### **SUMMARY OF INCLUDED STUDIES**

Author	Objectives	Design/Length	Sample/Setting	Results
Incontinence-Associat Baatenburg de Jong and Admiraal <sup>6</sup>	To compare the total cost of and prevention of skin breakdown of perianal/buttock skin in incontinent patients receiving a terpolymer pH-balanced barrier film and zinc oxide oil.	- Prospective randomized study - 14 d	40 patients with at least moderate skin damage resulting from incontinence	The terpolymer pH-balanced barrier film resulted in significantly better skin improvement after 14 d of application compared with zinc oxide.
Beeckman et al <sup>7</sup>	To compare 3-in-1 perineal care premoistened washcloth impregnated with a 3% dimethicone formula vs standard care consisting of water and pH-neutral soap	- RCT - 120 d	464 nursing home residents who experienced urinary or fecal incontinence	- The number of IAD significantly decreased in experimental group (day 1: 22.3%, day 120: 8.1%); IAD was less severe in the experimental group. The number of IAD increased in control group (day 1: 22.8%, day 120: 27.1%).
Beguin et al <sup>8</sup>	To test the effect of a skin-adapted incontinence brief on epidermal functions including skin pH and corneometry	- Experimental, nonrandomized design - 21 d	12 volunteer patients suffering from IAD in long-term rehabilitation care.	- Skin acid mantle was preserved with pH 4.6 in the experimental group compared with skin pH of 7.1 in the control group At the end of the observation period, 8 patients had no skin lesions, and remaining 3 patients had only slight improvements.
Brunner et al <sup>9</sup>	To compare a 1-step disposable wipe impregnated with 3% dimethicone (product A) with a 2-step pH-balanced cleanser containing glycerine dimethicone and a barrier film spray containing polymeric solution spray (product B)	Quasi-experimental design     Patients were evaluated for an average of 4–5 d	64 incontinent patients with intact skin from critical care and acute care units	<ul> <li>Among those who developed skin breakdown, the average time to skin breakdown was significantly longer in product B (n = 6; 213.3 h) group vs product A group (n = 6; 91.1 h) (F<sub>1, 11</sub> = 5.27, P = .045).</li> <li>No significant difference between products with overall skin breakdown.</li> </ul>
Clever et al <sup>10</sup>	To determine if the use of perineal care washcloths impregnated with 3% dimethicone on residents with incontinence decreased the incidence of nosocomial PUs in the sacral/buttock area	Quasi-experimental, retrospective study     Chart review	57 residents of a long-term-care facility	<ul> <li>No PUs among 30 residents with IAD following the use of perineal washcloths with 3% dimethicone.</li> <li>There was a significant association between the use of skin protectant and the prevention of skin breakdown (McNemar χ²₁ = 4.786, P = .015).</li> </ul>
Cooper and Gray <sup>11</sup>	To compare soap and water skin care to emollient skin cleanser regimens for incontinence	- RCT	93 incontinent patients were recruited from elderly or dependent service providers	At the end of the trial, only 17 of the soap-and-water group maintained healthy skin, compared with 27 in the emollient cleanser group.
Cooper et al <sup>12</sup>	To compare 2 commercial cleansers for the cleansing of skin following incontinence	- RCT - 14 d	27 patients with fecal or urinary incontinence and intact perineum skin	The skin was visually inspected on days 1, 7, and 14. Both groups maintained skin integrity throughout the study. Skin health improved in both groups as assessed by 3 experts in tissue viability.
				(continues)

# **SUMMARY OF INCLUDED STUDIES, CONTINUED**

Author	Objectives	Design/Length	Sample/Setting	Results
Fader et al <sup>13</sup>	To examine the effect of frequent pad changing compared with less frequent pad-changing regimen on skin health	- Crossover design - 8 wk (4 wk each condition)	81 subjects from a residential setting	<ul> <li>No significant difference was noted in the severity of erythema or skin pH between regimens.</li> <li>Measurements of TEWL were significantly higher in the less frequent pad-changing regime</li> <li>(P = .01; 95% Cl, 2.89–21.39).</li> </ul>
Kerr et al <sup>14</sup>	To test the efficacy of skin barrier cream in the management of uncomplicated IAD in elderly clients.	<ul> <li>Experimental: ultrasound and photographic evaluation</li> </ul>	10 incontinent patients with signs of IAD were selected	Statistical significance in favor of the skin barrier cream to reduce inflammatory signs
Lewis-Byers and Thayer <sup>15</sup>	To compare the effect of soap and water, followed by application of moisturizing lotion to a no-rinse pH-balanced liquid cleanser on skin condition, pain, and caregiver time	<ul> <li>Prospective descriptive study</li> <li>3 wk</li> </ul>	32 residents with incontinence living in a long-term-care facility	<ul> <li>Differences between control group and study group were not statistically significant.</li> </ul>
Palese and Carniel <sup>16</sup>	To assess the effects of a multi- intervention program consisting of absorbent products and structured skin care regimen	- Single-group, pre/post study - 14 d	63 patients with urinary incontinence and IAD from a nursing home	<ul> <li>The use of absorbent pads and structured skin care regimen reduced the relative risk of IAD to 0.24.</li> <li>Advice from continence nurses diminished relative risk of IAD to 0.15.</li> </ul>
Park <sup>17</sup>	To measure the effect of a silicone border foam dressing on the development of PUs and IAD in intensive care patients	<ul> <li>Quasi-experimental study</li> <li>9 d</li> </ul>	102 patients with a Braden Scale score of ≤16	<ul> <li>Incidence of PU development (P &lt;.001) and IADS scores (P &lt;</li> <li>.033) were significantly lower in the experimental group compared with the control group.</li> </ul>
Park and Kim <sup>18</sup>	To measure the effect of a structured skin care regimen consisting of no-rinse pH-balanced skin cleanser, a generic moisturizer, skin protectant (petrolatum, zinc oxide, dimethicone), and an indwelling fecal drainage system when indicated on IAD and PU development	<ul> <li>Quasi-experimental research design (comparison cohort)</li> <li>7 d</li> </ul>	76 patients with fecal incontinence, in the intensive care units	<ul> <li>The structured skin care regimen decreased IAD scores and occurrence of PUs.</li> <li>Higher IADS scores were associated with an increased risk for development of PUs (0R, 1.168; 95% CI, 1.074–1.271).</li> </ul>
Sugama et al <sup>19</sup>	To examine the efficacy of an improved absorbent pad against IAD. The control group (n = 30) used usual absorbent pad, and the experimental group (n = 30) used an absorbent polymer and pulp, located only in the frontal area of the pad	- Cluster RCT - 21 d	60 female inpatients aged ≥65 y, who had IAD	<ul> <li>Experimental group recovered significantly faster from IAD, as indicated by the Kaplan-Meier curve (P = .009, log-rank test).</li> </ul>
Zehrer et al <sup>20</sup>	To examine whether skin barrier could affect the absorbency of incontinent brief. The 4 tested products were a pH-balanced polymer-based barrier film (Product A), a zinc oxide and dimethicone-based moisture barrier (product B), vitamin A and vitamin D ointment (product C), and Vaseline petroleum jelly (product D)	Randomized,     balanced-block     design. Test products     and minidiapers     were applied to     forearms of     16 volunteers     Single visit	16 healthy volunteers aged between 18 and 45 y	<ul> <li>Less product A was transferred to the mini briefs than product B, C, or D (P &lt; .01).</li> <li>Mini briefs absorbed significantly less fluid on areas treated with products C and D than those areas that were treated with product B (P &lt; .01).</li> </ul>
				(continues)

# **SUMMARY OF INCLUDED STUDIES, CONTINUED**

Author	Objectives	Design/Length	Sample/Setting	Results
<b>Peristomal</b> Hosseinpour et al <sup>21</sup>	To compare the protective effects of <i>Acacia senegal</i> to zinc sulfate ointment in peristomal skin of neonates	Prospective controlled clinical study     4 wk	60 neonates	Acacia senegal barrier resulted in less severe inflammation ( $P = .05$ ).
Milne et al <sup>22</sup>	To determine the efficacy of topically applied cyanoacrylate to manage peristomal skin problems	- Case series	11 patients Acute care and outpatient settings	<ul> <li>Discomfort scores reduced from 9.5/10 at baseline to 3.5/10 after first wafer change and to no discomfort after the second wafer change.</li> <li>Increased wear time of wafers between changes.</li> <li>Epidermal resurfacing in outpatient population occurred within 10.2 d.</li> <li>Epidermal resurfacing in acute care population occurred within 7 d.</li> </ul>
Brown-Etris et al <sup>23</sup>	To compare clinical performance of a transparent absorbent acrylic dressing and a hydrocolloid dressing in the management of Stage II and III PU	- RCT - 56 d or until complete healing had occurred	35 patients received the transparent absorbent acrylic dressing, and 37 received the hydrocolloid dressing in wound care clinics, home care, and long-term care	<ul> <li>Periwound skin was visually inspected and photographed at weekly intervals.</li> <li>Transparent absorbent acrylic dressing had better absorptive properties absorption and barrier properties (<i>P</i> = .039) and left less residue on periwound skin (<i>P</i> &lt; .001).</li> <li>There was no statistical difference between the 2 groups considering periwound skin.</li> </ul>
Cameron et al <sup>24</sup>	To compare the efficacy and cost- effectiveness of 2 skin protectants: a pH-balanced polymer-based barrier film and zinc paste compound in the management of maceration and irritation of the periwound area of venous leg ulcers	- RCT - 12 w	35 patients with venous leg ulcers and surrounding skin problems.	- The decrease in wound area was 5.11 ± 8.39 cm² in the polymer-based barrier film group, and 4.59 ± 5.83 cm² in the zinc paste group.  - The pH-balanced polymer-based barrier film was easier to apply and less messy than the zinc paste.
Coutts et al <sup>25</sup>	To compare a pH-balanced polymer-based barrier film with traditionally used zinc oxide ointment or petrolatum-based barrier	- Case series	30 adult patients with chronic wounds of various etiologies	<ul> <li>No statistical significance between the two groups with respect to protecting the periwound skin from moisture damage.</li> </ul>
Cutting <sup>26</sup>	To evaluate the ability of a protease-modulating and moisture-managing dressing to promote a healing environment, including exudate management, protection of periwound skin, and improving condition of wound bed	<ul> <li>Prospective, multicenter, case cohort evaluation</li> <li>4 wk</li> </ul>	53 patients with wounds of mixed etiologies 42 wounds with high levels of exudate	- At the end of 4 wk, 30 (71.5%) had no maceration.
Durante et al <sup>27</sup>	To evaluate the therapeutic effects of a polyhexanide and propyl betaine-based gel in the treatment of chronic wounds	<ul><li>Multicenter observational study</li><li>60 d</li></ul>	124 patients presenting with wounds of mixed etiologies	<ul> <li>17% had undamaged periwound skin at baseline, whereas</li> <li>75.8% had undamaged skin at final visit.</li> </ul>
				(continues)

# **SUMMARY OF INCLUDED STUDIES, CONTINUED**

Author	Objectives	Design/Length	Sample/Setting	Results
Faucher et al <sup>28</sup>	To evaluate the clinical efficacy and absorbent capacity of a high-absorbent dressing with superabsorbent particles	<ul> <li>Multicenter, prospective, observational study</li> <li>7 d</li> </ul>	13 patients	<ul> <li>At day 7, maceration reduced from 46.7% to 6.7%.</li> <li>After 3 d, dressing change frequency reduced from once daily to twice weekly in 80% of patients.</li> </ul>
Hunter et al <sup>29</sup>	To examine the effectiveness of a silicone-based dimethicone skin protectant containing olivamine and methylsulfonylmethane (product B) and a polymer-based moisturizing lotion (product A) on venous ulcer periwound skin	Prospective, descriptive, comparative study     Retrospective patient charts	Retrospective group of 50 patients and a prospective group of 28 patients with venous ulcers	<ul> <li>Both products decreased periwound and ulcer size (P = .01) when compared with retrospective cases.</li> <li>Product B resulted in a reduction in the size of the periwound 3 times faster than product A.</li> </ul>
Jørgensen et al <sup>30</sup>	To compare the effect of a sustained silver-release foam dressing and a hydrocellular foam dressing without added silver in critically colonized venous leg ulcers with delayed healing	- Multicenter, open, block RCT - 4 w	129 patients with chronic venous or mixed venous/ arterial leg ulcer	<ul> <li>There were significantly fewer dressing changes associated with leakage in the sustained silver-release foam group (19%) compared with 49% in the hydrocellular foam group.</li> </ul>
Lázaro-Martínez et al <sup>31</sup>	To demonstrate the effectiveness in the periwound skin maceration reduction with the use of a pH-balanced polymer-based barrier film	- Observational study - 30 d	Included 40 patients with diabetic foot ulcers	- 70% of the ulcers showed healthy edge after 30 d of treatment ( <i>P</i> < .05).
Maume et al <sup>32</sup>	To compare the effects of a new self-adherent soft silicone dressing and a self-adherent hydropolymer dressing on stage II PUs	- RCT - 4 w	38 residents from nursing homes	<ul> <li>No statistically significant difference in granulation tissue, epithelialization, or exudate between the 2 groups</li> <li>Exudate leakage was reported on 13 occasions in the soft silicone dressing group and on 18 occasions in hydropolymer dressing group.</li> </ul>
Münter et al <sup>33</sup>	To compare the effect of the sustained silver-releasing foam dressing with local best practices on delayed healing ulcers using a real-life setting	- RCT - 4 w	619 patients with ulcers of varying etiologies	<ul> <li>Researchers visually assessed the wound for level of exudate and periwound skin condition.</li> <li>At final visit, the silver foam dressing group had lower level of exudation, whereas the local best practices group remained unchanged (P = .0055).</li> <li>Silver foam was rated to have better exudate handling capacity than local best practices (P &lt; .0001).</li> </ul>
Reyzelman et al <sup>34</sup>	To evaluate a nonabsorptive polyolefin foam for the protection of the periwound skin from exudate	- Case series - 2 d to 3 mo	14 subjects with chronic nonhealing wounds of mixed etiologies	Reduction of periwound itching and discomfort was reported.
Schuren et al <sup>35</sup>	To evaluate the effectiveness of a pH-balanced polymer-based barrier film for the protection of the	- Systematic review and meta-analysis	9 studies were included (7 RCTs, 463 participants and 2 case-control studies, 41	- pH-balanced polymer-based barrier film has a significant protective effect when compared
Vanscheidt et al <sup>36</sup>	periwound skin of chronic ulcers To compare the attributes of a foam composite dressing with those of a hydrocellular foam dressing in the management of venous leg ulcers	- RCT - 12 wk	participants) 107 patients with venous leg ulcers	with no treatment or placebo.  A 5-point scale was used to evaluate exudate leakage and periwound residue.  No difference between foam composite and hydrocellular foam with respect to wound exudate levels, skin maceration, erythema, eczema, lipodermatosclerosis, cellulitis, and dermatitis  (continues)
				,

# **SUMMARY OF INCLUDED STUDIES, CONTINUED**

Author	Objectives	Design/Length	Sample/Setting	Results
Woo et al <sup>2</sup>	To evaluate pain during dressing changes comparing a soft silicone foam dressing with an adhesive hydrocellular polyurethane foam dressing	<ul> <li>Randomized crossover study</li> <li>Seen for 5 visits with a maximum of 30 d</li> </ul>	32 patients ambulatory outpatients with below-the-knee leg ulcers	<ul> <li>Wounds treated with silicone foam were associated with a lower proportion of necrotic tissue or slough (P = .0123) and greater proportion of new epithelialization (P = .0110) than those treated with adhesive foam.</li> </ul>
MASD, Other Hoggarth et al <sup>37</sup>	To assess the barrier and skin hydration properties of 6 skin protectants with different formulations. zinc oxide—, water-in-oil—, non-aqueous-, glycerin-, and petrolatum-based formulations	- Controlled 3-phase study - Products and known irritants were applied to forearms of participants over 5-d period	18 healthy volunteers	- Glycerin-treated site was significantly improved ( <i>P</i> < .0001, 95% Cl) with respect to hydration, compared with untreated sites Oil-in-water- and non-aqueous-based product sites were significantly better than untreated sites related to their ability to moisturize the skin ( <i>P</i> < .0001).
Shannon and Chakravarthy <sup>38</sup>	To compare the efficacy of a solvent-free skin barrier and a solvent-containing skin barrier as methods of protecting skin from medical adhesive trauma	- RCT - Barrier products applied to 2 of 4 possible sites on the backs of participants - Procedure repeated for 5 d	12 volunteers made up of healthy white women and men aged 18–55 y	- Solvent-free formulation had lower mean scores of erythema (day 5, $P < .05$ ), TEWL (day 5, $P < .05$ ) and redness (day 4 and 5, $P < .05$ ) vs daily solvent-containing formulations or no treatment.  - There was no statistically significant difference between products in terms of pain on application or discomfort during removal of medical adhesive tape.
Woo <sup>39</sup>	To determine the cost difference between routine care and cyanoacrylate barrier during the treatment of superficial skin damage	Cost analysis     conducted 7 d     before and 7 d after     application of     cyanoacrylate     barrier film	12 patients	Routine care: average cost/wk for MASD was \$46.20 and for stage II PUs \$18.04      Cyanoacrylate barrier: average cost/wk for MASD was \$12.26 and for stage II PUs \$8.18.      Cost savings of using cyanoacrylate was estimated to be 73.5% for MASD and 55% for
Woo and Chakravarthy <sup>40</sup>	To investigate the ability of a cyanoacrylate polymer film to protect human skin against moisture and abrasion and to compare cyanoacrylate material to a traditional barrier film	Experimental study     Barrier products     applied to the arm of     subject and     synthetic urine     applied to the test     sites	12 subjects	<ul> <li>stage II PUs.</li> <li>Cyanoacrylate polymer film was significantly better at protecting the skin from abrasion, resulting in lower TEWL.</li> <li>Mean TEWL was significantly lower at sites treated with cyanoacrylate (q = 4.16, P &lt; .05).</li> </ul>
Young and Chakravarthy <sup>41</sup>	To compare the skin capacitance after application of 4 topical skin creams	- RCT - Products applied to 1 of 5 sites on forearms of participants.	21 subjects	- The mean change in capacitance as measured by corneometer was 13.9 for a barrier with cetyl dimethicone and antioxidants, 10.3 for the aloe vera—based skin conditioner, 8.7 for natural aloe and vitamin E cream, 1.6 for 6% dimethicone- and petrolatum-based barrier, and 0.8 for the control site.

Acronyms: CI, confidence interval; IAD, incontinence-associated dermatitis; IADS, Incontinence-Associated Dermatitis and Its Severity; MASD, moisture-associated skin damage; OR, odds ratio; PU, pressure ulcer; RCT, randomized controlled trial; TEWL, transepidermal water loss.