

**CADTH** 

September 2022 Volume 2 Issue 9

**CADTH Health Technology Review** 

# Therapeutic Support for Pressure Injuries



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ISSN: 2563-6596

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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## **Table of Contents**

Abbreviations	5
Key Messages	6
Context and Policy Issues	6
Research Questions	7
Methods	7
Literature Search Methods	7
Selection Criteria and Methods	7
Exclusion Criteria	8
Critical Appraisal of Individual Studies	8
Summary of Evidence	8
Quantity of Research Available	8
Summary of Study Characteristics	9
Study Design	9
Summary of Critical Appraisal	11
Summary of Findings	13
Limitations	17
Conclusions and Implications for Decision- or Policy-Making	18
References	21
Appendix 1: Selection of Included Studies	23
Appendix 2: Characteristics of Included Publications	24
Appendix 3: Critical Appraisal of Included Publications	29
Appendix 4: Main Study Findings	36
Appendix 5: Overlap Between Included Systematic Reviews	46
Appendix 6: References of Potential Interest	



## **List of Tables**

Fable 1: Selection Criteria	8
Table 2: Characteristics of Included Overview of Reviews, Systematic Reviews, and Network Meta-Analyses	24
Table 3: Characteristics of Included Primary Clinical Studies	26
Fable 4: Strengths and Limitations of Systematic Reviews and Network Meta-Analyses Using AMSTAR 2 and the ISPOR Questionnaire <sup>11</sup>	29
Table 5: Strengths and Limitations of Clinical Studies Using the Downs and Black Checklist <sup>12</sup>	33
Table 6: Summary of Findings for Therapeutic Support Surfaces for Prevention – Pressure Injury Incidence	36
Fable 7: Summary of Findings for Therapeutic Support Surfaces for Prevention – Time to Pressure Injury  Development	40
Table 8: Summary of Findings for Therapeutic Support Surfaces for Prevention – Adverse Events	41
Fable 9: Summary of Findings for Therapeutic Support Surfaces for Prevention – Health-Related  Quality of Life	42
Fable 10: Summary of Findings for Therapeutic Support Surfaces for Treatment – Proportion of Patients With Healed Pressure Injuries	42
Table 11: Summary of Findings for Therapeutic Support Surfaces for Treatment – Status of Pressure Injury	43
Fable 12: Summary of Findings for Therapeutic Support Surfaces for Treatment – Time to Pressure Injury Healing	43
Table 13: Summary of Findings for Therapeutic Support Surfaces for Treatment – Adverse Events	44
Table 14: Summary of Findings for Therapeutic Small Devices for Prevention – Pressure Injury Incidence	45
Fable 15: Summary of Findings for Therapeutic Small Devices for Prevention – Time to Pressure Injury  Development	45
Table 16: Overlap in Relevant Primary Studies Between Included Systematic Reviews	46
List of Figures	
Figure 1: Selection of Included Studies	23



## **Abbreviations**

AMSTAR 2 A MeaSurement Tool to Assess systematic Reviews 2

**EQ-5D-5L** EuroQol 5-Dimensions 5-Levels

**HR** Hazard ratio

ICU Intensive care unit
ITT Intention-to-treat
LTC Long-term care

NMA Network meta-analysis

**PU-QoL-UI** Pressure Ulcer Quality of Life Utility Instrument

PUSH Pressure ulcer scale for healing RCT Randomized controlled trial

RoB Risk of bias
RR Risk ratio

**SR** Systematic review



## **Key Messages**

- Reactive air surfaces, alternating-pressure (active) air surfaces, and reactive gel surfaces
  may be more effective at preventing pressure injuries compared to foam surfaces. The
  clinical effectiveness of therapeutic support surfaces to prevent pressure injuries may be
  influenced by the care setting (e.g., long-term care, acute care, intensive care units) as well
  as follow-up time.
- An overview of reviews with a network meta-analysis did not find any significant differences between different types of support surfaces on time to pressure injury.
   However, limited evidence suggests there may be a difference between foam surfaces, compared to other types of foam surfaces.
- Specialized skin protection cushions may also help to prevent pressure injuries compared to standard foam cushions, though there may be no difference between different types of air cushions.
- It was unclear if there are significant differences between support surfaces for the treatment of pressure injuries. Authors of an overview of reviews stated that reactive air surfaces may be more effective than foam surfaces, but this was not statistically significant.
- Limited evidence was identified regarding adverse events and health-related quality of life, as well as for pediatric patients.
- Limited evidence was identified for support surfaces other than mattresses, beds, and overlays (e.g., cushions), as well as therapeutic small devices for prevention of pressure injuries. No studies were identified for therapeutic small devices for treatment.

## **Context and Policy Issues**

Pressure injuries (also referred to as pressure ulcers, pressure sores, decubitus ulcers, or bed sores) are wounds to the skin and underlying tissue caused by rubbing (friction) or prolonged pressure. People with mobility problems or who lie in bed for long periods of time (e.g., following a surgical procedure) are at risk of developing pressure injuries. Comorbidities that can affect the skin or ability to heal can also increase risk of developing pressure injuries, including diabetes, cardiovascular disease, renal disease, and immunosuppression. Pressure injuries are painful and can lead to the development of serious infections including sepsis; they are also associated with lower health-related quality of life, longer length of stay in hospital, and greater risk of mortality. Systematic reviews have estimated the prevalence of pressure injuries to be 0.56 to 230 per 1,000 in the community or general population, and 128 per 1,000 for hospitalized adults. Canadian studies assessing various settings, including acute care, long-term care (LTC), home, tertiary care, and complex continuing care, have estimated the prevalence to be 128 to 292 per 1,000, and some have reported higher prevalence in LTC and complex continuing care facilities, compared to acute care or home settings.

Interventions that are used to prevent or treat pressure injuries include support surfaces (specific types of beds or bed systems, overlays, and mattresses), as well as therapeutic small devices. Both support surfaces and therapeutic small devices are designed to relieve or redistribute pressure on the body, increasing blood flow to the tissues and relieve distortion of the skin and soft tissue and thus prevent or treat pressure injuries. Here are many types of



support surfaces with different features. For example, support surfaces may be powered (i.e., operate with electricity) or not, or made of different materials (e.g., air cells, foam materials, gel materials), or designed to improve the skin microclimate. Examples of therapeutic small devices include total contact casting, which uses a cast to support the foot and lower leg, redistributing pressure over the sole of the foot and reducing pressure; and cast walkers, which hold the ankle at a 90-degree angle, also reducing pressure on the forefoot. Another type of therapeutic small device is purpose-designed positioning devices, which assist with body positioning and thus redistribute pressure.

Understanding what interventions are effective at preventing and treating pressure injuries will help health care providers understand best practices and improve patient outcomes. Thus, this report aims to summarize the clinical effectiveness of therapeutic support surfaces and therapeutic small devices for patients who have developed or are at risk of developing a pressure injury.

#### **Research Questions**

- 1. What is the clinical effectiveness of using therapeutic support surfaces for patients who have developed a pressure injury or are at risk of developing a pressure injury?
- 2. What is the clinical effectiveness of using therapeutic small devices for patients who have developed a pressure injury or are at risk of developing a pressure injury?

#### **Methods**

#### **Literature Search Methods**

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Cochrane Library, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were pressure injuries and therapeutic support surfaces/devices. Search filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses or network meta-analyses, randomized controlled trials, controlled clinical trials, and non-randomized studies. Comments, newspaper articles, editorials, and letters were excluded. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2017, and July 18, 2022.

#### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.



#### **Exclusion Criteria**

Articles were excluded if they did not meet the selection criteria outlined in <u>Table 1</u>, they were duplicate publications, or were published before 2020. Studies that focused on bundled interventions or intraoperative interventions were excluded. Systematic reviews in which all relevant studies were captured in other more recent or more comprehensive systematic reviews were excluded. Primary studies retrieved by the search were excluded if they were captured in at least 1 included overview and/or systematic review.

#### **Critical Appraisal of Individual Studies**

The included publications were critically appraised by 1 reviewer using the following tools as a guide: A MeaSurement Tool to Assess systematic Reviews 2 (AMSTAR 2)<sup>10</sup> for systematic reviews, the "Questionnaire to assess the relevance and credibility of a network meta-analysis"<sup>11</sup> for network meta-analyses, and the Downs and Black checklist<sup>12</sup> for randomized and non-randomized studies. Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included publication were described narratively.

## **Summary of Evidence**

#### **Quantity of Research Available**

A total of 517 citations were identified in the literature search. Following screening of titles and abstracts, 471 citations were excluded and 46 potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 33 publications were excluded for various reasons, and 14 publications met the inclusion criteria and were included in this report. These comprised 1 overview of reviews, 5 systematic reviews (SRs), 2 randomized controlled trials (RCTs), and 6 non-randomized studies. Appendix 1 presents the PRISMA<sup>13</sup> flow chart of the study selection.

Additional references of potential interest are provided in Appendix 6.

**Table 1: Selection Criteria** 

Criteria	Description
Population	Q1, Q2: Patients (of any age) who have developed a pressure injury or are at risk of developing a pressure injury
Intervention	Q1: Therapeutic support surfaces
	Q2: Therapeutic small devices
Comparator	Q1: Alternative surfaces; no treatment
	Q2: Standard of care; no treatment
Outcomes	Q1, Q2: Clinical effectiveness (e.g., injury prevention, injury relief, length of time to heal, patient quality of life, hospitalizations, hospital length of stay, safety, adverse events)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies



#### **Summary of Study Characteristics**

One overview of reviews with a network meta-analysis (NMA),  $^1$  5 SRs $^{14-18}$  including 2 with meta-analyses,  $^{16,18}$  2 RCTs,  $^{19,20}$  and 6 non-randomized studies $^{21-26}$  were included in this report.

Three SRs<sup>15,16,18</sup> had broader inclusion criteria than this report: 2 SRs<sup>16,18</sup> included a range of interventions to prevent pressure injuries other than therapeutic support surfaces or therapeutic small devices, while 1 SR<sup>15</sup> included studies that reported on alternative outcomes (e.g., measures of pressure relief using pressure mapping). Only the subset of relevant studies will be described in this report. The overview of reviews<sup>1</sup> and 1 SR<sup>14</sup> focused on support surfaces (beds, overlays, and mattresses), 1 SR<sup>15</sup> focused on wheelchair pressure-relieving cushions, and 1 SR<sup>17</sup> focused on pressure-redistributing static chairs. The SR of pressure-redistributing static chairs did not identify any relevant primary studies.<sup>17</sup>

Additional details regarding the characteristics of included publications are provided in Appendix 2. There was some overlap of studies included in the overview of reviews and SRs, and the degree of overlap is summarized in <u>Appendix 5</u>.

#### Study Design

This report includes 1 overview of reviews with an NMA,<sup>1</sup> 5 SRs<sup>14-18</sup> (2 with meta-analyses<sup>16,18</sup>), 2 RCTs,<sup>19,20</sup> and 6 non-randomized studies.<sup>21-26</sup> There was some overlap of studies included in the overview of reviews and SRs, and the degree of overlap is summarized in Appendix 5.

The overview of reviews¹ did not state their search range, but was published in August 2021 and included Cochrane reviews published up to 2021. The reviews were eligible if they only included RCTs. They identified a total of 69 RCTs, and conducted NMAs for 3 outcomes using a Frequentist approach and random-effects model. They also presented the direct pairwise comparisons where available. For the 3 outcomes, the number of RCTs included in each network and number of network contrasts were:

- prevention pressure injury incidence: 40 RCTs, with 78 network contrasts
- prevention time to pressure injury development: 10 RCTs, with 15 network contrasts
- treatment proportion of patients with completely healed pressure injuries: 4 RCTs, with 6 network contrasts.

One SR<sup>17</sup> searched until June 2021, and 2 SRs<sup>16,18</sup> reported their search was updated to the end of 2019. The remaining 2 SRs<sup>14,15</sup> did not report the date ranges covered by their searches or when they conducted their searches. Three SRs<sup>16-18</sup> were restricted to RCTs only, while 2 SRs<sup>14,15</sup> included RCTs and non-randomized studies. Two SRs<sup>16,18</sup> had broader inclusion criteria than this report: 1 SR had 8 relevant RCTs,<sup>16</sup> and the other SR had 29 relevant RCTs.<sup>18</sup>

The 2 RCTs were published in 2022<sup>19</sup> and 2020,<sup>20</sup> and the non-randomized studies were published in 2021<sup>21,22</sup> and 2020.<sup>23-26</sup> Within the non-randomized studies, study designs included cross-sectional,<sup>21</sup> before-after cohort,<sup>22,25</sup> retrospective observational cohort using health administrative data,<sup>23</sup> prospective observational cohort,<sup>24</sup> and prospective observational cohort with a historical control.<sup>26</sup> When reported, follow-up times varied across studies, and ranged from 3 days to 18 months.



#### Country of Origin

The first author of the overview of reviews was from the UK,¹ and the first authors of the SRs were from Australia,¹6,¹8 Indonesia,¹⁴ the UK,¹⁵ and the US.¹⁵ The primary studies included in these reviews came from Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Iran, Italy, Japan, Netherlands, South Korea, Sweden, Turkey, the UK, and the US.¹¹6,¹8

The RCTs were conducted in and enrolled patients from Australia<sup>19</sup> and China,<sup>20</sup> and the non-randomized studies were conducted in and enrolled patients from Belgium,<sup>22</sup> Denmark,<sup>25</sup> Finland,<sup>23</sup> Taiwan,<sup>24</sup> the UK,<sup>21</sup> and the US.<sup>26</sup>

#### **Patient Population**

Most included studies were restricted to adults. One non-randomized study<sup>21</sup> focused on children. Another non-randomized study<sup>24</sup> did not explicitly restrict to adults or report the age range, but reported a mean age of over 60 years.

The overview of reviews  $^1$  and  $^1$  SR $^{17}$  did not restrict by setting, including acute care and other hospital settings, LTC settings, and intensive care units (ICUs). This SR $^{17}$  also focused on patients who remained seated for extended periods of time. Two SRs, $^{14,16}$  1 RCT, $^{19}$  and 2 non-randomized studies $^{23,24}$  focused on patients in the ICU. One SR $^{18}$  and 2 non-randomized studies $^{21,25}$  focused on patients in acute hospital settings. Two non-randomized studies $^{22,26}$  focused on nursing home or LTC residents.

#### Interventions and Comparators

Two SRs<sup>16,18</sup> included a broader range of interventions, assessing multiple types of interventions to prevent pressure injuries; only the results from interventions relevant to this report are presented and discussed.

The overview of reviews, <sup>1</sup> 3 SRs, <sup>14,16,18</sup> and 6 non-randomized studies<sup>21-26</sup> assessed therapeutic support surfaces, specifically beds, mattresses, and/or overlays, comparing to other support surfaces. One SR<sup>15</sup> compared wheelchair pressure-relieving cushions to other types of cushions, and another SR<sup>17</sup> compared any type of pressure-redistributing static chair to any comparator. One RCT<sup>20</sup> compared a special postoperative cushion to standard of care (conventional sponge pads). Two SRs<sup>16,18</sup> and 1 RCT<sup>19</sup> assessed heel protection devices (e.g., heel-offloading boots) compared to standard care (pillow, standard pressure-redistributing surface, or defined as "per admitting ward") or an alternative protection device.

Most included studies assessed the interventions for prevention. The overview of reviews¹ also assessed these interventions for treatment of pressure injuries. One non-randomized study²²² had assessed a therapeutic support surface in 2 groups (1 group for prevention, the other group for treatment), but did not have a comparator group for the prevention group; thus, only the results for the treatment group are summarized in this report.

#### Outcomes

For preventive interventions, relevant reported outcomes from the overview of reviews and SRs included incidence of pressure injury,<sup>1,14-18</sup> time to pressure injury development,<sup>1</sup> health-related quality of life,<sup>1,17</sup> and adverse events.<sup>1,17</sup> Health-related quality of life was measured using the 100-point visual analogue scale, EuroQol 5-Dimensions 5-Levels (EQ-5D-5L) questionnaire, or Pressure Ulcer Quality of Life Utility Instrument (PU-QoL-UI). From the primary clinical studies, similar outcomes were reported, including incidence of pressure



injury,<sup>19,20,23-26</sup> time to pressure injury development,<sup>19,23</sup> pressure damage,<sup>21</sup> severity of pressure injuries that developed,<sup>19</sup> and adverse events.<sup>20</sup>

For treatment interventions, relevant reported outcomes from the overview of reviews included proportion of patients with completely healed pressure injuries, time to completely healed pressure injuries, and adverse events.<sup>1</sup> One non-randomized study assessed changes in pressure injury state based on the Pressure Ulcer Scale for Healing (PUSH) tool.<sup>22</sup>

#### **Summary of Critical Appraisal**

An overview of the critical appraisal of the included publications is summarized in the following text. Additional details regarding the strengths and limitations of included publications are provided in <u>Appendix 3</u>.

#### Overview of Reviews

In the overview of reviews with NMA,1 the protocol was published before the review, the inclusion criteria were clearly defined, the selection of reviews was described and presented in a flow chart, a list of included primary studies was provided, and characteristics of the included studies were described. The authors of the overview of reviews conducted study selection and risk of bias (RoB) assessment of the reviews independently, incorporated RoB assessment into the analysis, and declared their funding and potential conflicts of interest. They also reported the RoB assessments of the RCTs done by the Cochrane reviews' authors. RCTs that had been excluded from the Cochrane reviews were re-screened to assess if any could contribute data to the NMA, and 1 additional RCT was added. As this RCT had not undergone RoB assessment previously, the overview of review's authors assessed its RoB and used the Cochrane risk of bias tool. The authors did not provide a justification for why only Cochrane reviews were eligible. As this overview focused only on Cochrane reviews, other SRs were excluded, so it is possible some relevant primary studies were not included. Data extraction was conducted by 1 review author and checked by a second author, and it is not clear if they checked agreement or calculated a kappa score; thus, the potential for errors in data extraction is unclear.

For the NMAs, a rationale was provided for their choice of model (Frequentist approach with random-effects model), as the authors stated they assumed there is an average effect size for a range of similar populations. Indirect evidence was obtained from comparisons of treatments with a common comparator. Issues related to units of analysis, missing data, and transitivity assumptions were addressed, and if heterogeneity was identified, the certainty of evidence was downgraded. The NMAs included RCTs at unclear or high RoB, with a wide range of follow-up durations and multiple types of care settings. Pre-planned subgroup analyses based on 4 characteristics (RoB, care setting, baseline skin status, and follow-up duration) were done if a network had substantial heterogeneity (using the I2 measure, with P < 0.10 indicating heterogeneity due to the x<sup>2</sup> test's low power) and if there were sufficient studies. For pressure injury incidence, subgroup analyses indicated that care setting and follow-up time may be contributing to heterogeneity. For time to pressure injury, there was substantial heterogeneity, but the prespecified subgroup analysis could not be done due to few studies; therefore, it is unclear what factors were driving the heterogeneity for this outcome. The authors reported no heterogeneity for proportion of patients with completely healed pressure injuries.

Sensitivity analyses were conducted to assess the impact of missing data for 2 outcomes (incidence of pressure injury and proportion of patients with healed pressure injuries), which



did not substantially change the results. This analysis was not done for time to healing, which authors stated was due to the nature of the outcome. Primary studies were extracted from the included reviews; thus, there was no over-representation of primary studies. For all 3 outcomes, network estimates and direct pairwise estimates were provided, and network diagrams were also presented. Funnel plots were also presented and did not indicate publication bias for any outcome. Authors may have overstated some findings, including stating that specific interventions may lead to improved outcomes when the network contrast was not statistically significant.

#### Systematic Reviews

One SR<sup>15</sup> reported some details in supplementary materials that could not be accessed at the time of writing this report, including the PRISMA flow chart and descriptions of included studies; therefore, it was not possible to critically appraise these parts of the review. Another SR<sup>17</sup> did not have any included studies; a critical appraisal of its planned methods is summarized in the following text.

All 5 included SRs<sup>14-18</sup> had clearly defined research questions and inclusion criteria, and searched multiple databases. Four SRs<sup>14,16-18</sup> stated that 2 review authors determined study inclusion (1 SR<sup>14</sup> specified that title-abstract screening was done by 1 author), and that they searched reference lists of the studies that were included after screening. Data extraction was done by 2 authors in 2 SRs,<sup>16,18</sup> and by 1 author in 1 SR.<sup>14</sup> Four SRs<sup>14,16-18</sup> stated they used or planned to use the Cochrane risk of bias assessment tool for RoB assessment, with 1 SR<sup>14</sup> stating they also used the Oxford Centre for Evidence-Based Medicine guidelines to assess quality; 3 SRs<sup>16-18</sup> stated RoB assessment was done by 2 authors. One SR<sup>15</sup> did not provide details about how many authors conducted screening or data extraction, or about how RoB analysis was done. Three SRs that identified relevant studies<sup>14,16,18</sup> did not provide details about the included patients (e.g., mean age, proportion of male or female patients); for 1 SR,<sup>15</sup> it is unclear if these characteristics are reported in detail in their supplementary materials.

Four SRs<sup>15-18</sup> stated their conflicts of interest, and 3 SRs<sup>16-18</sup> stated the funding received for the review. Four SRs<sup>14,16-18</sup> stated their protocol was published in advance. None of the reviews explained their selection of study designs, with 3 SRs<sup>16-18</sup> limited to only RCTs. None of the reviews indicated that they had searched grey literature or contacted experts in the field.

Two SRs<sup>16,18</sup> conducted meta-analyses if there were at least 2 sufficiently similar primary studies. One SR<sup>18</sup> defined this as studies with the same intervention type and were similar with respect to population, intervention, comparator, outcome, and setting; the other SR<sup>16</sup> did not define "sufficiently similar," although both SRs share the same first author and thus may have used the same definition. Both included only RCTs and specified that they used random-effects models. For both SRs,<sup>16,18</sup> all relevant primary studies were at unclear or high RoB, with moderate to substantial heterogeneity; both also could not assess publication bias due to the limited number of studies. The heterogeneity may have been due to several factors, such as the small number of studies, small sample sizes, differences between interventions, and inclusion of studies at high or unclear RoB.

#### Randomized Controlled Trials

Both RCTs<sup>19,20</sup> clearly described their objective, outcomes, patient inclusion criteria, and interventions of interest; both recruited patients for both groups from the same population over the same time period and used appropriate statistical tests. Both also declared their funding source and if there were potential conflicts of interest. One RCT<sup>19</sup> clearly described



their main findings including the 95% confidence intervals, conducted a sample size calculation, and specified that they used the intention-to-treat (ITT) principle. For the other RCT,<sup>20</sup> the outcome of interest for this report was not reported in detail, and it is not reported if they conducted a sample size calculation or used the ITT approach. One RCT<sup>19</sup> reported that approximately 10% of the recruited patients were lost to follow-up for both the intervention and control groups, which may have introduced attrition bias. The other RCT<sup>20</sup> did not report that any patients were lost to follow-up.

One RCT<sup>19</sup> reported that they blinded the statistician who conducted the data analysis; this was not reported by the other RCT.<sup>20</sup> It is likely that due to the nature of the intervention, the patients and most research staff could not have been blinded to group assignment. Lack of blinding has the potential to introduce detection and/or performance biases; however, the study that did not report any blinding only assessed objective outcomes.

#### Non-Randomized Studies

The objective, main outcomes, and interventions were clearly described by all 6 non-randomized studies. <sup>21-26</sup> Five studies <sup>21-24,26</sup> described the characteristics of the included patients. Four studies <sup>23-26</sup> reported their outcomes in detail, including the 95% confidence interval and/or exact P values. It is unclear from all 6 studies <sup>21-26</sup> if all adverse events that occurred were reported. Due to lack of randomization, it is possible the findings from these studies may be biased due to confounding. Only 1 study <sup>24</sup> incorporated some potential confounding variables into their adjusted regression model; the other studies did not provide any lists of potential confounders. Three studies <sup>21-23</sup> reported both their funding and potential conflicts of interest; 1 study <sup>24</sup> reported their funding source but not potential conflicts of interest, while 2 studies <sup>25,26</sup> did not report their funding or conflicts of interest.

#### **Summary of Findings**

#### Clinical Effectiveness of Therapeutic Support Surfaces

One overview of reviews with an NMA,  $^1$  3 SRs $^{14,16,18}$  (2 with meta-analyses $^{16,18}$ ), and 5 non-randomized studies $^{21,23\cdot26}$  were identified regarding the clinical effectiveness of beds, mattresses, and/or overlays to prevent pressure injuries, while 2 SRs $^{15,16}$  and 1 RCT $^{20}$  reported on cushions or chairs to prevent pressure injuries. Additional details are available in Appendix 4 by outcome: pressure injury incidence (Table 6), time to pressure injury (Table 7), adverse events (Table 8), and health-related quality of life (Table 9).

#### Prevention With Therapeutic Support Surfaces — Beds, Mattresses, and Overlays

As the overview of reviews with an NMA¹ reported on many comparisons (27 direct comparisons and 78 network contrasts), this summary focuses on key comparisons as reported by the overview's authors. Key comparisons were defined as comparisons between support surfaces that the authors stated are likely widely used: alternating-pressure (active) air surfaces, reactive air surfaces, foam surfaces, reactive sheepskin surfaces, and reactive gel surfaces. The NMA's network comparisons found that reactive air surfaces, alternating-pressure (active) air surfaces, and reactive gel surfaces may reduce pressure injury incidence compared to foam surfaces. However, it is unclear if there is a significant difference between other key comparisons. All NMA findings agreed with the results of corresponding pairwise direct analyses where available. The authors also reported that alternating-pressure (active) air surfaces, reactive water surfaces, and reactive sheepskin surfaces may reduce risk compared to standard hospital surfaces, but noted these findings should be interpreted with caution, as what is considered "standard" may vary between studies.



Three SRs<sup>14,16</sup> (2 with meta-analyses<sup>16,18</sup>) had considerable overlap of included primary studies with the overview of reviews, but focused separately on the ICU14,16 and acute care settings, 18 while the overview of reviews' NMA1 pooled studies from various settings. Thus, the results of these SRs are presented, as they may indicate differences between settings. The SR with meta-analysis of acute care patients<sup>18</sup> included 24 RCTs for support surfaces, and 23 overlapped with the overview of reviews. The authors conducted meta-analyses for 3 types of support surfaces (active, reactive, and sheepskin) and reported that with ITT analyses, only sheepskin was associated with a significantly lower risk of pressure injury compared to standard care (a standard hospital mattress, with or without additional reactive surfaces). Subgroup meta-analyses did not find a significant difference between active and reactive support surfaces; compared to standard mattresses, active surfaces were found to be better, and reactive surfaces may also be better with borderline significance based on per-protocol analyses, but ITT analyses were not significant. 18 The SR with meta-analysis of ICU patients<sup>16</sup> included 5 RCTs assessing support mattresses; all were also included in the overview of reviews. They reported that for ICU patients, there was no statistically significant difference between 2 types of active support surfaces based on 1 RCT (a mattress with optional pulsation and low air loss features, compared to a continuous/alternating low-pressure control mattress), or between 2 types of reactive surfaces based on 1 RCT (2 viscoelastic foam mattresses); 2 RCTs reported lower pressure injury incidences for reactive surfaces compared to standard mattresses, but the pooled risk ratio (RR) was not statistically significant. Another SR14 also assessed support surfaces for adult ICU patients, including RCTs and non-randomized studies; as all the RCTs were included in the overview1 and/or the previously-described SR,16 only the results from the 4 non-randomized studies are summarized. Significantly fewer pressure injuries were found when alternating-pressure air mattresses were used compared to foam mattresses, and with low air loss mattresses compared to air pressure mattresses. No significant difference was found between viscoelastic foam mattresses versus air pressure mattresses, or alternating-pressure air mattresses versus alternating-pressure air overlays.14

Five non-randomized studies were identified that assessed a variety of interventions and comparators. Two studies had similar interventions and comparators, comparing a pressureredistributing foam mattress<sup>24</sup> or pressure-relieving mattresses<sup>21</sup> to a non-pressure-relieving foam mattress<sup>24</sup> or standard mattress<sup>21</sup>; an observational cohort<sup>24</sup> found the intervention to be associated with reduced pressure injuries, while the cross-sectional study21 did not find a significant difference. Two studies assessed overlays. 25,26 One observational study 25 assessed the introduction of 2 types of static overlays in a hospital setting. During the implementation period, 123 patients used an overlay and none developed a pressure injury; however, statistical analyses did not find a significant difference in pressure injury incidence between the pre- and post-implementation periods. Another cohort study<sup>26</sup> assessed a low-profile alternating-pressure overlay with a non-powered pressure redistribution mattress, which was associated with a significantly fewer pressure injuries when compared to a historical control (no overlay, mattress only). An observational cohort study<sup>23</sup> found 1 type of support surface (a non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology) was associated with a significantly lower risk of developing pressure injuries compared to 6 other types of support surfaces.

Time to pressure injury development was assessed by the overview of reviews with NMA¹ and 1 non-randomized study.²⁴ The overview of reviews' NMA reported that reactive air surfaces likely reduce hazard of developing pressure injuries compared to foam surfaces, though this network contrast was not statistically significant. All other comparisons with foam surfaces



did not provide clear evidence of an effect on pressure injuries. In their summary of reviews, the evidence was unclear as to whether reactive air surfaces differ in the hazard of developing new pressure injuries compared to alternating-pressure (active) air surfaces; the mixed-effects estimate from the NMA had a comparable hazard ratio (HR) to the direct comparison, but with a wider confidence interval that contains HR = 1 due to data sparseness in the network as opposed to the direct evidence which excluded the null. The authors speculated that, for this contrast, the direct comparison may be more reliable. The overview of reviews and 1 non-randomized study<sup>24</sup> also compared between 2 types of foam mattresses, and both reported there may be significant differences between types of foam mattresses.

The overview of reviews¹ assessed adverse events, and identified 5 comparisons. The authors reported that all data offered low or very low certainty evidence due to issues like RoB, imprecision, and/or inconsistency, and it was unclear if there were any differences in adverse event rates between the identified comparisons. They also assessed health-related quality of life and identified 2 comparisons. They reported that there may be little to no difference between reactive sheepskin surfaces and standard hospital surfaces in LTC settings, and it is unclear if there is a difference between alternating-pressure (active) air surfaces and foam surfaces at 90 days in acute care and LTC settings.

#### Prevention with Therapeutic Support Surfaces — Cushions and Chairs

One SR<sup>15</sup> assessed wheelchair pressure-relieving cushions compared to cushions made of different materials, although only 3 primary studies reported clinical outcomes (incidence of pressure injuries). Two studies compared multiple-compartment air cushions to single-compartment air cell cushions, and neither study reported a statistical difference in incidence of pressure injuries between groups. The third RCT<sup>15</sup> compared a skin protection cushion (consisting of air, gel, or contoured foam) to a segmented (flat) foam cushion, which review authors reported is standard care. The skin protection cushion was associated with fewer pressure injures under the ischial tuberosities, but there was no significant difference for incidence of pressure injuries under the ischial tuberosities and sacrum. Another SR<sup>16</sup> identified 1 RCT that compared tragacanth gel cushions to standard foam cushions for adult patients in the trauma ICU, and measured the days to developing a pressure injury. This study found that the tragacanth gel cushions led to a statistically significant delay in developing of pressure injuries.

One RCT<sup>20</sup> compared a special postoperative cushion to conventional sponge pads for patients following a percutaneous nephrolithotomy, and found patients who used the specially designed cushion had a lower incidence of pressure injuries. They were also the only study to report on adverse events for this intervention type, and found that the incidence of renal hemorrhage due to improper postoperative position and rate of tube folding of the renal fistula were lower with the special postoperative cushion. One SR<sup>16</sup> with 1 relevant RCT also reported on effect of pressure-redistributing cushions on time to pressure injury development for patients in the ICU. They found that compared to a standard foam cushion, a tragacanth gel cushion was associated with a statistically significant increase in mean days to injury, though the difference was just over 1 day.

One SR<sup>17</sup> focused on pressure-redistributing static chairs but did not identify any RCTs that met their criteria, and thus could not provide a summary of whether these chairs can help to prevent or manage pressure injuries.



#### Treatment With Therapeutic Support Surfaces

The overview of reviews with an NMA¹ and 1 non-randomized study²² were identified regarding the clinical effectiveness of support surfaces (beds, mattresses, and/or overlays) to treat pressure injuries. Additional details are available in Appendix 4 by outcome: proportion of patients with fully healed pressure injuries (Table 10), time to pressure injury healing (Table 11), change in skin status (Table 12), and adverse events (Table 13).

The overview of reviews with an NMA¹ compared different types of therapeutic support surfaces on the proportion of patients with healed pressure injuries. The authors concluded that more people with pressure injuries may heal completely with a reactive air surface than a foam surface; however, this statement should be interpreted with caution since the network contrast and direct pairwise comparison were not statistically significant. All other comparisons were uncertain. All network contrasts aligned with direct pairwise comparisons where available.

The overview of reviews<sup>1</sup> assessed adverse events, and concluded that it is unclear if there are any differences in adverse event rates between any of the identified comparisons.<sup>1</sup>

One non-randomized before-after study<sup>22</sup> assessed the impact of fully automated pulsating support system air mattresses, comparing patients' skin status as measured by the PUSH tool at baseline and after 30 days. The authors stated that most pressure injuries did not deteriorate and 4 pressure injuries completely epithelialized (healed), though deterioration was also observed.

#### Clinical Effectiveness of Therapeutic Small Devices

#### Prevention With Therapeutic Small Devices

Two SRs<sup>16,18</sup> and 1 RCT<sup>19</sup> reported on the clinical effectiveness of heel protection devices (e.g., heel-offloading boots) on pressure injury incidence. Additional details are available in Appendix 4 by outcome: pressure injury incidence (<u>Table 14</u>) and time to pressure injury development (<u>Table 15</u>).

Three RCTs from the 2 SRs, <sup>16,18</sup> as well as an additional RCT, <sup>19</sup> compared similar heel protection devices (heel protector, heel-offloading boot, or heel suspension boot) to standard of care or pillows in the ICU or hospital nursing units: all reported significantly lower incidence of pressure injuries in the intervention group. One SR<sup>18</sup> also identified 2 additional RCTs. One RCT compared a foot waffle to a hospital pillow: the incidence of pressure injuries was lower in the foot waffle group, but it was not statistically significant. The second RCT compared between a foot waffle, egg crate, and bunny boot, and reported that incidence was comparable across all 3 groups. <sup>18</sup>

Two RCTs<sup>18,19</sup> (1 from a SR<sup>18</sup>) reported on time to pressure injury development. One RCT<sup>18</sup> found no difference between a foot waffle device versus hospital pillow, while the other RCT<sup>19</sup> found a lower HR with a heel-offloading boot than standard practice (pillows).

#### Treatment With Therapeutic Small Devices

No studies were identified that reported on therapeutic small devices for treatment of pressure injuries; therefore, no summary can be provided.



#### Summary of Findings in LTC Settings

From the identified studies summarized above, the overview of reviews<sup>1</sup> and 2 non-randomized studies<sup>22,26</sup> provided evidence regarding the clinical effectiveness of therapeutic support surfaces in LTC settings.

The overview of reviews<sup>1</sup> and 1 non-randomized study<sup>26</sup> assessed therapeutic support surfaces to prevent pressure injuries. The overview of reviews'<sup>1</sup> narrative summary reported that for people in LTC settings, therapeutic support surfaces associated with a reduced incidence of pressure injury were:

- reactive air surfaces and alternating-pressure (active) air surfaces, compared to foam surfaces
- reactive air surfaces, compared to alternating-pressure (active) air surfaces.

One non-randomized study  $^{26}$  reported that using a low-profile alternating-pressure overlay with a pressure-redistributing mattress was associated with significantly lower incidence of pressure injuries, compared to the mattress without the overlay, over an average of 4.5 months. The overview of reviews also identified RCTs that assessed health-related quality of life and that included patients in LTC settings. They concluded there may be little to no difference between reactive sheepskin surfaces and standard hospital surfaces, and it is unclear if there is a difference between alternating-pressure (active) air surfaces and foam surfaces at 90 days.

One RCT from the overview of reviews¹ and 1 non-randomized study²² assessed therapeutic support surfaces for treatment of pressure injuries. The RCT reported that compared to foam surfaces, people using reactive air surfaces may be more likely to have healed pressure injuries.¹ The non-randomized study²² assessed a full automated pulsating support system air mattress and reported that after 30 days, most pressure injuries remained stable, a few improved, and 1 deteriorated.

### Limitations

There are several limitations that prevent definitive conclusions regarding the clinical effectiveness of therapeutic support surfaces and therapeutic small devices for the prevention or treatment of pressure injuries.

The overview of reviews¹ and SRs¹⁴¹8 noted many of their included primary studies were at unclear or high RoB. Due to the nature of the intervention, blinding of the patients and most study personnel is not possible. While 1 RCT¹9 stated they blinded the statistician who conducted the data analysis, it is unclear if similar measures were taken by other studies, which may have resulted in performance or detection bias for subjective outcomes. The sample size was also low for many primary studies included in the overview and/or SRs. Many of the included primary studies from the overview of reviews and SRs were published more than 10 years ago, and it is unclear if their findings are generalizable to newer surfaces and devices, as well as to modern settings.

There was considerable heterogeneity across studies, with different care settings, follow-up durations, and types of interventions being compared. Due to the many types of support



surfaces identified, although this report identified a large volume of primary studies, most pairwise comparisons only had 1 to 3 primary studies, and results may have varied due to differences in care setting. The overview of reviews and SRs were not always consistent in how they classified different types of support surfaces; for example, the overview of reviews¹ compared 12 types including different types of reactive surfaces (e.g., air, gel) while another SR¹8 grouped together all reactive support surfaces. Comparisons to standard surfaces may also include a range of surface types, as what is considered standard may vary by place and time.¹ Although potential differences between different care settings (acute and ICU) was partially assessed by 2 focused SRs,¹6₁¹8 these reviews were also based largely on the same RCTs as the overview of reviews and at unclear or high RoB.

Adverse events were reported by the overview of reviews<sup>1</sup> and 1 RCT.<sup>20</sup> Authors of the overview stated that little is known about differences in adverse event rates between different therapeutic support surfaces for treatment or intervention.<sup>1</sup> It is also unclear if no adverse events occurred or if they were not reported in the other included studies. As potential harms were not discussed by most included studies, the results may be biased toward favouring the intervention.

The overview of reviews with NMA¹ had sparse data for all 3 networks, which resulted in considerable uncertainty. The authors may also have overinterpreted some results despite this uncertainty, such as stating some interventions may lead to improved outcomes when the comparison was not statistically significant.

Many of the included studies in this report focused on therapeutic support surfaces for prevention. There were few studies regarding therapeutic support surfaces for treatment, or for therapeutic small devices for prevention, and thus the findings for these interventions should be interpreted with caution. There were also no studies identified for therapeutic small devices for treatment. Most studies also focused on adult patients with only 1 non-randomized study focused on pediatric patients,<sup>21</sup> so it is unclear if the findings are generalizable to children or adolescents.

The included studies were conducted from a wide range of countries. Only 5 RCTs from the overview of reviews¹ (including 1 RCT that also overlapped with a SR¹⁶) were conducted in Canada, and all focused on therapeutic support surfaces to prevent pressure injuries. Thus, it is unclear how generalizable these findings are to the Canadian context, or to specific geographical, ethnic, or cultural groups in Canada, particularly regarding therapeutic support surfaces for treating pressure injuries, and therapeutic small devices for prevention or treatment.

## Conclusions and Implications for Decision- or Policy-Making

This report identified 1 overview of reviews with NMA,<sup>1</sup> 5 SRs<sup>14-18</sup> (2 with meta-analyses<sup>16,18</sup>), 2 RCTs,<sup>19,20</sup> and 6 non-randomized studies<sup>21-26</sup> regarding the use of therapeutic support surfaces to prevent or treat pressure injuries, or therapeutic small devices to prevent pressure injuries. Most the identified evidence included in this report were focused on adults, regarding the use of therapeutic support surfaces (particularly mattresses, beds, or overlays) to prevent



pressure injuries. No relevant evidence was identified regarding the use of therapeutic small devices to treat pressure injuries.

For the clinical effectiveness of therapeutic support surfaces including mattresses, beds, and overlays to prevent pressure injuries, the overview of reviews' NMA found that alternatingpressure (active) air surfaces and reactive gel surfaces may reduce pressure injury incidence compared to foam surfaces.1 An SR with meta-analysis focused on acute care patients,18 which largely overlapped with the overview of reviews, reported that sheepskin reactive surfaces were associated with reduced incidence of pressure injuries; standard surfaces, compared to active or reactive support surfaces, led to mixed results depending on the type of analysis (ITT or per-protocol). Two SRs of ICU patients 14,16 (1 with a meta-analysis 16) were identified and also largely overlapped with the overview of reviews. The SR with meta-analysis<sup>16</sup> reported that reactive surfaces may reduce pressure injury compared to standard mattresses, though the meta-analysis of 2 studies was not statistically significant. Non-randomized studies from the other SR<sup>14</sup> reported that alternating-pressure air mattresses were better than foam mattresses and low air loss mattresses were superior to air pressure mattresses. Mixed results were found for the identified non-randomized studies comparing pressure-relieving mattresses compared to standard mattresses<sup>21,24</sup> and for overlays,<sup>25,26</sup> which may be due to differences between studies (e.g., care setting). One non-randomized study<sup>23</sup> indicated that a non-alternating, dynamic, minimum pressure air mattress system with a double-cell structure and reactive adjustment technology may reduce incidence of pressure injuries compared to other surfaces. The overview of reviews<sup>1</sup> and 1 SR<sup>16</sup> did not find significant differences between different types of active surfaces or reactive surfaces for pressure injury incidence or time to pressure injury, though there may be differences between different types of foam surfaces on time to pressure injury development.<sup>1,24</sup> Only the overview of reviews<sup>1</sup> reported on adverse events and health-related quality of life, and identified limited studies: it is uncertain if there are differences in adverse event rates between different support surfaces, and the effect on health-related quality of life is also unclear.

For the clinical effectiveness of cushions to prevent pressure injuries, from a SR<sup>15</sup> assessing wheelchair pressure-relieving cushions, 2 studies did not find a significant difference between multiple-compartment air cell cushions and single-compartment air cell cushions; 1 study compared a skin protection cushion to a standard foam cushion and found no significant difference was found between incidence of all pressure injuries. Another SR<sup>16</sup> identified 1 RCT where tragacanth gel cushions led to a delay in developing pressure injuries compared to standard foam cushions. One RCT<sup>20</sup> also reported that their specially designed postoperative cushion also led to lower incidence of pressure injuries and reduced adverse events compared to conventional sponge pads.

For the clinical effectiveness of therapeutic support surfaces including mattresses, beds, and overlays to treat pressure injuries, the authors of the overview of reviews¹ indicated that reactive air surfaces may be more effective than foam surfaces for treating pressure injuries; however, the network comparison and direct pairwise comparison were not statistically significant, so this should be interpreted with caution. It is also unclear if any other comparisons were clinically significant. Limited evidence was identified for adverse events, so it is unclear if there are differences in adverse event rates between types of therapeutic support surfaces. One non-randomized study²² found mixed results for fully automated pulsating support system air mattresses.

For the clinical effectiveness of therapeutic small devices including mattresses, beds, and overlays to prevent pressure injuries, the authors suggested that compared to standard care



(e.g., pillows), heel protection devices may reduce pressure injury incidence <sup>16,19</sup>; however, evidence was limited and a meta-analysis reported that the pooled RR was not statistically significant. Findings were also mixed for time to pressure injury development. <sup>18,19</sup> One RCT found no differences between a bunny boot, egg crate, or foot waffle. <sup>18</sup>

Overall, this review found some evidence to suggest that certain types of therapeutic support surfaces may help to prevent pressure injuries, such as active and reactive support surfaces compared to foam surfaces. There were comparatively fewer studies identified that assessed therapeutic support surfaces for treatment: authors of the overview of reviews stated that reactive air surfaces may be more effective than foam surfaces, but this finding should be interpreted with caution as it was not statistically significant. Two SRs and 1 RCT were identified regarding therapeutic small devices, and suggested that heel protection devices such as heel-offloading boots may lead to reduced pressure injuries compared to a pillow, although this finding should also be interpreted with caution due to limited evidence and a non-significant meta-analysis. The effects on these interventions for prevention or treatment on health-related quality of life and adverse events are unclear. Another gap is for pressure-redistributing static chairs, based on 1 SR<sup>17</sup> that did not identify any relevant RCTs.

The methodological limitations of the included literature should be considered when interpreting the findings from this report, including small sample sizes, various sources of heterogeneity, many primary studies at unclear or high RoB, and limited reporting on adverse events. Further research set in Canada to assess benefits and harms for these interventions — through adequately powered and high-quality RCTs, particularly for therapeutic small devices for the treatment of pressure injuries — is warranted.



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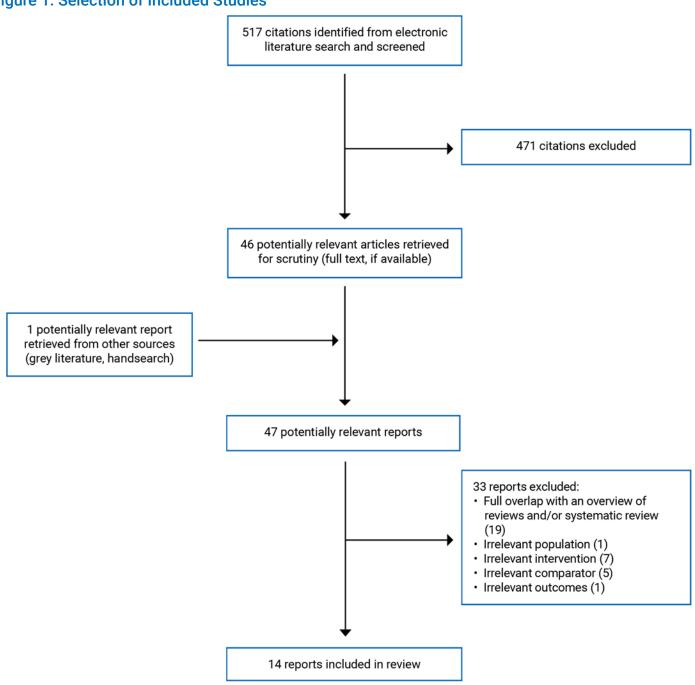
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## **Appendix 1: Selection of Included Studies**

Figure 1: Selection of Included Studies





## **Appendix 2: Characteristics of Included Publications**

Note that this appendix has not been copy-edited.

Table 2: Characteristics of Included Overview of Reviews, Systematic Reviews, and Network Meta-Analyses

Study citation, country, funding source	Objective, last search date, study designs and numbers of primary studies included	Population characteristics	Intervention and comparator(s)	Relevant clinical outcomes, length of follow-up
		Overview of Reviews		
Shi et al. (2021)¹ UK Funding source: NIHR	Last search date: NR  Number of included studies: 6 reviews, including  Prevention: 69 RCTs (1 added from reference list screening)  Treatment: 12 RCTs  Number of primary RCTs and network contrasts in the NMA:  Prevention – pressure injury incidence: 40 RCTs, 78 network contrasts  Prevention – time to pressure injury development: 10 RCTs, 15 network contrasts  Treatment – Proportion of patients with completely healed pressure injuries: 4 RCTs, 6 network contrasts	Prevention:  • Eligibility criteria: any population in any setting  • Total participants: 18,621  • Mean age: 37.16 to 87  • % female: NR; from the prevention – pressure injury incidence network, 54.9% of participants were female from the 38 studies that specified participant sex  • Setting: NR; from the prevention – pressure injury incidence network, 21/40 studies were in acute care  Treatment:  • Eligibility criteria: people with existing pressure injuries, any age and setting  • Total participants: 972  • Median sample size: 72  • Mean age: 64.0 to 86.5 (median: 82.7)  • % female: 53.7%  • Setting: acute care (6/12) or community/long-term care (6/12)	Interventions: Support surfaces (specialized medical devices designed to relieve or redistribute pressure on the body or both, to prevent and treat pressure ulcers) Comparator: Any other support surface; reference comparator for NMA was foam surfaces	Prevention outcomes:  Pressure injury incidence  Time to pressure injury development  Adverse events  Health-related quality of life  Prevention studies follow-up (range): days to 7 months (median: 14 days)  Treatment outcomes:  Proportion of patients with completely healed pressure injuries  Time to complete pressure injury healing  Adverse events  Treatment studies follow-up (range): 7 days to 18 months (median: 37.5 days)
Bambi et al. (2022) <sup>14</sup> Indonesia Funding: NR	Last search date: NR  Number of included studies: 8 (4 RCTs, 2 cohort studies, 2 quasi- experimental studies)	Systematic Reviews  Eligibility criteria: Adult ICU patients  Total participants: NR  Sample size (range): 52 to 1,654  Mean age: NR  % female: NR	Intervention: Active or reactive support surfaces Comparator: Any support surface	Outcome: Pressure injury incidence Follow-up (range): 7 to 30 days



Study citation, country, funding source	Objective, last search date, study designs and numbers of primary studies included	Population characteristics	Intervention and comparator(s)	Relevant clinical outcomes, length of follow-up
Damiao and Gentry (2022) <sup>15</sup> US Funding: NR	Last search date: NR  Number of included studies: 17 (3 relevant to this report: 2 RCTs, 1 non-randomized studies)	Eligibility criteria: NRª	Intervention: Wheelchair pressure- relieving cushions Comparator(s): Cushions made of different materials	Outcome: Development of pressure injury Follow-up: 1 study followed patients for 35 days; NR for 2 studies
Lovegrove et al. (2022) <sup>16</sup> Australia Funding: The Prince Charles Hospital Foundation (scholarship)	Last search date: end of 2019 Number of included studies: 26 RCTs (7 relevant: support surfaces = 6; heel protection devices = 1)b	Eligibility criteria: Adult patients in ICU settings Total participants: NR Sample size (range): NR Mean age: NR % female: NR	Relevant interventions: Support surfaces or heel protection devices Comparators: Alternative surfaces, standard care	Outcome: Pressure injury incidence Follow-up: NR for most studies, up to 2 weeks where reported
Stephens et al. (2022) <sup>17</sup> UK Funding: NIHR	Last search date: June 23, 2021 Number of included studies: 0 RCTs	Eligibility criteria: Adults who remain seated for extended periods of time, in any care setting	Intervention: Any type of pressure-redistributing static chair  Comparator: Any comparator, e.g., standard chairs, other types of pressure-redistributing chairs	Outcomes:     Pressure injury incidence     Health-related quality of life     Adverse events Follow-up: NA
Lovegrove et al. (2021) <sup>18</sup> Australia Funding: The Prince Charles Hospital Foundation (scholarship)	Last search date: end of 2019  Number of included studies: 45 RCTs  Number of relevant RCTs: 28 (support surfaces = 24; heel protection devices = 4) b	Eligibility criteria: Adult patients in acute hospital settings Total participants: NR Sample size (range): NR Mean age: NR % female: NR	Relevant interventions: Support surfaces or heel protection devices Comparators: Alternative surfaces, standard care	Outcome: Pressure injury incidence Follow-up: NR for most studies; when reported, ranges from 5 days to 60 days, or to discharge

ICU = intensive care unit; ITT = intention to treat; NA = not applicable; NIHR = National Institute for Health Research; NMA = network meta-analysis; NR = not reported; RCT = randomized controlled trial.

<sup>&</sup>lt;sup>a</sup>The supplementary materials could not be accessed at the time of writing this report; it is unclear if additional details about the population characteristics are presented in the supplementary materials or not reported.

<sup>&</sup>lt;sup>b</sup>Many of the primary RCTs included in the systematic reviews by Lovegrove et al. related to support surfaces were also included in the overview of reviews. Five out of 7 studies (6 related to support surfaces) included by Lovegrove et al. (2022)<sup>16</sup> are covered in the overview, while 23 out of 28 studies (24 related to support surfaces) by Lovegrove et al. (2021)<sup>18</sup> are covered in the overview.



**Table 3: Characteristics of Included Primary Clinical Studies** 

Study citation, country, funding source	Study design and setting	Population characteristics Randomized Controlled Tr	Intervention and comparator(s)	Clinical outcomes, length of follow-up
	a			
Barakat-Johnson et al. (2022) <sup>19</sup> Australia Funding: No funding; in-kind support was provided by each facility to conduct the study.  Xue and Yang (2020) <sup>20</sup>	Single-blinded RCT ICU RCT Hospital,	Eligibility criteria: Adult ICU patients at high risk of developing a pressure injury (Waterlow score ≥ 15 or Braden scale ≤ 12) but without pre- existing heel pressure injuries (N = 394) Mean (SD) age: 60.1 (16.7) Age range: 16.7 to 94.8 % female: 33.2%  Eligibility criteria: Patients who underwent percutaneous	Intervention: Heel- offloading boot (Prevalon™ boot)  Comparator: Standard hospital pillow or Posey® Heel Protector boot  Intervention: Special postoperative position	Outcome:  • Time to ICU- acquired pressure injury  • Incidence of heel pressure injury  • Severity of heel pressure injuries  Follow-up: 28 days from admission  Outcomes: • Incidence of
China Funding: National Social Science Foundation of China, Innovation Platform's Open Foundation of Education Department in Hunan, Provincial Department of Health, PI, General Project, China.	Department of Urology	nephrolithotomy (N = 450)  Number of female patients: 221  Mean (SD) age: 47.03 (8.9)  Age range: 18 to 76	cushion with a sacrococcygeal pad and a back pad  Comparator: Conventional hip sponge pads	pressure injury  • Adverse events (incidence of renal hemorrhage)  Follow-up: NR; patients typically need 5 to 7 days of rest after this procedure
		Non-Randomized Studie	s	
Marufu et al. (2021) <sup>21</sup> UK Funding: None	Cross-sectional study Children's hospital	Eligibility criteria: Children allotted to a pediatric or neonatal bed in June/July 2020 (N = 88)  Median (range) age: 0.85 (0 to 17.5) % female: 42.0%	Relevant intervention: Pressure-relieving mattress Comparator: Standard mattress	Relevant outcome: Pressure damage Follow-up: NA
Raepsaet et al. (2021) <sup>22</sup> Belgium Funding: Care of Sweden AB, Tranemo, Sweden	Cohort (before-after comparison) Nursing homes	Eligibility criteria: Adults residing in a nursing home (Total N = 40; relevant [treatment] = 18) Mean (SD) age: 86 (7.56) % female: 85%	Intervention: A fully automated pulsating support system air mattress Comparator: Before-after	Relevant outcomes: Changes in pressure injury state Follow-up: 30 days



Study citation, country, funding source	Study design and setting	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
Ahtiala et al. (2020) <sup>23</sup> Finland Funding source: Turku University Hospital Foundation	Retrospective observational cohort ICU	Eligibility criteria: Adult patients admitted to the ICU from 2010 to 2015 (N = 8,956 included in analysis)  Mean (range) age: 61.4 (18 to 95) % female: 36.1%	Intervention: Non- alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology  Comparators:  Polyurethane foam One-cell, dynamic, low- pressure air mattress system Alternating dynamic air mattress, every fourth cell Alternating dynamic air mattress, 20 cells in the cell system and cycle time 15 minute Alternating/ continuous low-pressure, dynamic air mattress, with 24 cells Complete therapy bed	Outcomes: Incidence of pressure injury Time to pressure injury development Follow-up: Study assessed 6 years of data (2010 to 2016)
Bai et al. (2020) <sup>24</sup> Taiwan Funding source: Ministry of Science and Technology, Taiwan; Yuan Ze University, Taiwan	Observational prospective cohort	Eligibility criteria: ICU patients from November 2017 to September 2018 with risk off developing a pressure injury (N = 254)  Mean age: 64.05 % female: 38.6% Risk of developing a pressure injury, based on Braden pressure injury risk assessment score:  Low risk: 22.4%  Moderate risk: 33.51% High risk: 28.7%  Very high risk: 15.8%	Intervention: Pressure- redistributing foam mattress  Comparator: Non-pressure redistributing foam mattress	Outcomes: Development of pressure injuries Follow-up: until discharge
Horup et al. (2020) <sup>25</sup> Denmark Funding: NR	Observational study (pre-post implementation) University hospital –	Eligibility criteria: Patients admitted during the 7 months before introducing static overlays, and 6 months after overlays were introduced (N = 1,557)	Interventions (chosen during the post-implementation period based on risk score with the Braden scale and clinical assessment):	<ul> <li>Outcome: Pressure injury incidence</li> <li>Mean hospital days: 6 days</li> </ul>



Study citation, country, funding source	Study design and setting	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
	geriatric and orthopedic wards	Mean age: NR % female: NR	<ul> <li>High-density         viscoelastic foam         overlay</li> <li>Thermoplastic         polyurethane overlay</li> <li>Comparators:         <ul> <li>Alternating air mattress</li> </ul> </li> <li>Standard mattress</li> </ul>	
• Stone (2020) <sup>26</sup> • US • Funding: NR	<ul> <li>Prospective, point-of-care observational study with a historical control</li> <li>LTC skilled nursing facilities</li> </ul>	<ul> <li>Eligibility criteria: Adults at risk of developing a pressure injury and staying in a ventilation unit for at least 5 days (N = 25)</li> <li>Mean (SD) age: 64.4 (18.9)</li> <li>Age range: 31 to 89</li> <li>% female: NR</li> </ul>	<ul> <li>Intervention: Low-profile alternating-pressure overlay on top of a pressure redistribution foam mattress</li> <li>Comparator: Standard of care: non-powered pressure redistribution mattress only (historical control, based on retrospective review)</li> </ul>	Outcome: Development of pressure injury  Mean (SD) days spent on the overlay: 140.9 (94.1) (range: 7 to 258)

ICU = intensive care unit; LTC = long-term care; NR = not reported; RCT = randomized controlled trial.



## **Appendix 3: Critical Appraisal of Included Publications**

Note that this appendix has not been copy-edited.

## Table 4: Strengths and Limitations of Systematic Reviews and Network Meta-Analyses Using AMSTAR 2<sup>10</sup> and the ISPOR Ouestionnaire<sup>11</sup>

AMSTAR 210 and the ISPOR Questionnaire11			
Strengths	Limitations		
Overview of Reviews			
Shi et al. (2021) <sup>1</sup>			
<ul> <li>The inclusion criteria were well-defined</li> <li>A protocol was published before the review (DOI: 10.1002/14651858.CD013761) and the review lists</li> </ul>	<ul> <li>As this overview focused on Cochrane reviews only, other systematic reviews were excluded; it is possible some studies of interest may have been missed</li> </ul>		
differences between the protocol and review  Review authors performed study selection in duplicate	<ul> <li>Authors did not explain their selection of study designs included in the review</li> </ul>		
<ul> <li>Excluded reviews were listed with a justification for exclusion</li> <li>Two review authors independently conducted risk of bias assessment of the reviews using the ROBIS tool</li> </ul>	<ul> <li>One individual carried out data extraction and a second review checked the extraction; while a piloting process was conducted, the review authors did not report if they checked agreement or provide a kappa score</li> </ul>		
<ul> <li>Review authors reported the quality of the individual primary</li> </ul>			

- Review authors reported the quality of the individual primary studies as assessed by the SR authors; 1 study that was not previously assessed was reviewed by the review authors using Cochrane's risk of bias tool
- Risk of bias was incorporated into the analysis by downgrading the certainty of the evidence, which was noted in the discussion
- The authors declared their funding and other potential conflicts of interest. The authors who conducted the risk of bias assessment were not authors of the included Cochrane Review
- The population, outcomes, and comparators used in the NMA are relevant to the current report
- As primary studies were extracted from included reviews, there was no over-representation of primary studies
- Authors screened the reference lists of the included reviews to identify RCTs that may have been excluded from the review but could be eligible for this overview
- Methodological quality of included SRs was assessed; risk of bias assessments of the RCTs done by the original reviews' authors were reported
- As the review was limited to RCTs, all intervention pairs were formed with RCTs
- Authors used a random-effects model and provided a rationale (assumption that there is an average effect size for a range of similar populations)
- No naïve comparisons were made
- Issues related to units of analysis, missing data, and transitivity assumptions were addressed; transitivity and

- Authors did not discuss the impact of risk of bias beyond its impact on pooled estimates and uncertainty
- Most of the studies that specified funding details were funded by industry
- NMAs included RCTs that were rated as unclear or high risk of bias
- The follow-up duration of studies included in the NMA had a wide range (5 days to 7 months) which may be introducing heterogeneity
- Pre-planned subgroup analyses could not be done for 1 outcome due to insufficient data
- Authors may have overstated some of their findings, including stating that some interventions may lead to improved outcomes when the analyses were not statistically significant



Strengths	Limitations
consistency assumptions held	
<ul> <li>Authors reported direct and network estimates (which agreed in treatment effects, where available), between-study variance, and heterogeneity for each outcome</li> </ul>	
<ul> <li>Network diagrams were provided for all outcomes</li> </ul>	
<ul> <li>Pre-planned subgroup analyses to assess potential causes of heterogeneity, sensitivity analyses and meta-regressions were conducted (except where there was insufficient data)</li> </ul>	
Systemati	c Reviews
Bambi et a	al. (2022) <sup>14</sup>
<ul> <li>The research questions and inclusion criteria were clearly defined with PICO components</li> <li>Review methods were established before the review was conducted (PROSPERO: CRD42020204919)</li> <li>RCTs and non-randomized studies (quasi-experiments and prospective cohort studies) were included</li> <li>Review authors searched multiple databases and screening reference lists of included studies</li> <li>Two authors determined eligibility of studies for inclusion (title-abstract screening was done by 1 author)</li> <li>Risk of bias was assessed for all individual studies using the Cochrane Risk of Bias Assessment tool and Oxford Centre for Evidence-Based Medicine guideline</li> </ul>	<ul> <li>Review authors did not justify included study designs</li> <li>It is not stated if the authors searched grey literature or specialized registers, or if they contracted experts in this field</li> <li>Justifications were not provided for search restrictions (studies available in English, published in the past 10 years)</li> <li>Data extraction was done by 1 author</li> <li>A list of excluded studies was not provided; the flow chart states that all studies excluded at the full-text screening phase were excluded due to non-relevant outcomes</li> <li>Descriptions of the included studies lacked details regarding the population and interventions</li> <li>Review authors did not report sources of funding for the included studies</li> <li>Risk of bias was not accounted for in the interpretation and discussion of the results</li> </ul>
	<ul> <li>Heterogeneity was not discussed</li> <li>Review authors did not report whether they had any conflicts of interest or any funding received for conducting the review</li> </ul>
Damiao et a	al. (2022) <sup>15 a</sup>
The research questions and inclusion criteria were clearly	<ul> <li>Unclear if review protocol was registered in advance</li> </ul>
defined	<ul> <li>Review authors did not justify included study designs</li> </ul>
<ul> <li>Multiple databases were searched and search terms were provided</li> </ul>	<ul> <li>It is not stated if the authors searched grey literature or specialized registers, or if they contracted experts in this field</li> </ul>
The authors reported no potential conflicts of interest.	<ul> <li>Justifications were not provided for search restrictions (studies available in English, published after 2005)</li> </ul>
	<ul> <li>Unclear if 2 authors conducted screening, data extraction, and/or risk of bias assessment</li> </ul>
	<ul><li>Unclear how risk of bias was assessed</li></ul>
	<ul> <li>A list of excluded studies was not provided</li> </ul>
	<ul> <li>Risk of bias was not accounted for in the interpretation and discussion of the results</li> </ul>
	<ul><li>Heterogeneity was not discussed</li></ul>
	<ul> <li>Review authors did not report whether they had received any funding received for conducting the review</li> </ul>



Strengths	Limitations			
Lovegrove et al. (2022) <sup>16</sup>				
<ul> <li>The research questions and inclusion criteria were clearly defined with PICO components</li> <li>Review protocol was published in advance (PROSPERO: CRD42019129556)</li> <li>Review authors searched multiple databases and screening reference lists</li> <li>Two authors determined eligibility of studies for inclusion, data extraction, and risk of bias assessment</li> <li>Studies were described in adequate detail</li> <li>The Cochrane Collaboration's tool for assessing risk of bias was used</li> <li>Appropriate methods were used for meta-analyses including separate analyses for different types of interventions</li> <li>The impact of risk of bias on meta-analyses was assessed through sensitivity analyses</li> <li>The authors discussed risk of bias and heterogeneity when discussing the results</li> <li>The authors declared their funding and other potential conflicts of interest.</li> <li>Conducted random-effects meta-analyses if there were at least 2 sufficiently similar primary studies</li> </ul>	<ul> <li>Review authors did not justify included study designs</li> <li>It is not stated if the authors searched grey literature or specialized registers, or if they contracted experts in this field</li> <li>Justifications were not provided for search restrictions (studies available in English)</li> <li>A list of excluded studies was not provided</li> <li>Funding for the included studies was not reported</li> <li>No rationale provided for choice of random-effects model for meta-analysis</li> <li>All relevant primary studies were at unclear or high risk of bias</li> <li>Substantial heterogeneity was present</li> <li>Only 2 primary studies were included in the meta-analysis</li> <li>Risk of bias was discussed generally, though not its impact on specific results (e.g., how it may have impacted the pooled estimates)</li> <li>Publication bias could not be assessed due to the limited number of studies</li> </ul>			
As review only included RCTs, did not need to conduct separate estimates for different study types				
Stephens et al. (2022) <sup>17</sup>				
<ul> <li>The research questions and inclusion criteria were well-defined</li> <li>Protocol was published in advance and the review lists differences between the protocol and review</li> <li>A comprehensive literature search strategy was used including multiple databases, screening reference lists, and contacting authors of key papers</li> <li>Review authors performed study selection in duplicate</li> <li>Excluded studies were with a justification for exclusion</li> <li>Stated they planned to assess risk of bias using the Cochrane risk of bias tool</li> <li>The authors declared their funding and other potential conflicts of interest</li> </ul>	<ul> <li>Authors did not explain their selection of study designs included in the review</li> <li>It is not stated if the authors searched grey literature, or if they contracted experts in this field</li> </ul>			
Lovegrove e	t al. (2021) <sup>18</sup>			
<ul> <li>The research questions and inclusion criteria were clearly defined with PICO components</li> <li>Review protocol was published in advance (PROSPERO: CRD42019129556)</li> </ul>	Review authors did not justify included study designs     It is not stated if the authors searched grey literature or specialized registers, or if they contracted experts in this field     Justifications were not provided for search restrictions     (studies available in English)			

(studies available in English)

• Review authors searched multiple databases and screening



Strengths	Limitations
reference lists	A list of excluded studies was not provided
<ul> <li>Two authors determined eligibility of studies for inclusion,</li> </ul>	<ul> <li>Funding for the included studies was not reported</li> </ul>
data extraction, and risk of bias assessment	No rationale provided for choice of random-effects model for
<ul> <li>Studies were described in adequate detail</li> </ul>	meta-analysis
<ul> <li>The Cochrane Collaboration's tool for assessing risk of bias was used</li> </ul>	<ul> <li>All relevant primary studies were at unclear or high risk of bias</li> </ul>
<ul> <li>Appropriate methods were used for meta-analyses including</li> </ul>	<ul> <li>Moderate to substantial heterogeneity was present</li> </ul>
separate analyses for different types of interventions	<ul> <li>Risk of bias was discussed generally, though not its impact</li> </ul>
<ul> <li>The impact of risk of bias on meta-analyses was assessed through sensitivity analyses</li> </ul>	on specific results (e.g., how it may have impacted the pooled estimates)
<ul> <li>The authors discussed risk of bias and heterogeneity when discussing the results</li> </ul>	<ul> <li>Publication bias could not be assessed due to the limited number of studies</li> </ul>
<ul> <li>The authors declared their funding and other potential conflicts of interest.</li> </ul>	
<ul> <li>Conducted random-effects meta-analyses if there were at least 2 sufficiently similar primary studies</li> </ul>	
<ul> <li>Specified sensitivity analyses to investigate effect of risk of bias and some sources of heterogeneity</li> </ul>	
<ul> <li>As review only included RCTs, did not need to conduct separate estimates for different study types</li> </ul>	

AMSTAR 2 = A MeaSurement Tool to Assess systematic Reviews 2; ISPOR = International Society for Pharmacoeconomics and Outcomes Research; NMA = network meta-analysis; RCT = randomized controlled trial; SR = systematic review.

<sup>a</sup>Some details, including the PRISMA flow chart and descriptions of included studies, were presented in supplementary materials that could not be accessed at the time of writing this report; thus, it is not possible to critically appraise these components.



Table 5: Strengths and Limitations of Clinical Studies Using the Downs and Black Checklist<sup>12</sup>

Strengths	Limitations		
Randomized Controlled Trials  Barakat-Johnson (2022) <sup>19</sup>			

#### Xue and Yang (2020)20

- The objective, main outcomes, characteristics of included patients, interventions of interest are clearly described in the introduction/methods
- For the primary outcome, the findings were reported in detail including exact P values
- The patients who were recruited and who participated may have been representative of the entire population from which they were recruited
- Appropriate statistical tests were used
- Outcome measures used were likely valid and reliable
- Patients from intervention and comparator groups were recruited from the same population over the same period of time
- No patients appear to have been lost to follow-up
- Declared funding and no potential conflicts of interest

- It is unclear if there were differences between the intervention and comparator groups for patient characteristics
- For the main outcome of interest for this report (incidence of pressure injury) the findings were not reported in detail; the difference in incidence and the exact P value was not reported
- It is unclear if the staff and facilities were representative of the treatment the majority of patients received
- Patients, investigators, and data collectors could not be blinded to group assignment due to the nature of the intervention. There was no indication that the statistician was blinded.
- Unclear if compliance with the intervention was reliable
- Unclear if intention-to-treat approach was used

#### **Non-Randomized Studies**

#### Marufu et al. (2021)21

- The objective, main outcomes, characteristics of included patients, interventions of interest are clearly described in the introduction/methods
- Some results were presented as an odds ratio with a 95%
- It is unclear if all important adverse events were reported
- It is unclear if the staff and facilities were representative of the treatment the majority of patients received
- A list of confounders was not provided



Limitations				
<ul> <li>For the main outcome of interest for this report (incidence of pressure injury) the findings were not reported in detail, possibly because it was not statistically significant</li> <li>As this is a non-randomized study, there was no blinding or randomization; thus, confounders may be an issue</li> </ul>				
al. (2021) <sup>22</sup>				
<ul> <li>It is unclear if all important adverse events were reported</li> <li>It is unclear if the staff and facilities were representative of the treatment the majority of patients received</li> <li>A list of confounders was not provided</li> <li>Findings were not reported in detail</li> <li>As this is a non-randomized study, there was no blinding or randomization; thus, confounders may be an issue</li> <li>Convenience sampling was used so it is possible the patients were not representative of the population they were recruited from</li> <li>Statistical tests were not conducted</li> </ul>				
Declared funding and no conflicts of interest  Ahtiala et al. (2020) <sup>23</sup>				
<ul> <li>It is unclear if all important adverse events were reported</li> <li>It is unclear if the staff and facilities were representative of the treatment the majority of patients receive</li> <li>A list of confounders was not provided</li> <li>As this is a non-randomized study, there was no blinding or randomization; thus, confounders may be an issue</li> </ul>				



#### **Strengths** Limitations Bai et al. (2020)24 • The objective, main outcomes, characteristics of included • It is unclear if all important adverse events were reported patients, interventions of interest are clearly described in the • It is unclear if the staff and facilities were representative of introduction/methods the treatment the majority of patients receive Results were presented with their 95% confidence interval and As this is a non-randomized study, there was no blinding or exact P values randomization; thus, confounders may be an issue • The patients who were recruited and who participated may • Did not explicitly state if there were any potential conflicts have been representative of the entire population from which of interest; stated that funders had no role in study or they were recruited manuscript A variety of comparators were included, which may suggest that most relevant comparators have been included Several confounding variables were included in the adjusted regression model Appropriate statistical tests were used Outcome measures used were likely valid and reliable Patients from intervention and comparator groups were recruited from the same population over the same period of time Stated funding source Horup et al. (2020)25 • The objective, main outcomes, interventions of interest are Characteristics of included patients were not well-described clearly described in the introduction/methods • It is unclear if all important adverse events were reported Result was presented with their exact p value • It is unclear if the staff and facilities were representative of • The patients who were recruited and who participated were the treatment the majority of patients receive representative of the entire population from which they were A list of confounders was not provided recruited, as all patients admitted to the study locations were As this is a non-randomized study, there was no blinding or included randomization; thus, confounders may be an issue Appropriate statistical tests were used • Did not report funding source or if there were any potential Outcome measures used were likely valid and reliable conflicts of interest Patients from intervention and comparator groups were recruited from the same population over the same period of time Stone et al. (2020)26 • The objective, main outcomes, characteristics of included • It is unclear if all important adverse events were reported patients, interventions of interest are clearly described in the • It is unclear if the staff and facilities were representative of introduction/methods the treatment the majority of patients receive Result was presented with their exact p value A list of confounders was not provided • The patients who were recruited and who participated may As this is a non-randomized study, there was no blinding or have been representative of the entire population from which randomization; thus, confounders may be an issue they were recruited • Did not report funding source or if there were any potential

conflicts of interest

Outcome measures used were likely valid and reliable
Patients from intervention and comparator groups were recruited from the same population over the same period of

Appropriate statistical tests were used

time



## **Appendix 4: Main Study Findings**

Note that this appendix has not been copy-edited.

Table 6: Summary of Findings for Therapeutic Support Surfaces for Prevention – Pressure Injury Incidence

Comparison (intervention vs. comparator)	Study design and citation	Study findings
Reactive air surfaces vs. foam surfaces	Shi et al. (2021)¹	RR (95% CI) from NMA: 0.46 (0.29 to 0.75)
	Overview of reviews with NMA	
Alternating-pressure (active) air surfaces vs. foam surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 0.63 (0.42 to 0.93)
	Overview of reviews with NMA	
Reactive gel surfaces vs. foam surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 0.47 (0.22 to 1.01)
	Overview of reviews with NMA	
Reactive gel surfaces vs. reactive air surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 1.02 (0.48 to 2.16)
	Overview of reviews with NMA	
Reactive sheepskin	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 0.58 (0.32 to 1.05)
surfaces vs. foam surfaces	Overview of reviews with NMA	
Reactive sheepskin surfaces vs. reactive air	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 1.25 (0.62 to 2.53)
surfaces	Overview of reviews with NMA	
Reactive sheepskin surfaces vs. alternating	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 0.93 (0.48 to 1.78)
(active) air surfaces	Overview of reviews with NMA	
Reactive sheepskin surfaces vs. reactive gel surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 1.23 (0.51 to 2.96)
	Overview of reviews with NMA	
Alternating-pressure (active) air surfaces vs. reactive air surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 1.35 (0.82 to 2.20)
	Overview of reviews with NMA	
Reactive gel surfaces vs. alternating-pressure (active) air surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 0.76 (0.34 to 1.66)
	Overview of reviews with NMA	
Reactive gel surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 2.88 (0.70 to
followed by foam surfaces vs. foam surfaces	Overview of reviews with NMA	11.83)
Standard hospital surfaces vs. reactive air surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 2.31 (1.41 to 3.79)
	Overview of reviews with NMA	
Reactive gel surfaces followed by foam surfaces vs alternating-pressure (active) air	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 4.60 (1.18 to
	Overview of reviews with NMA	17.86)
surfaces		
Standard hospital surfaces vs. alternating- pressure (active) air surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 1.71 (1.13 to 2.60)
	Overview of reviews with NMA	
Reactive gel surfaces followed by foam surfaces vs. reactive gel surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 6.09 (1.27 to 29.20)
Surfaces vs. reactive yel surfaces	Overview of reviews with NMA	29.20)



Comparison (intervention vs. comparator)	Study design and citation	Study findings
Standard hospital surfaces vs. reactive gel	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 2.27 (1.10 to 4.66)
surfaces	Overview of reviews with NMA	
Reactive gel surfaces followed by foam	Shi et al. (2021)¹	RR (95% CI) from NMA: 4.96 (1.10 to
surfaces vs. reactive sheepskin surfaces	Overview of reviews with NMA	22.33)
Standard hospital surfaces vs. reactive	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 1.85 (1.11 to 3.07)
sheepskin surfaces	Overview of reviews with NMA	
Reactive gel surfaces followed by foam surfaces vs. reactive water surfaces	Shi et al. (2021) <sup>1</sup>	RR (95% CI) from NMA: 6.68 (1.31 to
surfaces vs. reactive water surfaces	Overview of reviews with NMA	34.11)
Reactive surface vs. standard mattress	Lovegrove et al. (2022) <sup>16</sup>	ITT meta-analysis: RR (95% CI) = 0.24 (0.04 to 1.46)
	SR with NMA (2 RCTs) <sup>a</sup>	Both studies were statistically significant,
		with lower PI incidence in the reactive
		surface group than standard mattress group.
Two types of active support surfaces (optional	Lovegrove et al. (2022) <sup>16</sup>	PI incidence was not significantly different
pulsation and low air loss features vs. a continuous/alternating low-pressure control	SR (1 relevant RCT) <sup>a</sup>	(P = 0.35, per protocol)
mattress)		
Two types of reactive surfaces	Lovegrove et al. (2022) <sup>16</sup>	PI incidence was not significantly different
	SR (1 RCT) <sup>a</sup>	(P = 0.44, per protocol)
Viscoelastic foam mattress vs. air pressure	Bambi et al. (2022) <sup>14</sup>	RR (95% CI) after 7 days = 1.5 (0.2 to 2.6)
mattress	SR (1 relevant non-randomized study – quasi-experiment)	
Low air loss mattress vs. air pressure mattress	Bambi et al. (2022) <sup>14</sup>	PI incidence after 5 days:
	SR (1 cohort study)	• Low air loss mattress: 0%
		Air pressure mattress: 18.0%
		• P = 0.046
Alternating-pressure air mattress vs. alternating-pressure air overlays	Bambi et al. (2022) <sup>14</sup>	RR (95% CI) after > 14 days = 0.89 (0.42 to 1.83)
	SR (1 quasi-experimental study)	,
Alternating-pressure air mattress vs. foam mattress	Bambi et al. (2022) <sup>14</sup>	PI incidence after 21 days:
matacoo	SR (1 quasi-experimental study)	Alternating-pressure air mattress: 18.8%
		• Foam mattress: 48.5% P = 0.011
Active support surfaces vs. any comparator	Lovegrove et al. (2021) <sup>18</sup>	ITT (6 RCTs): RR (95% CI) = 0.79 (0.59 to
Active Support Surfaces vs. any Comparator	SR with MA <sup>a</sup>	1.06)
		PP (7 RCTs): RR (95% CI) = 0.54 (0.35 to 0.83)
Reactive support surfaces vs. any comparator	Lovegrove et al. (2021) <sup>18</sup>	ITT (5 RCTs): RR (95% CI) = 0.55 (0.24 to
	SR with MA <sup>a</sup>	1.26)



Comparison (intervention vs. comparator)	Study design and citation	Study findings	
		PP (4 RCTs): RR (95% CI) = 0.53 (0.30 to 0.95)	
Sheepskin surfaces vs. any comparator	Lovegrove et al. (2021) <sup>18</sup> SR with MA (2 RCTs) <sup>3</sup>	ITT: RR (95% CI) = 0.42 (0.22 to 0.78)	
Active support surfaces vs. reactive support surfaces	Lovegrove et al. (2021) <sup>18</sup> SR with MA <sup>a</sup>	ITT (3 RCTs): RR (95% CI) = 0.86 (0.72 to 1.02) PP (3 RCTs): RR (95% CI) = 0.77 (0.55 to	
		1.08)	
Active surfaces compared to standard mattress	Lovegrove et al. (2021) <sup>18</sup> SR with MA (2 RCTs) <sup>a</sup>	PP: RR (95% CI) = 0.31 (0.17 to 0.58)	
Reactive surfaces compared to standard mattress	Lovegrove et al. (2021) <sup>18</sup> SR with MA <sup>a</sup>	ITT (3 RCTs): RR (95% CI) = 0.38 (0.07 to 2.08)	
		PP (3 RCTs): RR (95% CI) = 0.39 (0.16 to 0.99)	
Pressure-relieving mattress vs. standard mattress	Marufu et al. (2021) <sup>21</sup> Non-randomized study (cross-sectional study, N = 88)	Protective mattress, compared to standard mattress, was not associated with risk reduction for pressure damage (P = NR), but was associated with risk reduction in skin assessment classification: OR (95% CI) = $-0.39$ ( $-0.66$ to $-0.1$ )	
Non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology vs. polyurethane foam	Ahtiala et al. (2020) <sup>23</sup> Non-randomized study (real-world observational cohort, N = 8,956)	HR (95% CI) for preventing pressure injuries until discharge = 3.330 (2.537 to 4.370)	
ro. polyaremane roam		Mean (range) days until discharge: 3.6 (0 to 64)	
Non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology	Ahtiala et al. (2020) <sup>23</sup> Non-randomized study (real-world observational cohort, N = 8,956)	HR (95% CI) for preventing pressure injuries until discharge = 2.866 (2.235 to 3.677)	
vs. one-cell, dynamic, low-pressure air mattress system		Mean (range) days until discharge: 3.6 (0 to 64)	
Non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology	Ahtiala et al. (2020) <sup>23</sup> Non-randomized study (real-world observational cohort, N = 8,956)	HR (95% CI) for preventing pressure injuries until discharge = 2.693 (1.931 to 3.757)	
vs. alternating dynamic air mattress, every fourth cell	3,700,	Mean (range) days until discharge: 3.6 (0 to 64)	
Non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology	Ahtiala et al. (2020) <sup>23</sup> Non-randomized study (real-world observational cohort, N = 8,956)	HR (95% CI) for preventing pressure injuries until discharge = 5.066 (2.346 to 10.940)	
vs. alternating dynamic air mattress, with 20 cells within the cell system cycle time 15 minute	2223.74.13.14. 33.13.14, 11 3,500)	Mean (range) days until discharge: 3.6 (0 to 64)	
Non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology	Ahtiala et al. (2020) <sup>23</sup> Non-randomized study (real-world observational cohort, N = 8,956)	HR (95% CI) for preventing pressure injuries until discharge = 3.410 (1.493 to 7.785)	



Comparison (intervention vs. comparator)	Study design and citation	Study findings		
vs. alternating/continuous low-pressure, dynamic air mattress, with 24 cells		Mean (range) days until discharge: 3.6 (0 to 64)		
Non-alternating, dynamic, minimum pressure air mattress system, with a double-cell structure and reactive adjustment technology vs. complete therapy bed	Ahtiala et al. (2020) <sup>23</sup> Non-randomized study (real-world observational cohort, N = 8,956)	HR (95% CI) for preventing pressure injuries until discharge = 2.877 (1.057 to 7.830)  Mean (range) days until discharge: 3.6 (0 to 64)		
Pressure-redistributing foam mattress vs. non-pressure redistributing foam mattress	Bai et al. (2020) <sup>24</sup> Non-randomized study (observational prospective cohort, N = 254)	Pressure injury incidence during ICU stay (mean length of stay in days = 8.9):  • Pressure-redistributing mattress: 1.6%  • Non-pressure redistributing mattress: 10.2%  • Adjusted OR (95% CI): 0.12 (0.03 to 0.56)  Difference in severity of pressure injuries was statistically non-significant (P = 0.280)		
Static overlays (high-density viscoelastic foam overlay, or thermoplastic polyurethane) vs. no overlay (standard mattress or alternating air mattress only)	Horup et al. (2020) <sup>25</sup> Non-randomized study (before-after implementation, N = 1,557)	Mean length of stay in days = 6 days  No patients on the overlays (n = 123) developed pressure injuries. No significant difference was found for pressure injury incidence in the periods before and after implementing the overlays (n = 1557; P = 0.874).		
Low-profile alternating-pressure support surface vs. standard of care (non-powered pressure redistribution mattress only)	Stone (2020) <sup>26</sup> Non-randomized study (historical control, based on retrospective review)	Mean (SD; range) days spent on the overlay: 140.9 (94.1; 7 to 258)  Pressure injury incidence:  Overlay: 0%  Historical control: 21.8%  P < 0.001		
Intervention - Pressure-Relieving Cushions				
Multi-component air cushion vs. single- compartment air cushion	Damiao and Gentry (2022) <sup>15</sup> SR (1 RCT, 1 non-randomized study – prospective observational)	Neither study found a statistically significant difference.		
Skin protection cushion (consisting of air, gel, or contoured foam) vs. segment (flat) foam cushion	Damiao and Gentry (2022) <sup>15</sup> SR (1 RCT)	There were fewer pressure injuries to the ischial tuberosities in the skin protection cushion group ( $P = 0.04$ ), but no significant difference when considering pressure injuries for the ischial tuberosities and sacrum ( $P = 0.14$ ).		
Tragacanth gel cushion vs. standard foam cushion	Lovegrove et al. (2022) <sup>16</sup> SR (1 RCT)	Shakibamehr et al., 2019:  • Erythema (which was extracted as pressure injury incidence) was high in both groups but significantly lower with the tragacanth gel cushion (P = 0.008; per-protocol; post hoc ITT P = 0.034).		



Comparison (intervention vs. comparator)	Study design and citation	Study findings
Special position cushion with a sacrococcygeal pad and a back pad vs. conventional hip sponge pad	Xue and Yang (2021) <sup>20</sup> RCT	Incidence of postoperative pressure injuries was lower in the intervention group (P = 0.05) during hospital stay.

CI = confidence interval; ITT = intention to treat; NMA = network meta-analysis; OR = odds ratio; PP = per-protocol; RR = risk ratio; RCT = randomized controlled trial; SR = systematic review.

# Table 7: Summary of Findings for Therapeutic Support Surfaces for Prevention – Time to Pressure Injury Development

Comparison (Intervention vs. comparator)	Study design and citation	Outcome		
Interven	Intervention - Support Surfaces (Mattresses, Beds, Overlays)			
Reactive sheepskin surfaces vs. standard hospital surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	HR (95% CI) from NMA = 0.45 (0.21 to 0.94)		
Foam surfaces vs. standard or undefined hospital surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	HR (95% CI) from NMA = 0.70 (0.32 to 1.54)		
Alternating-pressure (active) air surfaces vs. reactive air surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	HR (95% CI) from NMA = 2.25 (0.58 to 8.75) Direct pairwise HR (95% CI): 2.25 (1.05 to 4.83) <sup>a</sup>		
Alternating-pressure (active) air surfaces vs. foam surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	HR (95% CI) from NMA = 0.45 (0.17 to 1.16)		
Reactive air surfaces vs. foam surfaces	Shi et al. (2021)¹ Overview of reviews with NMA	HR (95% CI) from NMA = 0.20 (0.04 to 1.05)		
Reactive sheepskin vs. foam surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	HR (95% CI) from NMA = 0.64 (0.22 to 1.88)		
Alternating-pressure (active) air surfaces vs. reactive sheepskin surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	HR (95% CI) from NMA = 0.71 (0.17 to 2.95)		
Reactive air surfaces vs. reactive sheepskin surfaces  Shi et al. (2021)¹ Overview of reviews with NMA		HR (95% CI) from NMA = 0.31 (0.04 to 2.26)		
Alternating-pressure (active) air surfaces vs. standard hospital surfaces				
Reactive air surfaces vs. standard hospital surfaces	Shi et al. (2021)¹ Overview of reviews with NMA	HR (95% CI) from NMA = 0.14 (0.02 to 0.87)		
Alternating-pressure (active) air surfaces vs. another type of alternating-pressure (active) air surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (2 RCTs, N = 2581)	Both studies indicated no clear difference of developing a pressure injury at up to 60 days.		

<sup>&</sup>lt;sup>a</sup>The SRs by Lovegrove et al. largely overlap with the overview of reviews by Shi et al<sup>1</sup>: from the RCTs relevant to this report and this outcome, Lovegrove et al. (2022)<sup>16</sup> has 1 unique study, while Lovegrove et al. (2021)<sup>18</sup> overlaps entirely with the overview. Their meta-analyses results are presented here due to their focus on specific care settings (ICU and acute care, respectively), as the overview of reviews did not conduct analyses by different care settings, and this may be a cause of heterogeneity.



Comparison (Intervention vs. comparator)	Study design and citation	Outcome	
Foam surfaces vs. other types of foam	Shi et al. (2021) <sup>1</sup>	Direct comparison, HR (95% CI):	
surfaces	Overview of reviews (2 RCTs, N = 146)	<ul> <li>40 to 60kg/m³, vs. 33 kg/m³ in ICU: 0.33 (0.17 to 0.64)</li> </ul>	
		<ul> <li>Solid foam vs. convoluted foam in acute and LTC: 0.40 (0.20 to 0.80)</li> </ul>	
	Bai et al. (2020) <sup>24</sup>	Mean days to pressure injury:	
	Non-randomized study (observational	<ul><li>Pressure-redistributing mattress: 8.5</li></ul>	
	prospective cohort, N = 254)	<ul> <li>Non-pressure redistributing foam mattress: 4.3</li> </ul>	
		• P = 0.041	
Reactive air surfaces vs. another type	Shi et al. (2021) <sup>1</sup>	Reported no significant difference	
of reactive air surfaces	Overview of reviews (1 RCT, N = 123)		
Intervention - Pressure-Redistributing Cushions			
Tragacanth gel cushion vs. standard foam cushion	Lovegrove et al. (2022) <sup>16</sup>	Shakibamehr et al., 2019 – mean (SD) days	
	SR (1 relevant RCT, N = 100)	to erythema (pressure injury):	
		• Tragacanth gel cushion: 6.84 (1.58)	
		• Standard foam cushion: 5.67 (1.26)	
		• PP: P = 0.006	

CI = confidence interval; HR = hazard ratio; ICU = intensive care unit; NMA = network meta-analysis; PP = per-protocol; RCT = randomized controlled trial; SR = systematic review.

Table 8: Summary of Findings for Therapeutic Support Surfaces for Prevention - Adverse Events

Comparison	Author (Year), study design, length of follow-up	Setting	Outcome(s)
	Intervention - Ma	attress, Beds, Overla	ays
Alternating-pressure (active) air surfaces vs. foam surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (3 relevant RCTs)	Acute and LTC	Two studies reported similar rates of adverse events between both groups; the third study reported 1 death but did not specify which group.
Alternating-pressure (active) air surfaces vs. another type of alternating-pressure (active) air surface	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 relevant RCT)	Acute and LTC	Study reported total number of adverse events but did not report data by treatment vs. control group.
Foam surfaces vs. reactive air surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 relevant RCT)	Acute	Counts of adverse events were reported for each group. The review authors stated it is unclear if there is a difference.
Foam surfaces vs. undefined surfaces (Bedcare)	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 relevant RCT)	LTC	No adverse events were reported in either group.

<sup>&</sup>lt;sup>a</sup>The network contrast of reactive air surfaces vs. alternating-pressure air surfaces has a wide confidence interval with the review authors state is due to data sparseness, and they state they consider the direct pairwise comparison to be more reliable, so both are presented in the table. For all other network contrasts, there were no substantial differences between the results of the NMA and pairwise analyses.



Comparison	Author (Year), study design, length of follow-up	Setting	Outcome(s)
Reactive gel surfaces compared with undefined surfaces (Aiartex)	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 relevant RCT)	LTC	Study indicated no adverse events.
Intervention - Cushion			
Special postoperative position cushion with a sacrococcygeal pad and a back pad vs. conventional hip sponge pads	Xue and Yang (2021) <sup>20</sup> RCT	Hospital	Incidence of renal hemorrhage due to improper postoperative position and rate of tube folding of the renal fistula were lower in the intervention group than comparator group (P = 0.05).

LTC = long-term care; NR = not reported; RCT = randomized controlled trial.

Table 9: Summary of Findings for Therapeutic Support Surfaces for Prevention – Health-Related Quality of Life

Comparison	Author (Year), study design, length of follow-up	Setting	Outcome(s)
	Intervention – M	attress, Beds, Ove	rlays
Alternating-pressure (active) air surfaces vs. foam surfaces	Shi et al. (2021)¹ Overview of reviews (1 relevant RCT) Follow-up: 90 days	Acute and LTC	Mean difference (95% CI):  • 90-day EQ-5D-5L: 0.00 (-0.05 to 0.05)  • 90-day PU-QoL-UI: 0.00 (-0.03 to 0.03)
Reactive sheepskin surfaces vs. undefined 'standard hospital surfaces'	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 relevant RCT) Follow-up: NR	LTC	Mean score on visual analogue scale:  Reactive sheepskin: 62.1  Standard hospital surface: 61.3  P = 0.71

EQ-5D-5L = EuroQol 5-Dimensions 5-Levels; LTC = long-term care; NR = not reported; PU-QoL-UI = Pressure Ulcer Quality of Life Utility Instrument; RCT = randomized controlled trial.

Table 10: Summary of Findings for Therapeutic Support Surfaces for Treatment – Proportion of Patients With Healed Pressure Injuries

Comparison (Intervention vs. comparator)	Study design and citation	Outcome
	Intervention - Mattress, Beds, C	Overlays
Reactive water surface vs. alternative pressure (active) air surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	RR (95% CI) from NMA = 1.03 (0.27 to 3.98)
Reactive water surface vs. reactive air surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	RR (95% CI) from NMA = 0.76 (0.48 to 1.19)
Reactive water surface vs. foam surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	RR (95% CI) from NMA = 1.00 (0.72 to 1.38)



Comparison (Intervention vs. comparator)	Study design and citation	Outcome
Alternating-pressure (active) air surface vs. reactive air surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	RR (95% CI) from NMA = 0.74 (0.19 to 2.82)
Alternating-pressure (active) air surface vs. foam surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	RR (95% CI) from NMA = 0.97 (0.26 to 3.58)
Reactive air surface vs. foam surface	Shi et al. (2021) <sup>1</sup> Overview of reviews with NMA	RR (95% CI) from NMA = 1.32 (0.96 to 1.80)
Alternating-pressure (active) air surfaces compared with another type of alternating-pressure (active) air surface	Shi et al. (2021) <sup>1</sup> Overview of reviews (3 RCTs)	All RCTs reported no statistically significant differences for improvement, healing, or number of healed heel ulcers.
Reactive gel surfaces vs. undefined reactive surfaces (Aiartex)	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 RCT)	Direct pairwise RR (95% CI) = 1.58 (0.41 to 6.11)

CI = confidence interval; LTC = long-term care; NA = not applicable; NMA = network meta-analysis; NR = not reported; RCT = randomized controlled trial; RR = risk ratio.

### Table 11: Summary of Findings for Therapeutic Support Surfaces for Treatment – Status of Pressure Injury

Comparison	Author (Year), study design, follow-up	Setting	Outcome(s)
Fully automated pulsating support system air mattress (before-after comparison)	Raepsaet et al. (2021) <sup>22</sup> Multicenter cohort study Follow-up: 30 days	Nursing homes	Mean (range) PUSH score:  • Baseline: 9.36 (3 to 17)  • Follow-up: 7.7 (0 to 15)  Most existing pressure injuries did not deteriorate and some improved (reduced PUSH score), but deterioration was also seen. No statistical tests were conducted.

PUSH = Pressure Ulcer Scale for Healing.

### Table 12: Summary of Findings for Therapeutic Support Surfaces for Treatment – Time to Pressure Injury Healing

Comparison (Intervention vs. comparator)	Study design and citation	Setting(s)	HR (95% CI)	Certainty of evidence
Reactive air surfaces	Shi et al. (2021) <sup>1</sup>	LTC	2.66 (1.34 to 5.17)	Low
vs. foam surfaces	Overview of reviews (1 RCT)			
	Median follow-up: 37.5 days			

CI = confidence interval; HR = hazard ratio; LTC = long-term care; NR = not reported; RCT = randomized controlled trial.



Table 13: Summary of Findings for Therapeutic Support Surfaces for Treatment – Adverse Events

Comparison	Author (Year), study design	Setting	Outcome(s)
Alternating-pressure (active) air surfaces vs. foam surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 RCT)	Acute care	No major adverse events attributed to support surfaces. Uncertain if there is a difference.
Foam surfaces vs. reactive water surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 RCT)	LTC	Defined by primary study authors as eczema, maceration, and pain; incidence or difference between groups not reported by review authors. Uncertain if there is a difference.
Reactive air surfaces vs. foam surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (2 RCTs)	Acute care	Both studies did not clearly suggest any difference in adverse events. Uncertain if there is a difference.
Alternating-pressure (active) air surfaces compared with another type of alternating-pressure (active) air surface	Shi et al. (2021) <sup>1</sup> Overview of reviews (4 RCTs)	Acute and LTC	Studies largely reported death data but did not state other adverse events, outcome data were not pooled. Uncertain if there is a difference.
Reactive air surfaces vs. undefined standard hospital surfaces	Shi et al. (2021) <sup>1</sup> Overview of reviews (2 RCTs)	Acute and LTC	Review authors did not pool data due to different definitions of adverse events. Uncertain if there is a difference.
Reactive gel surfaces vs. undefined reactive surfaces (Aiartex)	Shi et al. (2021) <sup>1</sup> Overview of reviews (1 RCT)	LTC	Review authors did not pool data due to different definitions of adverse events. Uncertain if there is a difference.

CI = confidence interval; HR = hazard ratio; LTC = long-term care; RCT = randomized controlled trial.



Table 14: Summary of Findings for Therapeutic Small Devices for Prevention – Pressure Injury Incidence

Comparison (Intervention vs. comparator)	Study design and citation	Outcome
Heel protector for offloading heels vs. pillows	Lovegrove et al. (2022) <sup>16</sup> SR (1 RCT)	Meyers, 2017 – pressure injury incidence:  • Heel protector: 0%  • Pillows: 41.2%  • ITT: P < 0.001
Heel protection devices vs. standard care (per admitting ward, standard pressure- redistributing support surface) or pillow	Lovegrove et al. (2021) <sup>18</sup> SR with MA	ITT (3 RCTs): RR (95% CI) = 0.64 (0.22 to 1.87) PP (2 RCTs): RR (95% CI) = 0.38 (0.21 to 0.67)
Heel-offloading boot vs. standard practice (pillows)	Barakat-Johnson et al. (2022) <sup>19</sup> Single-blinded RCT	OR (95% CI) = 0.0883 (0.0104 to 0.749).  Severity of observed pressure injuries were:  Intervention group: Stage I (N = 1)  Control group: Stage I (N = 5), Stage II (N = 2), and suspected deep tissue (N = 4)
Bunny boot vs. egg crate vs. foot waffle	Lovegrove et al. (2021) <sup>18</sup> SR (1 RCT)	Gilcreast et al., 2005:  • Pressure injury incidence was similar across all groups (PP: P = 0.416)

CI = confidence interval; ITT = intention-to-treat; MA = meta-analysis; OR = odds ratio; RCT = randomized controlled trial; RR = risk ratio; SR = systematic review.

# Table 15: Summary of Findings for Therapeutic Small Devices for Prevention – Time to Pressure Injury Development

Comparison (Intervention vs. comparator)	Study design and citation	Outcome
Foot waffle device vs. heel elevation with a hospital pillow	Lovegrove et al. (2021) <sup>18</sup> SR (1 RCT)	Tymec et al., 1997 – mean days to pressure injury:  Foot waffle: 10  Pillow: 13  Analysis "did not demonstrate a significant difference"
Heel-offloading boot vs. standard practice (pillows)	Barakat-Johnson et al. (2022) <sup>19</sup> Single-blinded RCT	HR (95% CI) = 0.0896 (0.0110 to 0.727)  "hazard of ICU-acquired heel PI [pressure injury] from admission to ICU was 11.2 times less in the intervention group than in controls" (p.6)

CI = confidence interval; HR = hazard ratio; ICU = intensive care unit; RCT = randomized controlled trial.



### Appendix 5: Overlap Between Included Systematic Reviews

Note that this appendix has not been copy-edited.

Table 16: Overlap in Relevant Primary Studies Between Included Systematic Reviews

Primary study citation	Shi et al., 2021¹	Bambi et al., 2022 <sup>14</sup>	Damiao et al., 2022 <sup>15</sup>	Lovegrove et al., 2022 <sup>16</sup>	Lovegrove et al., 2021 <sup>18</sup>
Allman et al. <i>Ann Intern Med</i> 1987;107(5):641-8.	Yes	_	-	-	-
Andersen et al. <i>Acta Dermatovener (Stockholm)</i> 1982;63:227 to 30	Yes	_	-	-	Yes
Aronovitch et al. Ostomy Wound Manage 1999;45(3):34 to 44.	Yes	-	-	-	Yes
Bååth et al. Appl Nurs Res 2015;30, 170 to 175	_	-	_	_	Yes
Ballard K. <i>Prof Nurse</i> 1997;13(1):27 to 32.	Yes	-	_	_	_
Beeckman et al. Int. J Nurs Stud 2019;97:105 to 13.	Yes	-	-	_	_
Bennett et al. <i>J Am Geriatr Soc</i> 1998;46(5):569 to 76.	Yes	-	_	-	Yes
Berthe et al. <i>Acta Chirurgica Belgica</i> 2007;107(2):155 to 61.	Yes	_	-	-	Yes
Bharucha et al. <i>J Wound Ostomy Cont Nurs</i> 2018;45(4), 310 to 6.	_	-	-	-	Yes
Black et al. <i>J Wound Ostomy Cont Nurs</i> 2012;39:267 to 73	_	Yes	-	-	-
Bliss et al. <i>BMJ</i> 1967;1(5537):394 to 7	Yes	-	_	_	_
Bliss. Age Aging 1995;24:297 to 302	Yes	-	-	-	_
Brienza et al. <i>J Am Geriatr Soc</i> 2010;58(12), 2308 to 2314.	-	_	Yes	-	-
Brienza et al. <i>J Am Geriatr Soc</i> 2018;66(9), 1752 to 1759.	-	_	Yes	_	-
Bueno de Camargo et al. <i>Crit Care Res Pract</i> 2018;2018:Article ID 3712067.	Yes	Yes	-	Yes	-
Cassino et al. Acta Vulnologica 2013;11(1):15 to 21.	Yes	-	-	-	-
Cassino et al. <i>Minerva Chirurgica</i> 2013;68(1):105 to 16.	Yes	-	-	-	-
Cavicchioli et al. J Wound Care 2007;16(7):285 to 9.	Yes	-	-	_	_
Cobb et al. <i>TriService Nursing Research Program</i> (TSNRP) 1997.	Yes	-	-	-	Yes
Collier. J Wound Care 1996;5(5):207 to 11	Yes	_	-	_	_
Conine et al. Rehabilitation Nurs 1990;15(3):133 to 7.	Yes	-	-	-	_
Cooper et al. <i>J Wound Care</i> 1998;7(8):374 to 6	Yes	-	-	-	Yes



Primary study citation	Shi et al., 2021 <sup>1</sup>	Bambi et al., 2022 <sup>14</sup>	Damiao et al., 2022 <sup>15</sup>	Lovegrove et al., 2022 <sup>16</sup>	Lovegrove et al., 2021 <sup>18</sup>
Daechsel et al. <i>Arch Phys Med Rehabil</i> 1985;66(4):246 to 8.	Yes	-	-	_	-
Day et al. <i>Decubitus</i> 1993;6(1):32 to 43.	Yes	-	_	-	-
Demarre et al. <i>Int J Nurs Stud</i> 2012;49(4):416 to 26.	Yes	Yes	_	-	Yes
Devine. J Tissue Viability 1995;5(3):94 to 8.	Yes	-	_	-	-
Donnelly et al. <i>J Wound Care</i> 2011;20 (7), 309 to 318.	_	-	_	-	Yes
Evans et al. J Wound Care 2000;9(4):181 to 6.	Yes	-	_	-	-
Ewing et al. <i>Australian Nurses'</i> Journal 1964;1964 September:215 to 9.	Yes	-	-	_	-
Ferrell et al. <i>JAMA</i> 1993;269(4):494 to 7	Yes	-	_	-	-
Feuchtinger et al. J Clin Nurs 2006;15(2):162 to 7	Yes	-	_	-	-
Finnegan et al. <i>J Tissue Viability</i> 2008;17(1):2 to 9	Yes	-	_	-	-
Gilcreast et al. <i>J. Wound Ostomy Cont. Nurs.</i> 2005; 32 (2), 112 to 120.	-	-	-	_	Yes
Gray et al. J Tissue Viability 1994;4(4):128 to 32.	Yes	-	_	_	Yes
Gray et al. <i>J Wound Care</i> 2000;9(1):29 to 31.	Yes	-	_	-	Yes
Gray et al. Wounds UK 2008;4(4):124 to 8.	Yes	-	_	-	_
Grindley et al. <i>Br J Nurs (Mark Allen Publishing)</i> 1996;5(21):1303 to 10.	Yes	-	-	_	_
Groen et al. <i>Journal of Wound Care</i> 1999;8(7):333 to 5.	Yes	-	-	_	_
Gunningberg et al. <i>Journal of Wound Care</i> 2000;9(10):455 to 60.	Yes	-	-	_	Yes
Hampton. Br J Nurs (Mark Allen Publishing) 1997;6(3):167 to 70.	Yes	-	-	-	-
Hofman et al. <i>Lancet (London, England)</i> 1994;343(8897):568 to 71	Yes	-	-	-	Yes
Hoshowsky et al. <i>Res Nurs Health</i> 1994;17(5):333 to 9	Yes	-	-	_	_
Inman et al. <i>JAMA</i> 1993;269(9):1139 to 43	Yes	-	_	Yes	-
IRCT2015110619919N3. 2016	Yes	-	_	-	-
Jiang et al. Adv Skin Wound Care 2020;33(3):1 to 9	-	Yes	_	-	-
Jiang et al. Int J Clin Exp Med 2014;7(9):2820 to 7.	Yes	Yes	_	-	Yes
Jolley et al. <i>Med J Aust</i> 2004;180(7):324 to 7.	Yes	-	-	-	Yes
Kemp et al. Res Nurs Health 1993;16(2):89 to 96	Yes	-	_	-	-
Laurent. 3rd European Conference for Nurse Managers, 1997 Oct; Brussels (Belgium) 1998	Yes	-	-	-	-



Primary study citation	Shi et al., 2021 <sup>1</sup>	Bambi et al., 2022 <sup>14</sup>	Damiao et al., 2022 <sup>15</sup>	Lovegrove et al., 2022 <sup>16</sup>	Lovegrove et al., 2021 <sup>18</sup>
Lazzara et al. <i>Decubitus</i> 1991;4(4):42 to 4, 46, 48.	Yes	-	-	-	-
Malbrain et al. <i>J Tissue Viability</i> 2010;19(1):7 to 15	Yes	-	-	-	_
Manzano et al. <i>J Adv Nurs</i> 2013;69:2099 to 106.	_	Yes	_	_	_
Marvaki et al. Cureus 2020;12:e8785.	-	Yes	-	_	-
McGowan et al. Primary Intention 2000:127 to 34.	Yes	-	-	_	Yes
Meaume et al. <i>J Wound Care</i> 2017; 26(9), 537 to 544.	-	_	Yes	-	-
Meyers. J Wound, Ostomy Cont Nurs 2017;44(5):429e33.	-	_	_	Yes	-
Mistiaen P et al. Wound Repair Regen 2010;18(6):572 to 9.	Yes	_	-	_	-
Mulder et al. <i>J Geriatric Dermatology</i> 1994;2(3):87 to 91.	Yes	_	-	-	-
Munro et al. Geriatr Nurs 1989;10:190 to 2.	Yes	-	-	-	_
Nixon et al. Health Technology Assessment (Winchester, England) 2006;10(22):1 to 163.	Yes	-	_	_	Yes
Nixon et al. Health Technology Assessment (Winchester, England) 2019;23(52):1 to 176.	Yes	-	-	_	Yes
Nixon et al. Int J Nurs Stud 1998;35(4):193 to 203	Yes	-	-	-	-
Ozyurek et al. Clin Nurse Spec 2015;29(4):210 to 7	Yes	Yes	-	Yes	-
Park et al. <i>J Wound Ostomy Continence Nurs</i> 2017;44(5):440 to 4.	Yes	_	-	_	Yes
Phillips. <i>Br J Nurs (Mark Allen Publishing)</i> 1999;8(21):1447 to 52	Yes	_	-	_	_
Price et al. <i>J Wound Care</i> 1999;8(4):187 to 90.	Yes	-	-	-	Yes
Pring et al. J Wound Care 1998;7(4):177 to 9.	Yes	_	-	_	_
Rafter. <i>Br J Nur</i> s 2011;20(11):32.	Yes	_	-	_	_
Ricci et al. EWMA Journal 2013;13(1):27 to 32.	Yes	_	-	_	_
Rosenthal et al. <i>Arch Phys Med Rehabil</i> 2003;84(12):1733 to 42.	Yes	_	-	_	_
Russell et al. Adv Skin Wound Care 2003;16(6):317 to 27.	Yes	-	_	_	Yes
Russell et al. <i>Ostomy Wound Manage</i> 2000;46(2):46 to 51,54 to 5.	Yes	-	-	_	Yes
Sanada et al. <i>J Tissue Viability</i> 2003;13(3):112 to 4, 116, 118.	Yes	-	-	-	Yes
Santy et al. Report to Northern and Yorkshire Regional Health Authority 1994.	Yes	-	-	_	-
Sauvage et al. <i>J Wound Care</i> 2017;26(6):304 to 12.	Yes	_	-	-	-



Primary study citation	Shi et al., 2021 <sup>1</sup>	Bambi et al., 2022 <sup>14</sup>	Damiao et al., 2022 <sup>15</sup>	Lovegrove et al., 2022 <sup>16</sup>	Lovegrove et al., 2021 <sup>18</sup>
Schultz et al. <i>AORN Journal</i> 1999;70(3):434, 437 to 40, 443 to 9	Yes	_	_	_	_
Shakibamehr et al. <i>J Caring Sci</i> 2019;8(1):45e9. https://doi.org/10.15171/jcs.2019.007.	_	-	-	Yes	-
Sideranko et al. Res Nurs Health 1992;15(4):245 to 51.	Yes	-	-	_	-
Stapleton. <i>Geriatr Nurs (London, England)</i> 1986;6(2):23 to 5.	Yes	-	-	_	-
Strauss et al. <i>J Fam Pract</i> 1991;33(1):52 to 9.	Yes	-	_	-	-
Takala et al. Clin Intensive Care 1996;7(5):228 to 35.	Yes	-	_	Yes	-
Taylor. Br J Nurs (Mark Allen Publishing) 1999;8(12):771 to 4,776 to 8.	Yes	-	-	_	-
Theaker et al. Anaesthesia 2005;60(4):395 to 9	Yes	-	_	Yes	_
Tymec et al. Adv. Wound Care 1997; 10 (1), 39 to 44.	_	-	-	-	Yes
Van Leen et al. Adv Skin Wound Care 2018;31(1):1 to 5.	Yes	-	-	_	-
Van Leen et al. <i>J Tissue Viability</i> 2011;20(1):30 to 4.	Yes	-	_	-	-
Van Leen et al. Wounds 2013;25(10):287 to 92.	Yes	-	_	-	-
Vanderwee et al. Age Aging 2005;34(3):261 to 7.	Yes	-	_	-	Yes
Vermette et al. Wounds 2012;24(8):207 to 14.	Yes	-	_	-	Yes
Vyhlidal et al. Appl Nurs Res 1997;10(3):111 to 20.	Yes	-	_	_	_
Whitney et al. <i>J Gerontol Nurs</i> 1984;10(9):20 to 1, 24 to 5	Yes	_	-	-	-
Whittingham. J Tissue Viability 1999;9(3):104	Yes	-	_	_	_

Note: The systematic review by Stephens et al.  $(2022)^{17}$  is not included in this table since they did not identify any relevant studies.



### **Appendix 6: References of Potential Interest**

Note that this appendix has not been copy-edited.

#### **Previous CADTH Reports**

Off-Loading Devices for People with Diabetic Neuropathic Foot Ulcers: A Rapid Qualitative Review. Ottawa (ON): CADTH, 2020. https://www.cadth.ca/loading-devices -people-diabetic-neuropathic-foot-ulcers-rapid-qualitative-review. Accessed 2022 Jul 22.

Lateral Rotation Mattresses for the Prevention and Treatment of Pressure Injuries: Clinical Effectiveness and Guidelines. Ottawa (ON): CADTH, 2019. https://www.cadth.ca/lateral-rotation-mattresses-prevention-and-treatment-pressure-injuries-clinical-effectiveness-and. Accessed 2022 Jul 22.

Mattresses or Overlays Used in Palliative End-of-Life Care: Clinical Evidence and Guidelines. Ottawa (ON): CADTH, 2019. <a href="https://www.cadth.ca/mattresses-or-overlays-used-palliative-end-life-care-clinical-evidence-and-guidelines">https://www.cadth.ca/mattresses-or-overlays-used-palliative-end-life-care-clinical-evidence-and-guidelines</a>. Accessed 2022 Jul 22.

Non-Pharmacological Prevention of Pressure Injuries: An Environmental Scan. Ottawa (ON): CADTH, 2019. <a href="https://www.cadth.ca/non-pharmacological-prevention-pressure-injuries-environmental-scan">https://www.cadth.ca/non-pharmacological-prevention-pressure-injuries-environmental-scan</a>. Accessed 2022 Jul 22.

#### **Health Technology Assessments**

#### Published Before 2020

Fibreglass total contact casting, removable cast walkers, and irremovable cast walkers to treat diabetic neuropathic foot ulcers: a health technology assessment. Toronto (ON): Health Quality Ontario, 2017. Accessed 2022 Aug 08. <a href="http://www.hqontario.ca/Portals/0/Documents/evidence/reports/hta-fibreglass-1709-en.pdf">http://www.hqontario.ca/Portals/0/Documents/evidence/reports/hta-fibreglass-1709-en.pdf</a>

#### Systematic Reviews

#### Published Before 2020

Gaspar S, Peralta M, Marques A, Budri A, Gaspar de Matos M. Effectiveness on hospital-acquired pressure ulcers prevention: a systematic review. *Int. Wound J.* 2019;16(5):1087-1102. PubMed

Maki-Turja-Rostedt S, Stolt M, Leino-Kilpi H, Haavisto E. Preventive interventions for pressure ulcers in long-term older people care facilities: A systematic review. *J. Clin. Nurs.* 2019;28(13-14):2420-2442. PubMed

Rae KE, Isbel S, Upton D. Support surfaces for the treatment and prevention of pressure ulcers: a systematic literature review. J. Wound Care. 2018;27(8):467-474. PubMed

Shi C, Dumville JC, Cullum N. Support surfaces for pressure ulcer prevention: A network meta-analysis. PLoS ONE [Electronic Resource]. 2018;13(2):e0192707. PubMed