (44%).	RR 1.65 (1.10 to 2.48) There was no clear difference in pressure injury incidence between adhesive foam and no dressing.	Systematic review: LOW Individual studies: Very Serious

Individual study details: kang huier dressing vs. no dressing

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: Incidence rate of pressure injury						
(Taken from review Moore et al., 2018) Han et al., 2011	RCT	China	Total n=100 (1 RCT) In the intervention group a Kang' huier dressing Total Participants = 100 n=49 PI Incidence : 2/49 (4%)	No dressing n=51 PI Incidence: 5/51 (10%).	RR 0.42 (0.08 to 2.05) There was no clear difference in pressure injury incidence between the Kang' huier group and routine care.	Systematic review: VERY LOW Individual studies: Very Serious

Individual study details: pressure ulcer preventive dressing vs. no dressing

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: Incidence rate of pressure injury						
(Taken from review Moore et al., 2018)	1 RCT of SR	Japan	**Intervention:** In the intervention group a PPD was implemented.	No dressing	RR 0.18 (0.04 to 0.76) No clear difference in pressure injury incidence between PPD and no PPD.	Systematic review: LOW

Nakagami et al., 2007			Total Participants n = 74 n=37 PPD: this consists of a skin adhesive layer (hydrocolloid) containing an intercellular lipid ceramide, a support layer (urethane film) and an outer layer of multi-filament nylon fibers. PI Incidence: 2/37 (5%)	n=37		Individual studies: Very Serious

Acronyms
HCT = Health technology assessment
NRS = Numeric rating scale
PPD = Pressure ulcer preventive dressing
RCT = Randomized controlled trial
RR = Risk Ratio
SR = Systematic Review
vs. = Versus

Explanations
[a] 6 RCTs were included from a systematic review (Moore et al., 2018).
[b] The systematic review was appraised as low risk of bias using the ROBIS tool. Review authors rated studies using the ROB 2.0 tool. Most studies had serious risk of bias due to lack of blinding and unclear randomization and allocation concealment. We downgraded by 1.
[c] The number of events was below the optimal size of 300 (n=90). We downgraded by 1.
[d] 3 RCTs was included from a systematic review (Moore et al., 2018).
[e] The systematic review was appraised as low risk of bias using the ROBIS tool. Review authors rated studies using ROB 2.0 tool. Most studies had very serious risk of bias for multiple criteria, specifically selection and detection bias. We downgraded by 2
[f] The number of events was below the optimal size of 300 (n=43), and there were wide confidence intervals. We downgraded by 2.
[g] Risk of bias was assessed using the ROB 2.0 tool, and there were some concerns regarding effect of assignment to intervention, and measurement of outcome. We downgraded by 1.
[h] The number of participants was above the optimal size of 800 however there is no effect estimate. We downgraded by 1.
[i] Risk of bias was assessed using the ROB 2.0 tool, and there were some concerns regarding randomization, measurement of outcome, and selection of reported results. We downgraded by 1.
[j] The number of participants was below the optimal size of 800 (n= 310), We downgraded by 1.
[k] 1 RCT was included from a systematic review (Moore et al., 2018).
[l] The SR was assessed as low risk of bias following the ROBIS tool. Review authors rated the study using ROB 2.0 tool. The study had serious risk of bias due to risk of performance and attrition bias. We downgraded by 1.
[m] The number of events was below the optimal size of 300 (n=37). We downgraded by 2.
[n] Risk of bias was assessed using the ROB 2.0 tool, and there were some concerns regarding effect of assignment to intervention, and measurement of outcome. We downgraded by 1.
[o] The number of participants was below the optimal size of 800 (n=68). We downgraded by 2
[p] 1 RCT was included from a systematic review (Moore et al., 2018).
[q] The SR was assessed as low risk of bias following the ROBIS tool. Review authors rated study using ROB 2.0 tool. The study had serious risk of bias due to risk of performance and attrition bias. We downgraded by 2.
[r] The number of events was below the optimal size of 300 (n=7). We downgraded by 2.
[s] 1 RCT was included from a systematic review (Moore et al., 2018).
[t] The SR was appraised as low risk of bias using the ROBIS tool. The review authors appraised the individual study using the ROB 2.0 tool. The study had very serious bias due to risk of performance and attrition bias. We

downgraded by 2.
[u] The number of events was below the optimal size of 300 (n=45). We downgraded by 2.
[v] 1 RCT was included from a systematic review (Moore et al., 2018).
[w] The SR was assessed using the ROBIS tool. Review authors rated the study using ROB 2.0 tool. The study had serious risk of bias due performance, detection and other bias. We downgraded by 2.
[x] The number of events was below the optimal size of 300 (n=13). We downgraded by 2.
[y] Only one study reported on a specific health setting. We downgraded by 1 for indirectness.

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