TESTING THE EFFECTIVENESS OF PRESSURE MATTRESSES FOR PEOPLE OVER 65 YEARS RESIDING IN THE COMMUNITY: A PHD RESEARCH PROPOSAL AND PROTOCOL

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Introduction

Pressure injuries are defined as injury to tissue as a result of sustained pressure, occasionally in conjunction with shear forces (National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA), 2014). They tend to occur over bony prominences where circulation is more likely to be interrupted or areas that experience high levels of friction (NPUAP, EPUAP, & PPPIA, 2014). They occur globally with incidence rates varying dependent on country and setting, despite being a largely preventable condition (Graves & Zheng, 2014b). Graves and Zheng (2014b) reported pressure injury prevalence estimates across 11 countries of "1.1% to 26.7% in the hospital setting [and] 6% to 29% in the community setting" (p.5). Epidemiological studies have shown that risk factors for pressure injury development can include level of mobility; skin integrity; the presence of co-morbidities that impact on tissue oxygenation or blood perfusion; nutritional status; and skin microclimate (such as temperature and moisture) (NPUAP, EPUAP, & PPPIA, 2014). Pressure injuries are costly to a health service with costs to Australian health services in 2010-11 estimated to be US$1.64 billion (Graves & Zheng, 2014a). This cost includes increased lengths of stay, the need for additional intervention, and increasing complications and mortality rates. As a result they are often seen as an indicator of quality of care (Graves & Zheng, 2014b; Manzano et al., 2013).

Clinical guidelines recommend management of the extrinsic factors to reduce incidence and to treat existing pressure injuries (NPUAP, EPUAP, & PPPIA, 2014). One of the key strategies is the provision of appropriate support surfaces, such as pressure mattresses and pressure cushions (NPUAP, EPUAP, & PPPIA, 2014). There is a wide range of support surfaces available with differing techniques for providing pressure care. Reactive surfaces use envelopment and immersion to increase surface area, reducing interface pressure. Active surfaces use removal of pressure for short periods of time to allow improved re-perfusion. When prescribing an appropriate mattress the clinician needs to take into consideration a range of factors: the individual's pressure injury risk level as determined with risk assessment tools in conjunction with clinical reasoning, the individual's ability to move and reposition off the at risk area, their risk factors and the environment the support surface will be used (NPUAP, EPUAP, & PPPIA, 2014).

Often clinicians are reliant on supplier-stated claims of the degree of pressure care to prescribe mattresses with active support surfaces considered a higher level of pressure care than reactive, and thicker support surfaces also being seen as providing a higher level of pressure care. However technological advances have seen an increase in reactive mattresses that are supplier-stated to provide a comparable level of pressure care to active surfaces, with the added benefit of being easier to reposition on.

The research that has been completed to date in the area of pressure care mattresses has been lacking in quality with significant methodological limitations such as lack of blind assessors, underpowered and presence of confounding factors (Chou et al., 2013; McInnes, Dumville, Jammali-Blasi, & Bell-Syer, 2011; McInnes et al., 2015). The better quality studies have not found any statistically significant differences however as they have generally focused on mattress brands rather than the over-arching mattress types they are less transferable into other clinical settings, particularly as the studies age and technological advances occur.

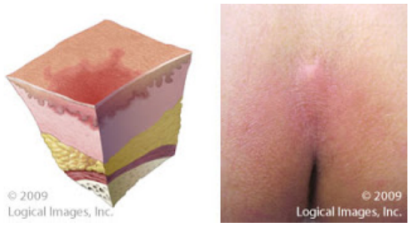
Definitions

Pressure injury grading

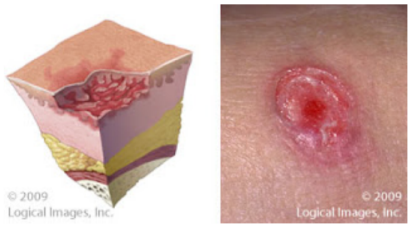
Pressure injuries are commonly classified using the international classification system described by the NPUAP, EPUAP, & PPPIA (2014). This international classification system defines the different levels of pressure injury based on the degree of damage to the skin and underlying tissues and include two categories for when the degree of damage is unable to be easily determined (Information Box 1).

INFORMATION BOX 1 **Pressure Injury Classification**

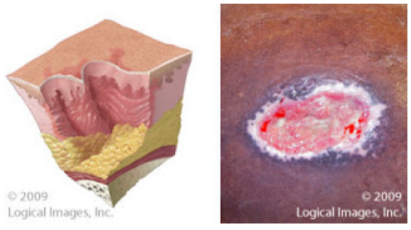
Grade 1: Nonblanchable Erythema – intact skin with nonblanchable redness, may be painful, difficult to detect in people with darker skin



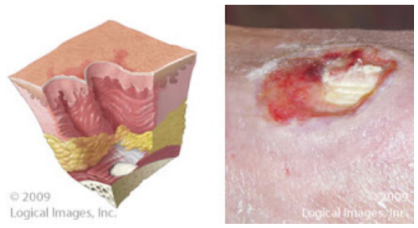
Grade 2: Partial Thickness Skin Loss – skin has broken however the wound bed remains shallow and without slough, may also present as a serum-filled blister (ruptured or unruptured)



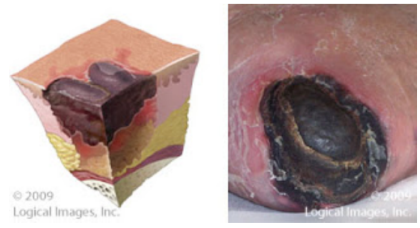
Grade 3: Full Thickness Skin Loss – deeper wound that has visible subcutaneous tissue however muscle, bone or tendons are not exposed, may include undermining and tunnelling, slough may be present but does not obscure the depth



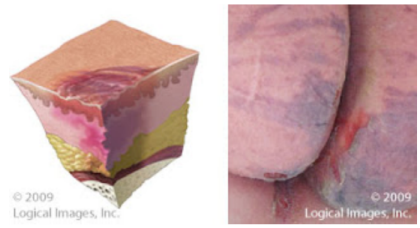
Grade 4: Full Thickness Tissue Loss – subcutaneous tissue is visible, as is bone, tendons or muscle, undermining and tunnelling often included.



Unstageable: Depth Unknown – full thickness tissue loss where the wound bed is obscured by slough and/or eschar. This classification is used until the slough/eschar can be removed safely.



Unstageable: Suspected Deep Tissue Injury – localised discoloured skin or blood-filled blister due to damage to underlying soft tissue from pressure or shear forces, may be painful, boggy or warmer/cooler than surrounding skin, difficult to detect in people with darker skin.



NPUAP, EPUAP & PPPIA (2014), images from John (2011)

Support surfaces

In Australia, occupational therapists play a role in the management of pressure injuries, in part through prescription of support surfaces such as mattresses. There are two main types of support surface, each designed with differing principles to providing pressure care: reactive surfaces and active surfaces (NPUAP et al., 2014).

Reactive support surfaces "provide pressure redistribution as the body increases or decreases its contact with the support surfaces" (Clark, 2011, p. 21). These support surfaces use the principle of pressure reduction through envelopment and immersion (Clark, 2011). Examples include ROHO overlay, Curocell AREA, Atmosair, Arjo Evolve, 4-core high specification foam, Softform Premier, Funke, SAM overlay.

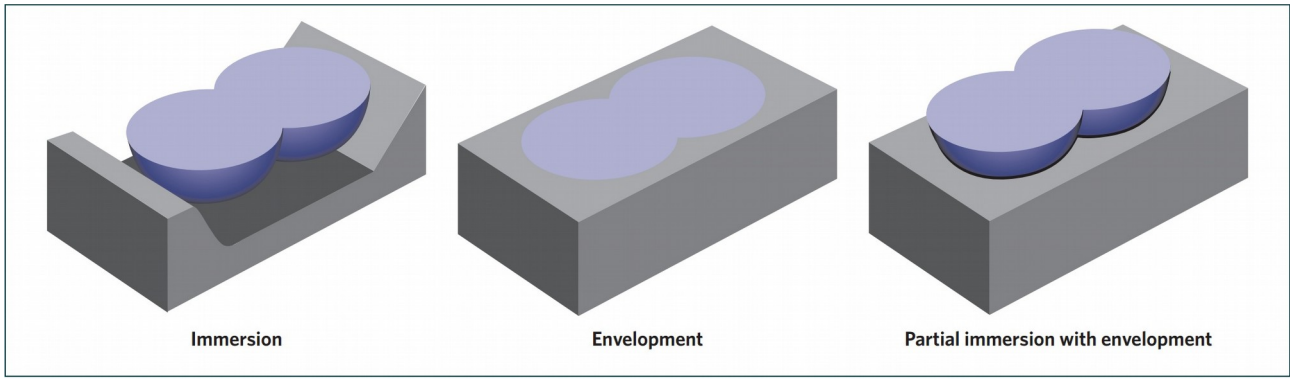


Image from MacGregor (2010)

An active support surface "has the ability to change its load distribution properties with or without an applied load" (NPUAP et al., 2014, p. 105), regardless of the amount of contact of the body with the support surface (Clark, 2011). These support surfaces utilise the principle of pressure relief, removing the pressure for a short period of time, rather than pressure reduction. Examples include Alpha Relief, Nimbus3, Novis Premium Digital 9 or 5, Harvest Cavalier.

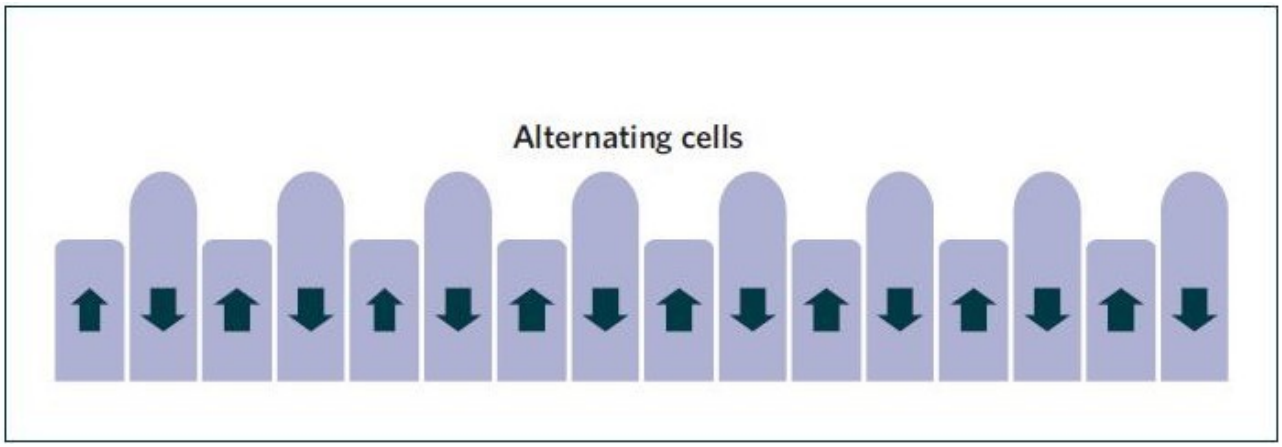


Image from MacGregor (2010)

Becoming more common in clinical practice are hybrid surfaces that utilise both types of support surfaces, either as alternative options within the one mattress (ie can switch between reactive and active options) or with both components working together as in combination (eg an alternating air component with a reactive viscoelastic surface on top)(Fletcher, Gefen, Jones, Sanada, & Irvine, 2015). Examples include Jay Fusion, Zephyr, Curocell Cirrus, Softform Premier Active.

Literature Review

A detailed review of the available literature was conducted to investigate the available evidence regarding the different types of pressure relief and their comparative effectiveness regarding pressure injury prevention and treatment. A search was conducted across CINAHL, Medline Plus, Scopus, Cochrane Library and PubMed. Additional articles were obtained from searches in Google Scholar and by reviewing reference lists in already identified articles.

To be included in the review articles needed to be a randomised-controlled trial (RCT) where the primary intervention was pressure-relieving support surfaces for beds for the purpose of pressure injury prevention or management. Studies were excluded if they focused on wound healing other than pressure injuries, such as traumatic or surgical wounds; pressure-relieving surfaces for pain management; or investigation of interface pressure using healthy participants. Articles solely about pressure-relieving cushions or repositioning beds were also excluded. Due to changes in technology and standards of care, a temporal

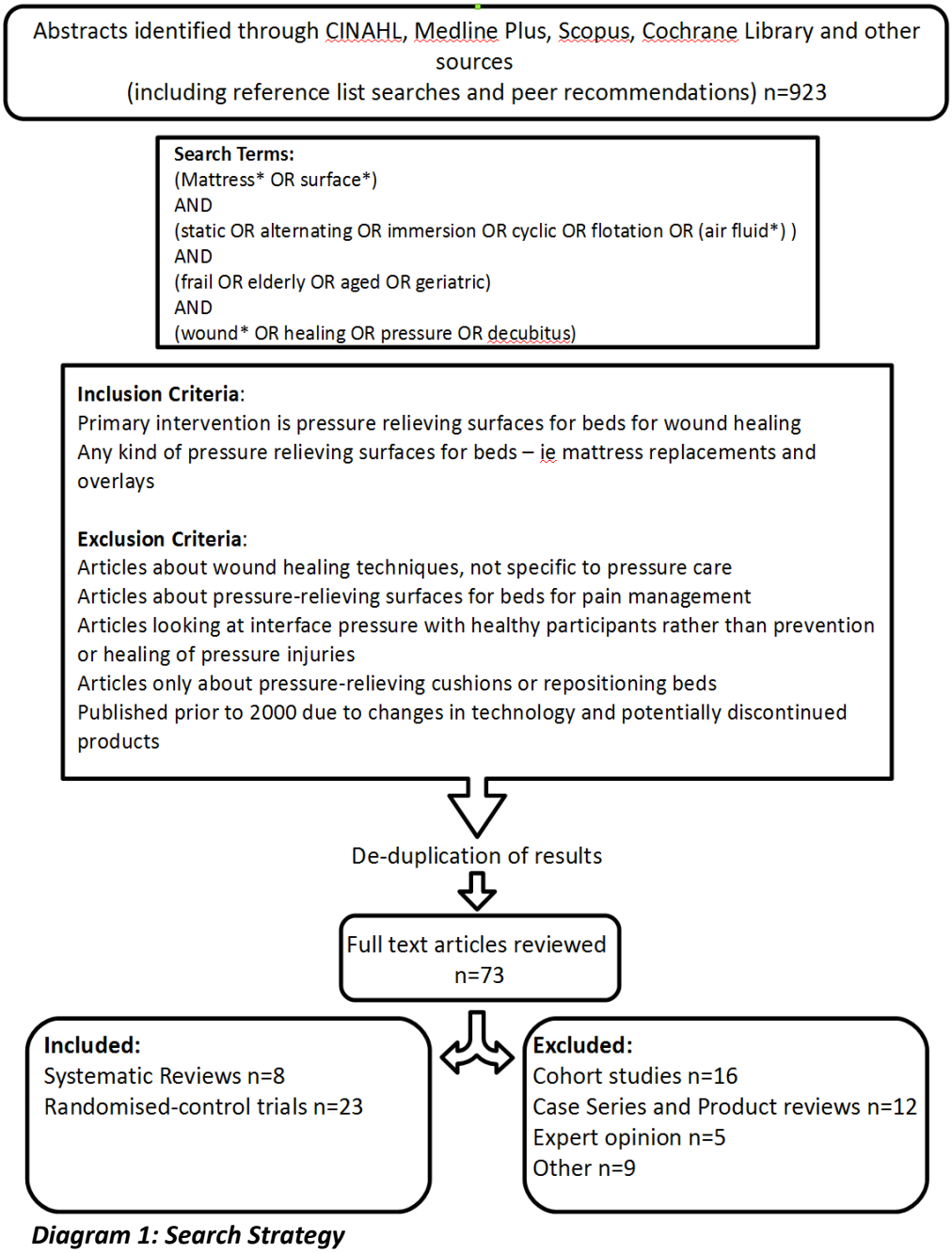


Diagram 1: Search Strategy

limiter was applied restricting the review to studies to those published since 2000. Identified RCTs were assessed for quality using the PEDro Scale (Physiotherapy Evidence Database (PEDro), 1999), a well reported measure of quality for quantitative research (De Morton, 2009; Maher, Sherrington, Herbert, Moseley, & Elkins, 2003).

A total of 20 articles were found to meet the inclusion and exclusion criteria. The quality of the RCTs varied, with PEDro scores ranging 3-9/11 (median=7), with 100% of studies lacking blinding of participants or clinicians and 78% lacking blinding of assessors. Other study limitations not identified by the PEDro Scale included: confounding factors (61%); and underpowered studies (52%) (Table 1). Studies were conducted primarily in acute settings with 87% taking place partially or wholly on hospital wards; 26% in residential care settings such as nursing homes; and 17% in sub-acute or rehabilitation settings. None of the RCTs took place in a community setting (Table 2).

Reactive Support Surfaces

Foam mattresses

Six of the articles included a comparison of viscoelastic foam with another surface (Cavicchioli & Carella, 2007; Gray & Smith, 2000; Gunningberg, Lindholm, Carlsson, & Sjödén, 2000; Russell, Reynolds, Park, et al., 2003; Van Leen, Hovius, Halfens, Neyens, & Schols, 2013; Vanderwee, Grypdonck, & Defloor, 2005). The conclusions arising from these moderate quality studies were that viscoelastic foam mattresses were more effective than standard care (Gray & Smith, 2000; Gunningberg, et al., 2000) however there was inconclusive results when comparing viscoelastic mattresses with other pressure care mattresses (Russell, Reynolds, Park, et al., 2003; Van Leen, et al., 2013; Vanderwee, et al., 2005). Where studies use a 'standard' hospital mattress as the control the definition of standard varies geographically and temporally, with these mattresses often remaining undefined in the publication. In the case of Russell, Reynolds, Park, et al. (2003), this meant that some of the standard care mattresses were pressure-reducing mattresses, meaning the study was really comparing one brand of viscoelastic foam with other brands, for which the data was pooled.

Often these studies were biased by confounding factors, such as one treatment groups receiving frequent repositioning or other pressure mattresses being introduced (Gray & Smith, 2000; Gunningberg, et al., 2000; Russell, Reynolds, Park, et al., 2003; Vanderwee, et al., 2005). Repositioning has been determined as beneficial for reducing the risk of pressure injury development, regardless of the support surface in place (National Pressure Ulcer Advisory Panel, et al., 2014). Other limitations for these studies include unequal recruitment of groups (Cavicchioli & Carella, 2007) and underpowered samples (Cavicchioli & Carella, 2007; Gray & Smith, 2000; Gunningberg, et al., 2000; Van Leen, et al., 2013).

Continuous low pressure

For the purposes of this study, continuous low pressure support surfaces are reactive surfaces that utilise high degrees of immersion and envelopment to reduce interface pressure. Examples of continuous low pressure surfaces includes static air, water, gel and polymer surfaces. Some of the more modern multi-layer foam mattresses would also be considered continuous low pressure surfaces as they provide a higher degree of immersion and envelopment that a single layer viscoelastic foam mattress.

Of the six studies looking at continuous low pressure mattresses one was low quality (Branom & Rappl, 2001), three were moderate quality (Malbrain et al., 2010; Russell, Reynolds, Towns, et al., 2003; Van Leen, et al., 2013) and two were good quality (Jiang et al., 2014; Van Leen, Hovius, Neyens, Halfens, & Schols, 2011). As all except Jiang, et al (2014) were underpowered their results are inconclusive as no statistically significant difference was found in pressure injury prevention or treatment in any of the studies (Branom & Rappl, 2001; Jiang, et al., 2014; Malbrain, et al., 2010; Russell, Reynolds, Towns, et al., 2003; Van Leen, et al., 2013; Van Leen, et al., 2011). Two studies had groups that were dissimilar at baseline, meaning the groups are less comparable, favouring the experimental group (Malbrain, et al., 2010; Russell, Reynolds, Towns, et al., 2003). Branom & Rappl (2001) used a mattress that is supplier-stated to be for treatment of people with up to Grade 2 pressure injuries however excluded participants from their study unless they had a Grade 3 or 4 pressure injury, meaning the tested mattress was already indicated to be a less effective support surface.

Low-Air-Loss Mattresses

Low-air-loss mattresses can be either reactive or active surfaces with the primary feature of a small amount of warmed air to control the skin microclimate (McInnes, et al., 2015). Four studies were identified that addressed low-air-loss: one low quality (Branom & Rappl, 2001); two moderate quality (Cavicchioli & Carella, 2007; Rosenthal et al., 2003); and one good quality study (Theaker, Kuper, & Soni, 2005). As with the studies addressing continuous low pressure mattresses, all were underpowered so their results are inconclusive as no statistically significant difference was found in pressure injury prevention or treatment (Branom & Rappl, 2001; Cavicchioli & Carella, 2007; Rosenthal, et al., 2003; Theaker, et al., 2005). One study had statistical errors that resulted in inappropriate power calculations (Theaker, et al., 2005). Another study was comparing a specific cushion design with a low-air-loss mattress however inadvertently introduced confounding factors, as sitting out of bed results in differing peak pressure points regardless of the surface (Rosenthal, et al., 2003).

Active Support Surfaces

Currently all active support surfaces use an alternating system to redistribute pressure over a period of time, regardless of the user's ability to reposition. However, support surfaces vary with regards to inflation cycle times and inflation ratios. Of the articles reviewed there were twelve RCTs of variable quality that addressed alternating surfaces: 2 of low quality (Demarré et al., 2013; Russell, Reynolds, Carr, Evans, & Holmes, 2000); 5 of moderate quality (Cavicchioli & Carella, 2007; Jiang, et al., 2014; Malbrain, et al., 2010; Russell, Reynolds, Towns, et al., 2003; Vanderwee, et al., 2005); and 5 of good quality (Demarré et al., 2012; Evans, Land, & Geary, 2000; Nixon et al., 2006; Sanada et al., 2003; Theaker, et al., 2005).

Although seven studies were underpowered (Evans, et al., 2000; Malbrain, et al., 2010; Russell, et al., 2000; Russell, Reynolds, Towns, et al., 2003; Sanada, et al., 2003; Theaker, et al., 2005), there was no significant difference between active support surfaces when compared either with other active support surfaces or reactive support surfaces. One good quality multi-centre RCT found no significant difference when comparing alternating mattresses with single-layer alternating overlays (Nixon, et al., 2006). The stand-out factor of this study is they did not specify a brand, instead using a standardised definition for each treatment arm, increasing clinical applicability of their results.

Sanada, et al. (2003) suggests that a double layer overlay would provide better pressure prevention than a single layer overlay for people who are required to rest with their head elevated greater than 30 degrees as the second layer prevents bottoming out from the increased pressures through the sacrum (Sanada, et al., 2003). Although this study was well designed, it was under-powered for a three arm study, so a larger study would be required to confirm these results.

Four of these studies had confounding factors included in their design, including variable frequency of repositioning between groups (Demarré, et al., 2013; Russell, et al., 2000; Vanderwee, et al., 2005); use of differing equipment (Russell, et al., 2000). One study (Russell, et al., 2000) used equipment that has since been discontinued, reducing the clinical applicability of their results.

Hybrid Support Surfaces

A component of Cavicchioli & Carella's study (2007) compared the effectiveness of two modalities of the Duo2 hybrid mattress, which has an active modality, using alternating low pressure, and a reactive modality, using continuous low pressure. They found no statistically significant difference in pressure injury incidence between the two modalities, although acknowledge that their study may have been underpowered (Cavicchioli & Carella, 2007).

There has only been one RCT to date that investigates a hybrid mattress that uses both reactive and active modalities together (Gray, Cooper, Bertram, Duguid, & Pirie, 2008). This poor quality study found no difference when investigating a brand of hybrid mattress compared with an air mattress, with poor reporting of statistical analysis, selection bias and assessment bias and no concealed allocation or blinding occurring.

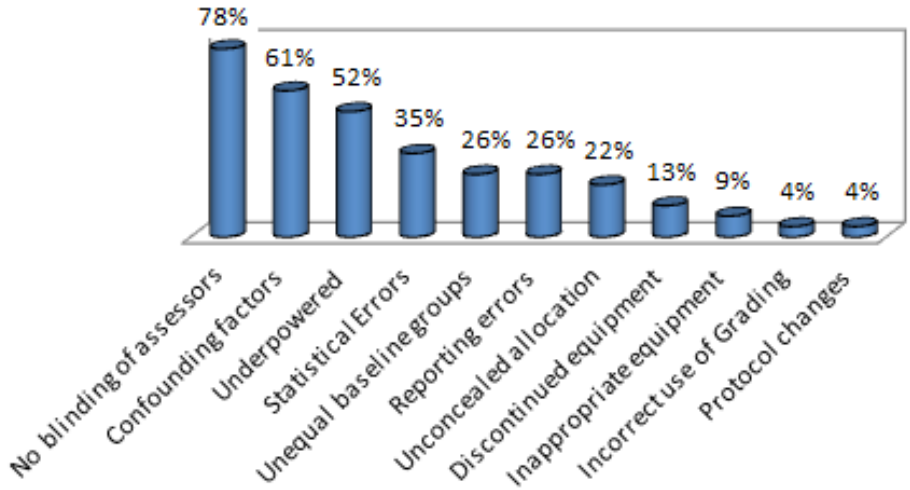
Discussion

The results from the RCTs show a general consensus that pressure mattresses are an effective tool for aiding pressure injury prevention and wound healing and are deemed a more appropriate care method than using a standard foam mattress. When the studies have been of higher quality, the results indicate there is no difference between the higher-specification mattresses. However, further conclusions regarding comparability of the varying mattress types are unable to be drawn from the available literature due to conflicting results and methodological limitations (Table 1).

Of the RCTs reviewed, 52% were underpowered or suspected to be underpowered, meaning their results may not reflect the general population. 36% of the RCTs had statistical errors – some using inappropriate data analysis, some poorly reporting their data, making interpretation difficult.

61% had groups with confounding factors: such as more frequent repositioning or elevating heels so that pressure is offloaded; differing time spent sitting out of bed or provision of an additional pressure-relieving device. This will bias the results towards receiving these additional treatments as it is not necessarily the support surfaces that are aiding the pressure relief or in combination with the additional factors.

Table 1: Study Limitations

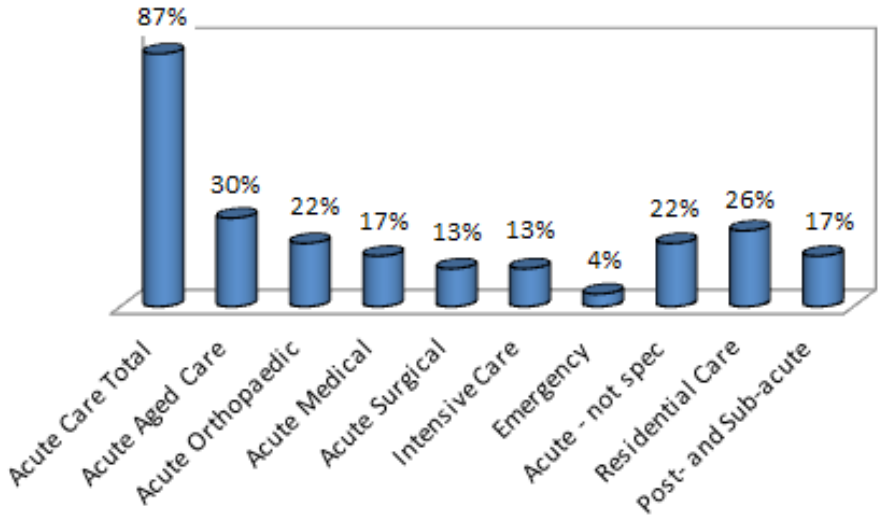


78% of the studies lacked assessors who were blind to treatment group and none had participants or treating clinicians who were blind to treatment group. One of the difficulties with researching mattresses is the visible difference between the mattress types so blinding of participants and treating clinician is not possible. Where assessors are working directly with the participants this means they are unable to be blinded as well.

In a number of the older RCTs (13% of total RCTs), the mattresses and cushions used have either been discontinued or superceded, making applicability of their results more problematic. Similarly, those studies that provide specific mattress brands are only really able to compare that brand with other brands. This is an area where is constant change due to suppliers push for sales and fast changes in technology to create a better product. As a result, studies that focus specifically on one brand have less clinical applicability over time. The study by Nixon, et al. (2006) has a high degree of clinical applicability as they did not specify brands, instead looking at the different principles behind mattress overlays and mattress replacements, determining that there is no statistical difference between the two surface types, regardless of brand. It is important for future research to focus more on the components of the mattress and the way it provides pressure relief to increase clinical applicability in the changing environment.

The focus of the available literature has been overwhelmingly focused on the acute sector, with 87% of the RCTs having participants from an acute ward (primarily on geriatric wards or non-specified acute wards), 26% of studies having participants in a residential or long-care facility and 17% of studies in a sub-acute or post-acute setting (Table 2). None of the studies were in a community-based setting, despite the push for primary health care (Department of Health and Ageing, 2013). People living in their homes are less likely to be familiar with pressure mattresses due to less exposure and have differing levels of functional ability and care support which can impact pressure care. For example, a person living in a nursing home or staying on a medical ward will have nursing staff available to assist with repositioning, meal provision and managing continence accidents whereas a person in their home may be alone for long periods of time or have family carers who do not have the level of understanding of pressure care management or ability to assist with repositioning. Future research to explore the effectiveness of pressure mattresses in a community setting will be able to include use of the mattress and troubleshooting.

Table 2: Study Setting



Conclusion

Although pressure injuries are a preventable condition, they remain prevalent in health settings across the globe. Pressure mattresses are a recognised tool for prevention and healing of pressure injuries with two primary techniques for providing pressure care: reactive surfaces that increase the surface area to reduce pressure and active surfaces that use moving components to periodically offload parts of the body to relieve pressure. Research supports the use of pressure mattresses however research into the comparative effectiveness of the different types of mattress is lacking in quality. Without clear evidence regarding the comparative effectiveness, clinicians must rely on their own clinical reasoning and unreliable supplier-stated claims when prescribing pressure care mattresses. Future studies should ensure that focus is spent on methodology design to minimise the limitations inherent in the available literature, particularly in relation to blinding of assessors and sample size to ensure a meaningful result.

Due to the rapid changes in technology in recent years, and the fact that this is expected to continue to occur at a fast pace, studies that focus specifically on comparing brands do not have a high degree of clinical applicability or longevity. This is because they are only testing the comparison of the two specific brands, which may or may not be available globally. Research needs to focus on the principles behind the pressure care: pressure reduction (reactive surfaces) compared with pressure relief (active surfaces) to ensure clinical applicability and longevity through future technological advances.

The available literature on pressure mattresses is significantly skewed towards the acute sector. Although research was found in the literature review that took place in a community setting, these were low level evidence: case studies and very small clinical studies. It is hypothesised that additional complications may arise from the use of pressure care mattresses in a community setting due to a lack of familiarity with pressure mattresses, however as all the contemporary literature is focussed in either acute or sub-acute settings or residential care settings there is no means to confirm these complications. As pressure prevention is something that will reduce burden on the health care system, it is important to understand the effectiveness of support surfaces in a home environment.

Methodology

Research Question and Design

Q: What is the comparative effectiveness of active and reactive pressure mattresses with regards to pressure injury healing for people aged 65 years or older living in the community?

Given the limitations identified in the available literature, the research aim is to compare the effectiveness of the two main types of pressure mattress commonly prescribed for clients over 65 years in a community setting. It is hypothesised that additional issues regarding mattress use in a community setting are likely to arise due to less familiarity with the equipment and less availability of support for pressure care.

As the primary focus is the measured effectiveness, a quantitative approach will be taken utilising a randomised-controlled trial (RCT) methodology. A RCT will eliminate biases such as selection bias and will monitor and control for many of the confounding variables by having a high likelihood of being representative of the population. Although current literature has had methodological limitations, trends indicate that the two mattress types are equivalent or, at a minimum, non-inferior. As a result, the analysis and hypotheses will reflect an equivalency RCT with the methodology represented in Diagram 2. A pilot study is also planned to test the methodology prior to commencement of the main study.

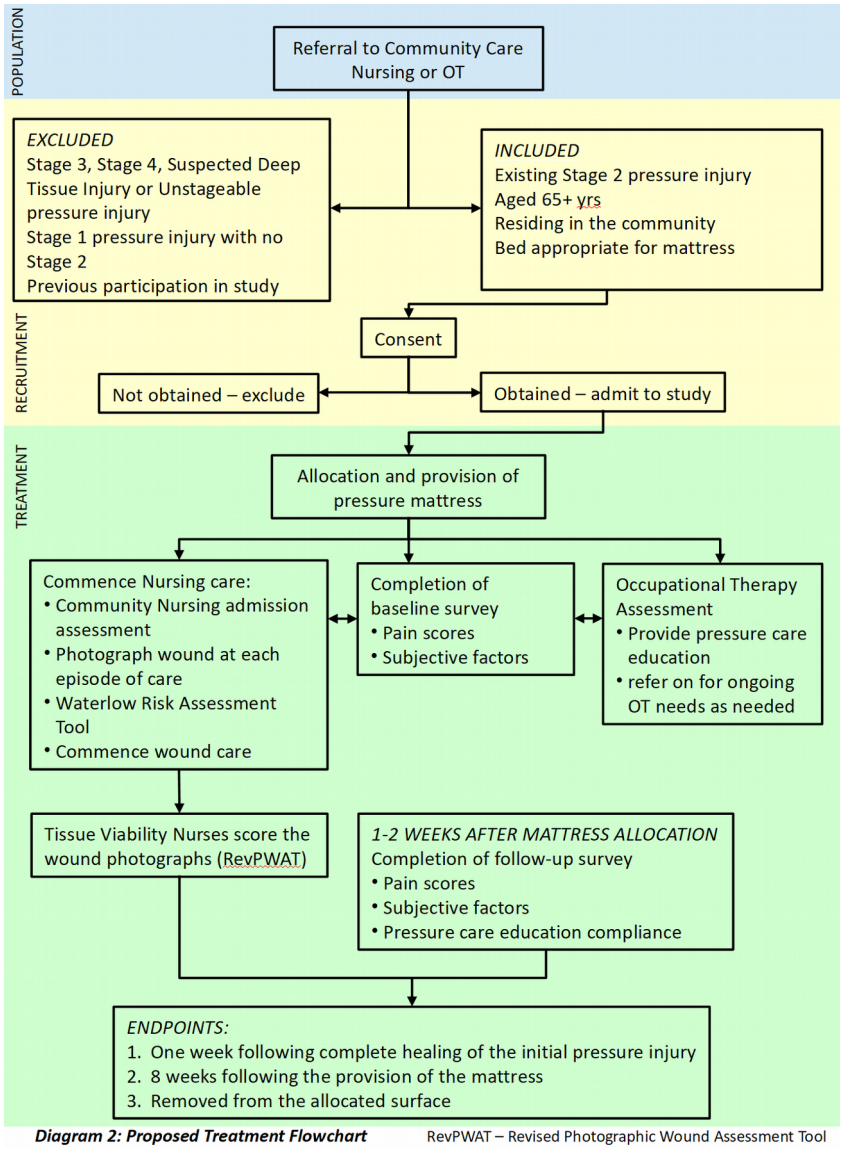


Diagram 2: Proposed Treatment Flowchart RevPWAT – Revised Photographic Wound Assessment Tool

Equivalency RCT Hypotheses

Primary Outcome (Wound healing times)

Ho: One mattress type is clinically more effective at improving wound healing times for pressure injuries

Ha: The type of pressure mattress provided makes no difference on wound healing times for pressure injuries

Secondary Outcome (Subjective factors of mattress acceptability)

Ho: One mattress type is easier to use and more acceptable to use

Ha: Both mattress types are equally easy to use and equally acceptable

Recruitment

All incoming referrals to ACT Health Community Care Nursing or Community Care Occupational Therapy will be compared against the inclusion and exclusion criteria.

Inclusion Criteria

1. aged 65 years or older – elderly people are more prone to development of pressure injuries due to reduce skin elasticity and connective tissue and increased number of health complications, which in turn impacts on the extrinsic and intrinsic risk factors (Lake, 2015; Palese et al., 2015).
2. residing in a community setting ie in a private home
3. existing Grade 2 pressure injury – the majority of pressure injuries managed in the community setting in ACT are Grade 1 or 2 (Lake, 2015).
4. have a bed that is appropriate for the test support surfaces
5. inability to reposition off the pressure injury– if the participant is able to offload the pressure injury then the support surface is only acting in a preventative manner rather than aiding wound healing.

Considered

Participants with Grade 1 pressure injuries will only be included if they also have a Grade 2 pressure injury, with the Grade 2 pressure injury being considered the primary pressure injury for the purposes of the study. Participants with Grade 1 pressure injuries only will be excluded as Grade 1 pressure injuries do not have any broken skin. It is expected that these will heal much faster and could skew the results with regards to effect size.

Exclusion Criteria

1. existing Grade 3, Stage 4, Suspected Deep Tissue Injury or unstageable pressure injury – these pressure injuries are not seen as frequently in the community setting (Lake, 2015) and have widely variable healing times, inclusion will skew the results.
2. Participation in the study during a previous episode of care

If accepted against the inclusion and exclusion criteria then prospective participants will be offered opportunity to participate in study – provided with consent paperwork and information package. Upon receipt of consent participant will be randomly allocated to one of three treatment arms.

Outcome Measures

Primary - Time to complete healing based on the Revised Photographic Wound Assessment Tool (Thompson, Gordey, Bowles, Parslow, & Houghton, 2013)

The Revised Photographic Wound Assessment Tool (RevPWAT) is an assessment tool based on the Bates-Jensen Wound Assessment Tool (formerly known as the Pressure Sore Status Tool) for assessments based on photographs of wounds rather than bedside assessments (Thompson, et al., 2013). This outcome measure has been chosen as it does not require the assessors to be at the bedside of the participants, thus blinding them from the allocated mattresses. Blinding assessors from allocated mattresses has been problematic for many of the studies in the literature as the mattresses have visible differences. Thompson, et al. (2013) tested the RevPWAT for reliability and found a strong correlation between bedside assessments and assessments from photographs (intraclass correlation coefficient of 0.89). See Appendices A and B for the assessment tool and instructions on how to score it.

DELIVERY AND FREQUENCY: Photographs for this assessment tool will be taken by clinicians at each wound care session to measure the progression of wound healing and will be scored by assessors blinded to allocated treatment group.

Secondary - Subjective Factors of Pressure Mattresses

Research has shown that there is a strong correlation between non-use of assistive technology and user dissatisfaction, with some of the factors relating to comfort and ease of use (Federici & Borsci, 2011). Regarding pressure mattresses, this means that equipment abandonment will be more likely if the client does not find the mattress comfortable or struggles with moving on it. These subjective measures are considered just as important as wound healing time and so will be measured through surveys provided approximately one week after mattress provision, utilising a Likert scale. The following factors will be included in the survey:

- participants' perceptions of the allocated mattress – positives and negatives
- perceived change in sleep habits including:
    - time spent in bed
    - frequency of repositioning
    - sleep position
- comfort of the mattress, including changes in pain levels (see Pain Scale below)
- ease of transfers
- ease of use, including any troubleshooting they have needed to do to date

DELIVERY AND FREQUENCY: This survey will be completed at baseline and then again approximately 1-2 weeks after mattress provision. It will be completed by the participants and facilitated by the primary researcher.

Secondary - Pain Scale using 10-point Scale (Richards, 2015)

To aid the comparisons of the mattresses with relation to changes in pain levels, a 10-point scale will be used for participants to rate their pain levels. To provide a degree of objectivity, definitions for each level of pain will be provided to participants based on descriptors in Richards (2015).

DELIVERY AND FREQUENCY: This assessment tool will be completed as part of the survey completed at baseline and again approximately one week after mattress provision. It will be completed by the participants and facilitated by the primary researcher.

Confounding Factors

As this is a pragmatic trial, many of the confounding factors cannot be controlled. As a result they need to be monitored to ensure similarities across both groups.

Extrinsic and intrinsic factors

Factors that impact on pressure injury need to be monitored as these will impact on pressure injury development. This includes medical history, level of mobility, level of nutrition and skin integrity. This data will be collected as part of the Community Nursing Admission assessment, currently completed as part of standard practice at the commencement of services.

Waterlow Risk Assessment Tool (Waterlow, 1985)

The Waterlow Risk Assessment Tool will be used to track the risk level of participants throughout the study. This assessment tool was chosen as it identifies the most risk factors as determined by epidemiological studies (NPUAP et al., 2014). As participants will not be acutely unwell, it is not anticipated that there will be significant changes in the score however the subscores will be utilised to ensure the groups are similar at baseline, particularly in relation to nutritional level, degree of mobility and continence.

DELIVERY AND FREQUENCY: This assessment tool will be completed by treating clinicians at each wound care session. As the Community Nurses already complete this as part of their standard practice, no additional training for this assessment will be required.

Adherence to pressure injury prevention education

All participants will receive education on general techniques to aid prevention of pressure injuries. This education will focus on behavioural changes rather than the provision of assistive technology. Adherence to recommendations from this education will impact on pressure injury healing as participants who are more compliant will be expected to have a quicker healing time. This adherence will be explored as part of the survey investigating the acceptability of the mattress.

Sleeping habits

The positions a participant sleeps in, their frequency of repositioning in bed and the location of the pressure injury will impact on the healing of the pressure injury. For example, a person with a sacral pressure injury who sleeps on their back with their head elevated is expected to take longer to heal their injury then a person with a hip pressure injury who sleeps in the same position. Baseline and changes in sleeping habits will be collected as part of the survey investigating the acceptability of the mattress.

Intervention

For details regarding the study protocol, please see Appendix A

Random allocation

Participants will be assigned to treatment groups using allocations in sealed envelopes:

a) Experimental Group 1 – reactive mattress/overlay
b) Control Group – active mattress/overlay

Support Surfaces

Mattresses

All mattresses used need to be supplier stated to be appropriate for Grade 2 pressure injuries.

Mattresses can be either full mattress replacements or mattress overlays. A high-quality randomised-controlled trial completed by Nixon et al. (2006) found no statistical difference between the effectiveness of alternating mattress replacements and alternating mattress overlays. In a community setting, the available beds for using a support surface will not always be hospital-type beds and will vary widely. There is likely to be occasions when use of a mattress replacement will not be possible. By grouping the treatment arms by mattress classification rather than a specific overlay or replacement, clinical applicability is increased, due to the increasing range of brands.

Mattresses that have dual-functionality are excluded. This may be the ability to switch between static and alternating, such as Talley Quattro or Arjo Duo2; or mattresses that use combined static and alternating functionality, such as Curocell Cirrus or Talley Quattro Fusion. Although these mattresses may have clinical applicability in a community setting, their use during the study could confound results, particularly if they are not used as allocated, for example switched to alternating when the participant has been allocated to the static treatment group.

Cushions

To ensure that changes in pressure injuries are due to the mattress and not impacted by time spent sitting out of bed, all participants will be provided with the same air pressure cushion. Air cushions have been shown to have the lowest interface pressure, along with water cushions (Defloor & Grypdonck, 2000). As there are not many water cushions commercially available, an air cushion will be used (high profile ROHO cushion). These cushions are commonly prescribed for people at high risk of developing pressure injuries and so will be familiar to the treating clinicians should any trouble-shooting be required.

Wound Care

Wound care will be provided to the participants as per the current practice for Community Care Nursing, ACT Health. This includes the use of best-practice methods, such as Mepilex range as wound dressing with foam or cavity fillers as needed. Frequency of wound care days will vary depending on the stage of healing. Generally for Grade 2 wounds, wound care occurs every second day, reducing quickly to twice a week, then once per week. Once the wound reaches the stage of visits once per week the wound is considered almost healed as per the RevPWAT (score <2) and thus endpoint for the study.

Data Collection

Participants will be individually coded to prevent identification by assessors and by primary investigator when collecting survey data. Data will be kept in a limited-access folder on secure ACT Health servers behind ACT Health firewalls.

The methodology will be piloted prior to commencement of the full study to ensure that all components are feasible in practice. From a snapshot taken of the services over a period of 4 months, it is anticipated that intake will be an average of one participant a week so the methodology will be piloted for approximately 8-12 weeks (until endpoint is reached for four participants). It is anticipated that using this same average of intake that data collection for the primary study will take approximately 24 months.

Training of Community Nurses of standardised requirement for taking photographs

To ensure accurate and reliable data is collectable from the photographs a standard operating procedure will be developed. Thompson, et al. (2013) provided tips for ensuring a photograph is taken that is going to reduce the risk of discrepancies between assessors (Information Box 2). In addition to these tips, they also recommend the bedside clinician (ie the person taking the photograph) makes a note of the dressing removed as the dressing type may impact on the surrounding skin or leave residue (Thompson, et al., 2013).

INFORMATION BOX 2: **WOUND PHOTOGRAPHY TIPS**

- Patient identification number, date and time of when the photograph was taken
- A measurement scale (mm markings preferred) should be placed adjacent to the wound in the same plane as the wound opening.
- Background should be clear of clutter – consistent blue or green background is preferred.
- Cleanse, debride and dry the wound area thoroughly before taking photograph
- Use at least a 3.0 megapixel digital camera. Larger than 10 megapixels is not required – just results in file storage problems.
- Take photograph close to wound (30-60 cm) and include wound base, all wound edges, sample of periulcer skin (10cm around).
- Use even consistent, reproducible lighting – external ring or extended flash is preferred.
- Avoid shadows and bright spots (open windows, flashlights)
- Take photographs at right angles to the wound opening.
- Stabilise arms or use tripod when taking photograph to avoid shake/movement during photograph.
- Several photographs can be taken at different distances to get "full picture".
- Make notes when taking photographs so subsequent photographs are taken in the same orientation.
- Prevent camera cross contamination – follow aseptic technique and disinfection procedure.
- Ensure informed consent is obtained for defined use (time frame and purpose) of photographs.
- Patient's privacy should be respected at all times – use drapes to obscure the view of body parts not involved with the wound.
- Develop a consistent file labelling system and a secure back-up system with ample storage space.
- Store de-identified photos in a secure location and develop or follow relevant site policies and procedures to ensure patient confidentiality is maintained.

Thompson, N., Gordey, L., Bowles, H., Parslow, N., & Houghton, P. (2013) p. 365

Data Analysis

Sample size

Power calculations were unable to be completed due to unavailable data regarding standard deviations (SD) in previous literature. Articles reviewed either did not utilise similar outcome measures or did not report the SD due to non-normal distributions. A priori sample was determined for a total sample of n=80 to aim for a minimum final total sample of n=60 (to allow n=30 for each group, utilising the central limit theorem

(Field, 2013)) after allowing for withdrawals. Power calculations, including Cohen's d for effect size, will need to be completed at the completion of data collection.

Test inter-rater reliability of assessors of photographs

Although Thompson, et al. (2013) describe the inter-rater reliability of the RevPWAT, it is important to ensure the inter-rater reliability of the assessors with this wound type. Thompson, et al. (2013) tested reliability using a range of wound types that included pressure injuries however also had strict guidelines regarding the wounds at baseline to ensure good photographs were able to be taken, such as circumferential wounds (Thompson, et al., 2013). Photographs from the pilot study will be used to test inter-rater reliability of assessors.

Statistical Analysis

As the study has a non-inferiority design, data analysis will be completed twice and compared: one a Per Protocol analysis and one an Intention to Treat analysis. This is because each type of analysis biases different treatment groups (Scott, 2009) so by comparing the two analyses the results will be cross-validated. For a similar reason, analysis will look at p-values of the relevant statistical tests as well as confidence intervals (where the confidence interval falling outside the pre-determined effect size will indicate equivalence or non-inferiority)(Greene, Morland, Durkalski, & Frueh, 2008).

Provided the relevant assumptions have been met, the following statistical tests will be completed:

Outcome Measure	**Statistical Test**
Comparing wound healing times	*Independent t-test* (average healing time reactive surfaces vs average healing time active surfaces)
Comparing number of new pressure injuries developed	*Independent t-test* (total number of new pressure injuries reactive surfaces vs total number of new pressure injuries active surfaces)
Comparing number of pressure injuries not healed at 8 weeks	*Independent t-test* (number of pressure injuries not healed at 8 weeks for reactive surfaces vs active surfaces)
Changes in Pain scores	2-way Mixed ANOVA – between group analysis to compare pre- and post-pain scores for each mattress type, independent group analysis to compare the mattress types
Changes in time spent in bed	2-way Mixed ANOVA – between group analysis to compare pre- and post-time for each mattress type, independent group analysis to compare the mattress types
Changes in frequency of repositioning	2-way Mixed ANOVA – between group analysis to compare pre- and post-frequencies for each mattress type, independent group analysis to compare the mattress types

If the assumptions cannot be met, despite data transformation, then the relevant non-parametric tests will be completed (eg Mann-Whitney instead of Independent t-test).

Ethical Considerations

Ethics Approval

Ethics approval for this study will be sought from the ACT Health Human Research Ethics Committee and the University of Canberra Human Research Ethics Committee. As the design of the study reflects current

practice, with all chosen mattresses being supplier-stated to be appropriate for Grade 2 pressure injuries, there will be minimal risk to participants for participating.

Data Management

During the data collection phase, data will be kept in restricted folders on ACT Health servers behind ACT Health firewalls so that all required parties will be able to access the data, negating the need for data to be emailed or transferred via USB. At the completion of the project the data will be de-identified and a copy provided to University of Canberra for archiving. This record is expected to be maintained for a minimum of seven years as per ACT Legislative requirements ("Health Records (Privacy and Access) Act 1997 (Republication No 27) (ACT)," 2016). Clinicians will continue to document in the clinical file as per current policy, including the allocated mattress.

Consent and cognitive impairment

It is likely that through coincidence there will be participants who do not have capacity to consent to participate. Potential participants will be screened for cognitive impairment and flagged for additional investigation via a cognitive screening assessment. This study is considered by ACT Legislation as 'low risk research' due to the fact it is comparing the effectiveness of two established standard treatments during routine health care (ACT Health Research Ethics and Governance Office, no date). As a result, if a cognitive impairment is determined then consent will be sought from the potential participant's (in priority order):

- person with enduring power of attorney;
- their guardian; or
- their health attorney, defined as a domestic partner, their carer or a close relative or friend (ACT Health Research Ethics and Governance Office, no date).

This is the most likely vulnerable population to be included in the study.

Adverse Event - Deterioration or development of new pressure injuries

All new pressure injuries and all deteriorating pressure injuries will be referred to the Data Safety and Monitoring Board (DSMB), consisting of Community Care Wound CNC, Community Care Wound Nurse Practitioner and Primary Investigator. This committee will review the circumstance to determine the cause of the deterioration or new pressure injury. If the suspected cause is something external to the mattress then the mattress may be able to remain in place. If no external cause can be found, then it is possible the mattress may have been a factor and the participant may need to leave the trial. This will also be the case should the pressure injury deteriorate to become a Stage 3, Stage 4, Suspected Deep Tissue Injury or Unstageable pressure injury.

Support surface provision during the study

Support surfaces being provided for the study are being supplied by one of two options:

- Equipment suppliers Astris Lifecare and Invacare (mattresses and cushions are being donated for the duration of the study, provided on a needs-basis).
- ACT Health Equipment Loan Service

Which service provides the support surfaces will depend on availability at the time and speed that delivery can occur. Agreements are being drawn up with Astris Lifecare and Invacare with regards to maintaining the privacy of participants and the intellectual property of the results, including the agreement that the results

will be published, regardless of the outcome. ACT Health equipment will only be utilised for participants who would normally be accessing this equipment, as per current practice.

Support surface provision at the end of the study

As a large number of people with a pressure injury are likely to need pressure care on a long term basis, systems need to be in place to aid the long term provision once the study has completed. At the intake of the study, participants will be receiving an initial occupational therapy assessment which will anticipate any long term equipment needs and refer on appropriately. This initial assessment will be handed over to the treating occupational therapist for follow up at the completion of the study.

Study protocol audits

The DSMB will be responsible for the completion of a quarterly audit to ensure adherence to the protocol is maintained. This will involve checking consent forms have been obtained, photograph documents and assessment documents are saved in the appropriate places and that surveys and mattress provision within the allocated timeframes.

Project Plan

Date	Activity
Nov 2017 – Jan 2018	HREC Approval sought (ACT Health and UC) Training of Community Nurses for team participating in Pilot
Feb – Apr 2018	Pilot Study to test methodology
Apr – Jun 2018	Review results of Pilot Study regarding methodology and data collection – proposed changes to methodology submitted to HREC for approval
Apr – Jun 2018	Training of Community Nurses for remaining participating teams
Jul 2018 – Jul 2020	Primary data collection phase – data collection expected to take approx 18-20 months with an average of one participants enrolled each week (based on snapshot of potentially eligible participants from Aug-Dec 2016)
Jul 2020 – Jul 2021	Data analysis
Jul 2021 -	Writing results, including publications and thesis

Research Outcomes

Primary Publication	PhD Thesis
Proposed Journal Publications	Literature review
	Pilot study
	Primary RCT focusing primarily on the wound healing component with subjective factors as supportive
	Article focusing in more detail on the survey results and subjective factors of the mattresses
Conference Papers	Literature review
	Results regarding Pilot Study
	Results regarding Primary RCT
Possible conferences would include Occupational Therapy conferences, Wound Care conferences, Nursing conferences, Assistive Technology conferences	

Budget and Resources Required

As this project will form the basis of a PhD the available budget is minimal however support has been given by ACT Health Community Care on an in-kind basis so no additional funds will be required for the clinical component of the study. The methodology has been designed to reflect current standard practice within ACT Health Community Care and so no additional wound care resources will be required. The only change from standard care will be photographs taken at each episode of wound care when usually they are taken less frequently.

Mattresses and cushions will be accessed either through ACT Health Equipment Loans Service on an in-kind basis or donated through equipment suppliers Astris Lifecare and Invacare.

A submission has been made for an Allied Health Research Support Grant through the ACT Chief Allied Health Office. If this is successful then funds will be used for stationary costs and administration support for data entry.

Appendices

A) Study protocol
B) RevPWAT
C) RevPWAT scoring instructions
D) Evidence Table

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Appendix A: Proposed Study Protocol

Step	Who
1. Participant is compared against the study eligibility criteria: a) Not eligible – continue with standard practice b) Eligible • Discuss eligibility with potential participant and provide study information sheet • Obtain verbal consent for primary researcher to follow up regarding study participation • Photograph wound as per study recommendations • Complete Community Nursing admission assessment and Waterlow Risk Assessment NOTE: data obtained at this point is part of standard wound care practice for Community Nurses and this information would remain in the clinical file until consent obtained from the potential participant.	Community Nurse
2. Follow up with client to obtain consent for participation in study: a) If flagged for possible cognitive deficits then complete cognitive screen. b) If cognitive impairment determined then consent to be sought from Enduring Power of Attorney (evidence of this to be provided either sighting original or on clinical file). ○ Consent obtained – continue with study protocol ○ Consent not obtained – return to standard practice	Primary Researcher
3. Participants will be entered into the study Sub-folder created for participant in "Photographs and Completed Assessments"	Primary Researcher
4. Baseline data to be provided from clinical file • baseline photograph • Waterlow Risk Assessment • Community Nursing admission assessment	Community Nurses
5. Initial Occupational Therapy assessment: • To determine whether mattress overlay or mattress replacement will be appropriate. This will be dependent on the available surface for the mattress. • To determine the appropriate size for the ROHO cushion • To determine likelihood of long term equipment needs. If likely to need equipment on a long term basis (ie following the study end-point) then referral to be made to participant's preferred Occupational Therapy service. Referral at this point to is to minimise delays in service once participation in the study is finished and the allocated support surface is returned.	Primary Researcher
6. Pressure care education provided to participant: Provision of ACT Health brochure for preventing pressure injuries Verbal, face-to-face education to include discussion of the following principles: • regular repositioning and offloading • maintaining nutrition, including protein in diet • maintaining skin health, including regular skin checks, managing continence and moisturising	Primary Researcher
7. Participant provided with Baseline survey and Pain Scale	Primary Researcher

Step	Who
8. Allocation of support surface Participant allocated to a treatment group using a random-number generator • 1=active • 2=reactive	Primary Researcher
9. Provision of support surface (mattress and cushion) TARGET: Participant to be provided with allocated support surface within 2 days to minimise clinical risk of wound deteriorating Participant will be provided with a mattress chosen from the allocated group based on availability. For example if participant is allocated to the 'active' group then they may be provided any of the mattresses listed in that group, based on availability. The following considerations will be made when determining supplier of the allocated mattress: • Is the required equipment clinically applicable? In some cases provision of a mattress may not be clinically applicable as a less invasive technique is often trialled first, such as heel elevation when the person has no previous history of pressure injuries. Similarly, not all people would require a cushion for sitting out of bed. In these instances, the allocated equipment will provide an appropriate level of care but may be marginally more intrusive than standard care. • Mattress availability from the supplier.	Primary Researcher
Suppliers of Support Surfaces: a) ACT Health Equipment Loan Service (ELS) – if allocated equipment is available and clinically applicable b) Astris Lifecare – if allocated equipment is not available from ELS or clinically applicable c) Invacare – if allocated equipment is not available from ELS or Astris Lifecare	Information only
Active mattresses: a) Premium Digital 5 (overlay) – ELS, Invacare b) Premium Digital 9 (replacement) – ELS, Invacare c) Nimbus3 (replacement) – ELS d) Curocell Uno (replacement) – Astris e) Virtuoso (replacement) – Astris f) Salsbury (overlay) – Astris Reactive mattresses: g) ROHO Sections (1x foam and 3x ROHO sections, overlay) – ELS, Astris h) Atmosair (replacement) – ELS i) Softform Premier (replacement) – ELS, Invacare j) Curocell AREA (replacement) – Astris k) Curocell SAM (overlay) – ELS, Astris l) Pressureguard CFT (replacement) – Invacare m) BetterLiving Triple Layer (replacement) - Invacare Cushion: 18"- 20" single valve high profile ROHO – ELS, Astris	Information only
10. Referral to be made to the appropriate supplier for provision of support surfaces:	Primary Researcher

Step	Who
A) ELS a) Complete referral form listing all appropriate mattresses in ELS pool. b) Provision of support surface will be based on availability. c) Mattress and cushion to be provided and set-up	Primary Researcher ELS Staff Primary Researcher OR ELS Staff
B) Astris Lifecare and Invacare a) Email to Sales Representative requesting delivery of allocated mattress type and ROHO cushion b) Sales Representative to choose mattress from pre-determined list based on mattress type and storeroom availability c) Mattress and ROHO cushion to be provided and set-up	Primary Researcher Sales Representative Primary Researcher OR Sales Representative
11. Participant to be provided with general trouble-shooting information for mattress and cushion, including contact information	Primary Researcher
12. Wound Management: Wound Management as per standard practice with the following additions: • Photograph to be taken as per study recommendations at every dressing change • Review participant for changes in function, including skin check for new pressure injuries • if new pressure injury has developed this should be photographed and referred to Wound Nurse Practitioner and Primary Researcher for review for ethical impact • Repeat Waterlow weekly	Community Nurses
13. Photograph Management: Photograph will be placed in ACT Health e-note template for photographs in a clinical file with unique identifier only (photograph enlarged for one photograph per page). Document to be saved in PATHFILE (Saved as: "Photograph [Unique identifier] – [date YYMMDD]"), where date is date photo was taken	Community Nurses
14. Assessment of wound photograph: TVN accesses document for assessment and completes RevPWAT Documents to be saved in the following places: • Completed RevPWAT saved in PATHFILE (Saved as: "RevPWAT [Unique identifier] – [date YYMMDD]"), where date is date photo was taken • Photograph document saved in PATHFILE (Saved as: "Photograph [Unique identifier] – [date YYMMDD]"), where date is date photo was taken Photograph document deleted from PATHFILE This should be completed on a weekly basis at minimum	Tissue Viability Nurses
15. Second survey to be provided 10-14 days after mattress provision	Primary Researcher
16. Data Entry • Data from RevPWAT to be entered into data spreadsheet on a weekly basis by Research Team • Data from hard-copy surveys will be entered into Qualtrics by Research Team as they are completed (to be entered within one week of survey) • Data from surveys will be extracted from Qualtrics for analysis in SPSS and the conclusion of the data collection period.	Research Team/Admin Support Research Team/Admin Support Primary Researcher

Step	Who
Participant Completion of study Endpoints will be determined by one of the following: • one week following complete healing of the initial pressure injury as determined by the RevPWAT (ie at the point when Community Nursing would be leaving the dressing on for a week – PWAT score of 0 for all subscores except subscore 8, where a score of up to 2 can be permissable) • 8 weeks following the provision of the mattress • removed from the allocated surface – for example by request, move areas, hospitalisation, death, significant deterioration of existing wounds (such as progression to a Grade 3 pressure injury or development of an unstageable pressure injury)	Information only
16. Collect final data: • Photograph initial pressure injury and any remaining pressure injuries as per study recommendations and store as per previous photographs (see Photograph Management) • Final Waterlow Risk Assessment • Review for changes in function, including a final skin check for additional pressure injuries not previously identified	Community Nurses
17. Scoring of remaining photographs (see Assessment of wound photograph)	Tissue Viability Nurses
18. Closure of study: • Follow up with participant to ensure ongoing pressure care needs will be met by referral on to the appropriate services • Organise for collection of the study mattress and cushion • Thank participant for taking part	Primary Researcher

Data/Secure Folder Management

Data will be kept on ACT Health servers in a secure folder. Access will be limited to the following people with additional restrictions in place:

- Research Team (primary researcher and supervisors, administration support for data entry) (RT)
- Community Nurses providing wound care (CN)
- Tissue Viability Nurses (TVN)

Breakdown of the folder will include the following sub-folders:

- Data Collation documents (additional password protection – access for RT only)
  - Mattress allocation document
  - Spreadsheet for RevPWAT
  - Spreadsheet for demographic data
- Photographs for assessment (this is where the CN will save the de-identified photograph e-note)
  - subfolders for each participant
- Completed Assessments
  - subfolder for each participant which will include
    - Photograph e-notes (TVN or CN responsibility)
    - Completed RevPWATs (TVN responsibility)
    - Completed Waterlows (CN responsibility)
    - Completed surveys (RT responsibility)
    - Completed consent forms (RT responsibility)

- Study Documents (read-and-print-only documents, RT able to modify folder contents)
  - How to Take Wound Photographs
  - How to Complete RevPWAT
  - Study Protocol
  - Information sheets
  - Blank Consent Forms
  - Blank Baseline Survey
  - Blank Follow-up Survey

Appendix B: Revised Photographic Wound Assessment Tool

developed from the Bates-Jensen Wound Assessment Tool (formerly known as PSST) (Thompson, et al., 2013, p 363)

Item	Assessment			Score
1. Size	0 = wound is closed (skin intact) or nearly closed (<0.3 cm^2) 1 = 0.5 – 2.0 cm^2 2 = 2.0 – 10.0 cm^2 3 = 10.0 – 20.0 cm^2 4 = >20.0 cm^2			
2. Depth	0 = wound is healed (skin intact) or nearly closed (<0.3 cm^2) 1 = full thickness 2 = unable to judge because majority of wound base is covered by yellow/black eschar 3 = full thickness involving underlying tissue layers 4 = tendon joint capsule visible/bone present in wound base			
3. Necrotic tissue type	0 = none visible or wound is closed (skin intact) or nearly closed (<0.3 cm^2) 1 = majority of necrotic tissue is thin, white/grey or yellow slough 2 = majority of necrotic tissue is thick, adherent white/yellow slough or fibrin 3 = majority of necrotic tissue is white/grey devitalized tissue or eschar 4 = majority of necrotic tissue is hard grey to black eschar			
4. Total amount of necrotic tissue	0 = none visible in open wound or wound is closed (skin intact) or nearly closed (<0.3 cm^2) 1 = <25% of wound bed covered 2 = 25% - 50% of wound covered 3 = >50% and <75% of wound covered 4 = 75% or more of wound covered			
5. Granulation tissue type	0 = wound is closed (skin intact) or nearly closed (<0.3 cm^2) 1 = majority (>50%) of granulation tissue is healthy-looking (even, bright red appearance) 2 = majority of granulation tissue is unhealthy (eg pale, dull, dusky, hypergranulation) 3 = majority of granulation tissue is damaged, friable, degrading 4 = there is no granulation tissue present in the base of the open wound (all necrotic)			
6. Total amount of granulation tissue	0 = wound is closed (skin intact) or nearly closed (<0.3 cm^2) 1 = 75% or more of open wound is covered with granulation tissue 2 = >50% and <75% of open wound is covered with granulation tissue 3 = 25% to 50% of open wound bed is covered with granulation tissue 4 = <25% of wound bed is covered with granulation tissue			
7. Edges (directly touching and within 0.5 cm of wound edge)	0 = wound is closed (skin intact) or nearly closed (<0.3 cm^2) or edges are indistinct, diffuse, not clearly visible because of re-epithelialisation 1 = majority of edges (>50%) are attached with an advancing border or epithelium 2 = majority of edges (>50%) are attached even with wound base (not advancing) 3 = majority of edges (>50%) are unattached and/or undermined 4 = majority of edges are rolled, thickened or fibrotic (do not include callus information)			
8. Periulcer skin viability (consider skin visible in photo or within 10 cm of wound edge)	Number of factors affected: 0 = none 1 = one only 2 = two or three 3 = four or five 4 = six or more	• Callus • Dermatitis • Maceration • Desiccation or cracking • Bright red erythemic skin	• Oedema • Excoriation • Skin tearing/ irritation related to wound dressing or tape • Hypo-/hyper-pigmentation	
Total Score				
Comments				

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Appendix C: RevPWAT Scoring Instructions

(Thompson, et al., 2013, p 364)

Assess the wound photograph and rate each PWAT domain according to the response that best describes observed wound findings. When more than 1 characteristic is evident, score according to the majority of other variables that are visible in the photograph. Sub-scores are added to obtain the total score. Total scores range from 0 to 32, where lower scores indicate characteristics of better or healing wounds.

1. Size

Place a disposable ruler adjacent to, but not covering, the wound edge and perpendicular to the camera lens. Use the calibrations on the ruler included within the photograph to determine the longest and widest dimensions of the wound. Width is located perpendicular to length avoiding diagonals. Multiply length by width to determine total surface area in cm^2. A wound that is closed with skin intact is scored as 0.

2. Depth

Describe the extent of tissue layers involved in the wound. Full-thickness wounds extend beyond the epidermis and the dermis into or through subcutaneous tissue and are categorised according to the depth of involvement of subcutaneous tissue. Wounds with distinct wound edges are considered full thickness and are scored as 1. When deeper underlying layers such as subcutaneous fat, muscle and other soft tissue layers are involved, the score is 3. Evidence of tendon, joint capsule or bone indicates deeper tissue involvement and changes the score to 4. Presence of yellow/black eschar may obscure the majority of the wound base and the depth of tissue injury, resulting in a score of 2.

3. Necrotic tissue type

Score the majority of necrotic tissue visible in the photograph. Slough can be yellow, white/yellow, thin, mucinous or fibrinous material scattered throughout the wound bed. Granulation tissue is visible through thin white/yellow slough. Necrotic tissue may also be thick and adherent, impairing visualisation of granulation or healthy tissue. Necrotic tissue may appear as white/grey, soft, boggy or devitalized tissue. Hard grey or black eschar is given a score of 4.

4. Total Amount of Necrotic Tissue

Determine the total percentage of all types of necrotic tissue visable on the wound bed by picturing the wound as a circle and visually dividing it into 4 equal quadrants to determine percentage. Thorough wound cleansing and/or debridement is essential to remove loose slough, debris and residual dressing products prior to assessing necrotic tissue type and amount.

5. Granulation Tissue Type

Select the majority of granulation tissue type visible in the photograph. Granulation tissue is comprised of small blood vessels and connective tissue that grow to fill the wound defect in full-thickness wounds. Healthy granulation tissue is bright, beefy pink/red, firm tissue with a shiny, bumpy, granular appearance. Unhealthy granulation tissue may appear pale, dull, dusky, or hyper-granulated. Hyper-granulation tissue is exuberant bright red tissue extending above the edge of the wound. Granulation tissue that is degrading may appear as bridges, be friable and bleed easily or appear pitted rather than granulated.

6. Total amount of Granulation tissue

Determine the percentage of the wound that is covered by granulation tissue by picturing the wound as a circle and visually dividing it into 4 equal quadrants.

7. Edges

Observe the wound edges that are directly touching and within 0.5cm of the wound edge. Epidermal tissue appears as pale pink, silvery/grey tissue that extends into the wound from the wound edge. Edges that are diffuse, indistinct, or not clearly visible occur as the wound surface is covered with new epithelial tissue and closes the wound. Undermining may be displayed in the photograph by the insertion of a cotton applicator into the detached area. Wound edges maybe attached to the wound base or have undermining and may

appear thick, hard, and fibrotic with scar tissue or rolled when epithelium rolls under the wound edge, all which impair wound healing and are scored as 4. Determine the majority percentage of the wound edge appearance by picturing the wound as a circle and visually dividing in half.

8. Periculcer Skin Viability

Assess skin visible in the photograph or within 10cm of the wound edge. Select all visible items. Count the number of items identified to determine the appropriate score.

Callus: thick, hard, dry skin often located over an area of friction and/or pressure

Dermatitis: red, itchy, scaly and flaky skin

Maceration: white, wet, boggy, opaque-looking skin resulting from excessive moisture

Bright red erythemic skin: redness of the skin resulting from infection or an allergic reaction

Oedema: fluid accumulation in the intercellular spaces around the wound, difficult to visualise in a photograph. Non-pitting oedema may appear as skin that is shiny and taut. Pitting oedema may be identified in the photograph if a finger was pressed into the periulcer skin resulting in a visible indentation or an indentation from a dressing

Excoriation: abrasions, scratches, or weeping dermatitis

Skin tearing/irritation: may be related to removal of adhesive products or tapes or product allergy. Look for product outline if allergy is suspected.

Hypopigmentation/hyperpigmentation: hypopigmentation shows lack of colour in the skin and may result from scar tissue from previous skin injury. Hyperpigmentation may result from leakage of hemosiderin into the tissues perhaps from venous stasis or previous injury. Other findings can be added to the list.

Should you encounter a wound that is covered by a thin, white/yellow layer of slough, the recommended score for necrotic tissue type/amount and granulation tissue type/amount is as follows:

Item	Assessment	Score
3. Necrotic tissue type	0 = none visible or wound is closed (skin intact) or nearly closed (<0.3cm²) (1) = majority of necrotic tissue is thin, white/grey or yellow slough 2 = majority of necrotic tissue is thick, adherent white/yellow slough or fibrin 3 = majority of necrotic tissue is white/grey devitalized tissue or eschar 4 = majority of necrotic tissue is hard grey to black eschar	1
4. Total amount of necrotic tissue	0 = none visible in open wound or wound is closed (skin intact) or nearly closed (<0.3cm²) 1 = <25% of wound bed covered 2 = 25% - 50% of wound covered 3 = >50% and <75% of wound covered (4) = 75% or more of wound covered	4
5. Granulation tissue type	0 = wound is closed (skin intact) or nearly closed (<0.3cm²) 1 = majority (>50%) of granulation tissue is healthy-looking (even, bright red appearance) 2 = majority of granulation tissue is unhealthy (eg pale, dull, dusky, hypergranulation) 3 = majority of granulation tissue is damaged, friable, degrading (4) = there is no granulation tissue present in the base of the open wound (all necrotic)	4
6. Total amount of granulation tissue	0 = wound is closed (skin intact) or nearly closed (<0.3cm²) 1 = 75% or more of open wound is covered with granulation tissue 2 = >50% and <75% of open wound is covered with granulation tissue 3 = 25% to 50% of open wound bed is covered with granulation tissue (4) = <25% of wound bed is covered with granulation tissue	4

Appendix D: Literature Review Evidence Table

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
RCTs : Evidence level 1b-							
Jiang et al (2014) Multicenter comparison of the efficacy on prevention of pressure ulcer in postoperative patients between two types of pressure-relieving mattresses in China	To compare the efficacy of a non-powered static mattress with a dynamic air mattress with LAL	RCT across 12 general hospitals Inclusion criteria were: - age 18+ yrs - Braden score ≤ 16 pts - general anaesthesia with - operating time ≥ 2 hr - admitted to ICU or surgical ward post-op - clear consciousness - able to express their feelings correctly - contraindications for using air mattress replacement - completed informed consent Exclusion criteria were: - declined participation - critical condition and repositioning limited by doctor's orders - using ice blanket - shed from intervention ≤ 72 hrs - unable to determine the efficacy - incomplete data on the efficacy or safety judgement PEDro score = 7/11 Power calculations were not reported	Study was set in 12 general hospitals in 9 cities across 4 provinces of China. 14.34% from surgical ICU, 32.03% from orthopaedic wards, 53.63% from general surgery wards n=1074 Mean age = 57.9 yrs Intervention group: Sanma mattress overlay n=512 Nil pre-existing pressure ulcers Control Group: Waffle mattress overlay n= 562 One person in this group had a pre-existing pressure ulcer	Data collected for 5 days post-op: 1/ Skin inspection and PIs assessment - Both groups were repositioned 2 hourly with daily skin inspection head to toe - Skin breakdown reviewed to determine if PIs or not - graded the PIs as per NPUAP 2007 guidelines - noted location and occurrence time of PIs 2/ Braden assessed daily 3/ Mattress checked to ensure correct inflation 4/ Daily evaluation of patient's comfort using 1-5 scale 5/ Daily evaluation of procedure convenience for nurses using 1-5 scale	Surgical Pressure Ulcer Risk Assessment (SPURA) Braden scale Visual Analogue scale to assess pain at incision site 1-5 Rating scale for patient comfort (1= very uncomfortable, 5 = very comfortable) 1-5 Rating scale for nursing procedure convenience (1= very inconvenient, 5= very convenient)	At baseline the groups were statistically similar 11 PIs developed during the study period – 9x Stage 1, 2x Stage 2 - 5 in Intervention group and 6 in Control group Overall, - No difference in PI incidence was found between the two surfaces (1.07% vs 0.98%, p.0.05) - No difference in convenience to nurses - No difference in patient comfort level Note that static overlay is likely to be more beneficial in circumstances where power is not available	Allocation was not concealed Nil blinding of assessors discussed Not possible to blind participants due to obvious visual differences between the two surfaces (dynamic overlay has a pump and a visually different surface)

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
Demarrè et al (2013) The effectiveness of three types of alternating pressure air mattresses in the prevention of pressure ulcers in Belgian hospitals	To compare the effectiveness of multi-stage and single-stage active mattresses and overlays in hospitalised patients	2x RCTs – pooled data from Demarrè et al (2012) and Vanderwee et al (2005) Inclusion for pooled data - allocation to an alternating surface - Braden score <17 - no pre-existing pressure injuries - admitted to geriatric or internal medicine ward only Exclusion criteria - Friction impact on wounds PEDro – 5/11 Power calculations unable to be reported as retrospective study	Acute wards in Belgian hospitals – geriatric ward and internal medicine wards Median age = 80 yrs Group 1: Multi-stage alternating mattress – HillRom ClinActiv mattress replacement n= 252 Group 2: Single-stage alternating mattress replacement n= 264 Group 3: Single-stage alternating mattress overlay Alpha Xcell n= 101	All participants were provided with an air cushion for periods sitting out of bed Daily skin checks No standard repositioning protocol used Endpoints: - Discharged from participating ward - Death - Development of G2+ pressure injury - Consent withdrawn	Cumulative pressure injury incidence rate for G2+ within 14 days Time until pressure injury development (measured in days)	Overall Cumulative Incidence Rate – 4.9% Statistically significant difference in incidence rate for multi-stage mattress (3.6%) and overlay (8.9%) (OR=0.33, p=0.047). No significant difference between single-stage mattress (4.5%) and overlay (8.9%) (OR=0.40, p=0.126) Most PIs developed at the hip or sacrum No difference in time to PI development	Flaws and biases from original studies still present and compounded Vanderwee et al (2005) had unequal treatment of the treatment groups No randomisation due to pooled data although randomisation occurred in original studies Unequal group sizes
Van Leen et al (2013) Pressure relief with visco-elastic foam or combined static air overlay? A prospective, crossover randomised, clinical trial in a Dutch nursing home	To evaluate the clinical efficacy of a combination of a 15cm VE foam mattress with a static air overlay compared with VE foam alone in preventing pressure injuries.	Single-centre randomised crossover trial with 6 months in each treatment group. Inclusion criteria: - Braden ≤ 19 - age 65+ yrs Exclusion criteria: - pre-existing pressure injury PEDro – 7/11 Power calculations were reported	Nursing home in Naaldwijk, The Netherlands n= 41 Group A: Visco-elastic foam mattress replacement (Duosmart) n= 40 Group B: Visoc-elastic foam mattress replacement with static air overlay	All participants were provded with a static air cushion for use when sitting out of bed-bound Weekly skin inspections Repositioning commenced only when a G1 pressure injury developed Any new pressure injuries were healed before commencing Phase 2	Development of a G2+ pressure injury	Although more people developed a pressure injury in Group A (8 pressure injuries) than in Group B (2 pressure injuries) these results were not statistically significant (p=0.087). 2 people in Group A developed G3 pressure injuries and were removed from the phase and placed on low-air-loss mattresses and none in Group B. Significantly more people needed repositioning (ie	Possible carry-over effect from crossover design Due to deaths of 5 participants, study may be underpowered as required sample size as determined by power calculations was only just met at the beginning of the study.

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
			(Duosmart with Repose overlay) n= 39			developed a G1 pressure injury) in Group A (n=8) compared with Group B (n=1) (p=0.014)	
Demarrè et al (2012) Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled trial	To compare the effectiveness of alternating mattresses with single-stage inflation and deflation with alternating mattresses with multi-stage inflation and deflation	RCT performed across 5 hospitals Selection of hospitals and wards was based on geographical proximity and willingness to participate. Inclusion criteria: - Braden score <17pts - Patients with G1 PIs were eligible - aged 18+ yrs Exclusion criteria: - had a PIs G2+ on admission - expected admission time <3 days - DNR code specified end of all therapeutic interventions - weight < 30kg or >160kg (outside mattress specs) - informed consent not obtained PEDro score = 8/11 Power calculations were reported	Study was set in 5 hospitals (25 wards) across across Belgium 8 geriatric wards 3 rehab wards 14 medical wards of differing specialities Mean age = 76.3yrs Intervention group: HillRom ClinActiv multi-stage air mattress replacement n= 298 Control Group: Study device based on HillRom Alto mattress replacement n= 312	Braden completed on admission and twice weekly during inclusion period No standard repositioning protocol used Identical seating protocol was used (HillRom Reflex cushion – static air) Daily skin inspection completed by ward nurses Differentiation between PIs and incontinence-associated dermatitis Trial completed when: - Development of G2+ PIs - 14 days of attending trial - transfer to non-participating ward - discharge from hospital - death - withdrawal of consent	Primary outcome measure was cumulative pressure injury incidence Secondary Outcome – time to develop a PIs G2+ Braden Scale Mini-Nutritional Assessment Patient acceptability was measured indirectly by no of participants withdrawing consent during period of observation	At baseline the groups were statistically similar Total PIs incidence was 35 (5.7%) with 26 sacral PI and 9 heel PIs Intervention group - 17.1% incidence of new Grade 1 PIs - 17 new PIs Grade 2+ (5.7%) - 4 new Grade 3-4 PIs (1.3%) Control Group - 12.2% incidence of new G1 PIs - 18 new PIs G2+ (5.8%) - 7 new G3+ PIs (2.2%) Overall, no difference in PIs incidence between the surfaces (p=0.97)	Decrease in power due to lower-than-anticipated PIs incidence Limited predictability of Braden Scale
Van Leen et al. (2011) Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical	To evaluate the clinical efficacy of combining a cold foam mattress with a static air overlay versus a cold foam mattress alone	RCT – prospective, single centre Inclusion criteria: - age>65 - Norton score 5-12 - informed consent of resident or representative in cases of incapacity	Study took place in a nursing home in the Netherlands with an observational period of 6 months n= 83 Mean age = 82.1yrs	Data collected for 6 months: 1/ Norton scale completed at the beginning and the end of the observation period 2/ Identical seating protocol was used (static air cushion)	Primary outcome measure was development of G2+ PIs at the heel and/or sacrum Norton scale	Apart from Norton score, at baseline the groups were statistically similar Intervention group: PI Incidence =2 1x G2 and 1x G3 Control group:	No indication of blinding of assessors Not possible to blind participants due to obvious visual differences

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
trial in a Dutch nursing home		Exclusion criteria: - PIs in the past 6 months PEDro score = 8/11 Power calculations were reported	Intervention Group: Waffle mattress overlay and cold foam mattress n= 42 Lower Norton score noted but nil other relevant differences Control Group: Cold foam mattress n= 41	3/ No participants received repositioning at night 4/ Weekly skin inspections completed by an independent nurse 5/ Repositioning commenced upon development of a G2+ PIs as per NH protocol		PI Incidence =7 2x G2 and 5x G3 PI incidence p=0.088 CI 1.3% - 25.9%	between the two surfaces (dynamic overlay has a pump and a visually different surface) Used p<0.10 as significant
Malbrain et al. (2010) A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients	To compare PIs outcomes in ICU patients nursed on a reactive mattress overlay or an active alternating mattress replacement	RCT – pilot, single blinded, prospective Inclusion criteria: - admitted to ICU with Norton score ≤8 - requiring mechanical ventilation for at least 5 days - existing PIs were permitted Exclusion criteria: - Relatives refused consent (all participants were unconscious and thus unable to give consent) - not at least one of each mattress available PEDro score = 6/11 Power calculations were not reported	Study took place in a medical ICU in Belgium. n= 16 Mean age = 64.7yrs Intervention group: Nimbus3 alternating mattress replacement n= 8 mean age = 56.9 yrs mean pre-albumin =6.7mg/dl Control group: ROHO mattress overlay n=8 mean age = 71.5yrs mean pre-albumin =20.3mg/dl	Participants were repositioned 2 hrly from semi-Fowler position to R or L 30º lateral position Slide sheet was used for repositioning Heels were floated using a pillow underneath the calves for the Control group only All participants had IDCs and received additional nutritional support, aggressive treatment of infection and other concurrent illnesses Daily skin inspections for bony prominences Daily Norton scores	Norton scale PUSH scale and category as per NPUAP guidelines were assessed at inclusion and then weekly Photographs and tracings of wound borders	At baseline, the control group were significantly older and more malnourished Prevention – both groups had 2 participants each develop PIs so no difference between the surfaces More people in the Intervention group had wounds that improved (82%) compared with the control group (0%), (p=0.002). More people in the control group had deteriorating wounds (67%) than the intervention group (0%), (p=0.006)	Very small sample size indicates that study is underpowered The two groups were uneven for two key risk factors for PIs development, with both increased factors in the control group skewing the results Floating heels of control group but not intervention group skews the results
Gray et al (2008) A clinical audit of the Softform Premier Active mattress in	To compare the effect of the Softform Premier Active versus a standard air	RCT in two acute aged care wards in UK Inclusion criteria: High risk for developing a	Inpatients admitted to the participating wards during a 6 month period n=100	Repositioning and skin checks as per best practice 2hours max sitting out of bed followed by 1 hour min	Primary: Ward pressure injury Incidence Survey	PI Incidence for both groups was 8% Intervention: 4x G2 PIs (3 sacrum, 1 heels) Control 4x G2 PIs (2 sacrum,	No statistical analysis makes comparability with other studies difficult

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
two acute care of the elderly wards	mattress	pressure injury as determined by Waterlow and clinical judgement Exclusion criteria: Not described PEDro score – 3/11 Power calculations were not reported	Intervention group: Softform Premier Active mattress n=50 Mean age = 82.4 yrs No of chronic conditions = 3.2 Mean Waterlow = 22.2 Control group: Standard air mattress (not described) n=50 Mean age = 84 No of chronic conditions = 3.1 Mean Waterlow = 21.6	resting in bed When sitting out of bed all participants sat on a Softform Premier Active cushion Endpoints not described	investigating comparative performance of the two surfaces regarding ease of use for manual handling, cleaning, set-up and acceptability to patient	2 heels) Staff reporting Softform Mattress as good regarding all aspects discussed Statistical analysis not provided	Very limited information provided with regards to survey so it is difficult to interpret results No reporting of blinding or concealed allocation so biases are highly likely No description of control mattress – unable to determine if active or reactive surface Exclusion criteria not described and inclusion criteria very broad – likely to introduce selection biases
Cavicchioli & Carella (2007) Clinical effectiveness of a low-tech versus high-tech pressure-redistributing mattress	To compare the effectiveness of high-spec foam with the two modalities (alternating and continuous low pressure) of the high tech pressure mattress	RCT conducted in 3 hospitals across Italy Inclusion criteria: Braden ≤17 with mobility and activity scores ≤3 admission expected to last at least 2 wks maximum one G1 PIs Exclusion criteria: Braden >17 and activity or mobility scores >3 More than one PIs at study entry Existing PIs G2+	Participants from acute, post-acute and long-term care settings Mean age = 77.3 yrs Control group: Decufin foam mattress n= 33 Participants came from 2 hospitals in post-acute and long-term care settings	Data was collected for two weeks: Braden score completed on admission to study and at the end of the observational period All groups received the following: - 3-4 times during the day and once or twice at night - frequent bed linen changes to manage continence - daily inspection of at-risk area	Braden scale PI Incidence	Braden scores statistically different between Control group and Intervention groups at baseline and study end with Control group have higher scores (baseline $p<0.001$, study end $p<0.005$) PIs Incidence: Control 36.4% Alternating low pressure 2.9% Continuous low pressure 1.4% Pre-existing wounds healed:	Study is underpowered to provide a statistically significant result (would have needed n= 1467 for each group) Foam mattress now possibly discontinued

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
		No blinding between Control and Intervention Groups but blinding existed between the two intervention groups Random allocation only reported for allocation between the Intervention groups PEDro score = 7/11 Power calculations were reported at the end of study only, once PIs incidence determined	Intervention Group A: Duo2 mattress replacement using alternating low pressure modality n= 69 Intervention Group B: Duo2 mattress replacement using continuous low pressure modality n= 71	- Zinc oxide cream used for skin protection when deemed at risk - G1 PIs managed with polyurethane film or thin hydrocolloids to protect the area		Control n=0 of 6 Alternating low pressure n=4 of 6 Continuous low pressure n=3 of 3 Results are more significant given that Intervention groups were at greater risk of PIs with higher Braden scores however statistical analysis for this is notreported.	
Nixon et al (2006) Pressure relieving support surfaces: A randomised evaluation	To determine differences between alternating pressure overlays and alternating pressure mattresses as well as to investigate the impact of PIs on patients' well-being.	RCT in 11 hospital-based research centres across England Inclusion criteria: - aged ≥ 55 yrs - written informed consent obtained - acute patients with expected LOS of ≥ 7days and who were bedfast or chairfast and immobile or had very limited mobility and/or had a pre-existing G2 PIs on admission - OR surgical patients who were undergoing a surgical procedure with an average LOS of ≥ 7days and/or expected to be bedfast or chairfast and immobile or to have very limited mobility for at least 3 days post-op	Participants from acute or aged care wards Mean age = 75.2 yrs 5.6% participants had a pre-existing G2 PIs Group A: mattress replacement n= 982 Group B: mattress overlay n= 989 Mattresses varied between settings but had strict specifications to be adhered to preventing inclusion of hybrid mattresses	Twice weekly Skin assessment Twice weekly Braden Scale Twice weekly review of mattress to determine if changed, if working correctly and record reason for change All participants were provided with a high-spec foam mattress for 3 days following trial completion. Trial was completed when: Primary end-point – development of a new G2+ PIs on any skin site improved mobility and activity (Braden score of 3 or 4) transfer to non-participating ward discharge from hospital	PIs incidence G2+ on any skin site Time to healing of existing PIs Patient acceptability Cost-effectiveness	No statistically significant difference for PIs incidence – 10.3% Group A, 10.7% Group B, p=0.75 No statistically significant difference for time to healing – median time was 20 days for both groups, p=0.86 More participants allocated overlays requested changes due to dissatisfaction (23.3% vs 18.9%) - p= 0.02 More than one third of participants in both groups reported difficulties with bed mobility Cost analysis showed that mattress replacements were more cost-effective than overlays to an average saving	Standardised mattress overlays and replacements were not used, which could reduce the power of the study 25.7% of participants had 1 or more mattress changes which means that selection bias can be present for all data collected afterwards and can impact of a person's level of risk. This was

First author, year, title	Study purpose	Study design (incl inclusion & exclusion criteria)	Study population & setting	Intervention description	Outcome measures	Findings	Limitations
		Exclusion criteria: - participated in this trial during a previous admission - pre-existing G3+ PIs on admission - elective surgical patient with a planned post-op admission to ICU - elective surgical patient admitted more than 4 days pre-op - slept in a chair - weighed more than 140kg (upper limit for overlay mattress) - weighed less than 45kg (lower limit for mattress replacements with automatic sensor mats) Also conducted a qualitative review with 20-30 participants to assess the impact of PIs on their well-being PEDro score = 8/11 Power calculations were reported		60 days from randomisation death Secondary End points: healing of existing PIs using median time to healing, change in surface area (traced on transparent film on a weekly basis), and grade of ulcer at trial completion patient acceptability using no. of participants requesting to be moved due to dissatisfaction, and recording at trial completion of overall comfort as well as specific examples eg excessive noise, difficulty moving in bed		of £74.50 per patient, an analysis that also checked purchase vs hire and took into consideration lifespan of the support surface	attempted to be managed with ITT and 'as-treated' analysis Study unable to be blinded due to visual differences in the mattresses. This will impact on potential bias from ward nurses re: co-interventions such as repositioning Data re: impact of co-interventions not collected
Vanderwee et al. (2005) Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers	To evaluate whether an alternating pressure air mattress is more or equally effective as the standard prevention	RCT in 7 hospitals across Belgium Inclusion criteria: - age >18 yr - expected LOS ≥ 3 days - no pre-existing G2+ PIs on admission - weight <140kg - no contraindication to repositioning	Participants from surgical, medical or, primarily, geriatric wards Median age = 82 yrs Intervention group: Alpha Xcell alternating overlay n= 222	Both groups had identical sitting protocols using an air cushion and being asked to stand every 2 hours. Both groups had heels elevated using a standard cushion underneath the legs Control group received 4 hourly repositioning.	Incidence of PIs Braden scale	No statistically significant difference in the incidence of PIs between the groups. Intervention – 15.3% Control – 15.6% p=1 Significantly more heel ulcers in the control group (p=0.006)	Questionable comparability as the groups didn't receive the same repositioning. Had the intervention group received the same of repositioning, then a

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		- in need of PIs preventative measures as determined by either Braden score <17 or pre-existing G1 PIs Nil specific exclusion criteria mentioned PEDro score = 7/11 Power calculations were reported	Control group: Tempur viscoelastic foam mattress n= 225	Intervention group did not receive any repositioning Braden score on admission and every 3 days Daily skin inspection by ward nurse			statistically significant difference may have been found in favour of the intervention group Mathematical errors in reporting
Theaker et al. (2005) Pressure ulcer prevention in intensive care – a randomised control trial of two pressure-relieving devices	To evaluate to effectiveness of 2 devices – HillRom Duo and KCI Therapulse	RCT - single-centre Inclusion criteria: - considered high risk by non-standardised assessment used on ward - consent from relatives Exclusion criteria: - pre-existing PIs on admission - age<18 yrs - nursed on pressure-relieving mattress (other than standard hospital mattress) prior to admission to ICU PEDro score = 8/11 Power calculations were reported based on incidence not number or subjects with PIs	ICU setting Mean age = 65 yrs Intervention group: Therapulse LAL mattress replacement n= 30 Control group: Duo alternating mattress replacement n= 32	Study duration was time of admission in ICU + 2 week follow up period (not on study surface) Skin assessment 8 hourly. If PIs suspected then it was photographed and blindly assessed by 2 tissue viability nurses for confirmation and assessment of severity Nil indication if any additional interventions were used	Number of patients who develop PIs Total number of new PIs not reported and unable to be determined from data.	No statistically significant difference in the number of patients who develop PIs between the groups. Intervention – 10% Control – 18.7% p=0.35 2 participants who are highly predisposed to PIs were on the same support surface (Duo)	Non-standardised assessment tools used Outcome measure was number of patients who developed PIs rather than PIs incidence, which is much more widely reported. As a result study isn't really comparable and powered calculations inaccurate
Russell, Reynolds, Park et al. (2003) Randomized clinical trial comparing two	To determine if a viscoelastic foam mattress was superior to a standard hospital	RCT – unblinded, prospective across 3 hospitals Inclusion criteria - age ≥ 65 yrs	Elderly acute care, rehabilitation and orthopaedic wards in 3 hospitals in UK	Both groups were given standard nursing care PIs were assessed daily	Development of G1 PIs Waterlow	Statistically significant decrease in incidence of blanchable erythema with intervention surface (19.6% vs 26.7%, p=0.004) but non-	Used blanchable erythema as starting point for PIs – this is no longer

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support surfaces: Results of the Prevention of Pressure Ulcers study	mattress To analyse the cost-effectiveness of these two surfaces	- Waterlow score 15-20, indicating 'at risk' of developing a PIs - informed consent - presence of small areas of blanchable erythema (<1cm2) were permitted Exclusion criteria - weight >155kg - previous trial participation - refusal of consent PEDro score = 7/11 Power calculations were reported	Median age = 83 yrs n= 1168 Intervention group: CONFOR-Med mattress/cushion combination (viscoelastic) n= 562 Control group: standard mattress/cushion combination (information re: varieties was provided) n= 604	PIs were graded using Torrance scale rather than the now-standard NPUAP scale Participants has non-standardised seating protocols. End Points: Primary – death, discharge with no PIs, development of a newG1 PIs or worse, and transfer to other pressure-relieving surface. If blanchable erythema was present initially then this progressing to G1 was also considered and end point Secondary – development of blanchable erythema, however remained in trial on provided surfaces until primary end point occurred	Comfort scale 1-10 (1=completely relaxed and comfortable, 10= unbearable pain)	statistically significant decrease in the incidence of G1 PIs (8.5% vs 10.9%)	considered significant in regards to PIs staging Statistical analysis reported is more about blanchable erythema despite reported primary outcome measure being for G1 PIs Some of the 'standard' surfaces are reportedly pressure-relieving surfaces as well
Russell, Reynolds, Towns et al. (2003) Randomized-controlled trial of the RIK and the Nimbus 3 mattresses	To compare the effectiveness of the RIK mattress with the Nimbus 3 mattress	RCT – single centre Inclusion criteria: - existing G1+ pressure injury Exclusion criteria: - non-consenting - previously included in the trial - obese (>25 stone) PEDro = 6/11 Power calculations were reported	Acute wards at hospital in UK Intervention group: RIK mattress n= 75 Control group: Nimbus 3 mattress n= 83	4-hourly repositioning, or more frequently when requested Weekly photos taken for blind analysis of pressure injuries (but not mentioned in reported outcome measures) Endpoints: • discharge from participating ward • development of G3+ pressure injury	Length of stay 3-point score of wound response to mattress (worse, no change, improved)	No statistically significant difference with regards to length of stay (Intervention 20.05 days vs Control 22.17 days, p=0.23) or to improved overall wound progression (Intervention 74.7% vs Control 72.3%, p=0.67) 17.3% had a deteriorating wound that was upgraded to an active support surface (usually to Nimbus 3) and then to low-air-loss mattress	Study was under-powered, requiring n=100 for each group Unequal groups with the Intervention group being more mobile, thus decreasing their PI risk Unclear descriptions of outcome measures makes

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							interpretation of results difficulties Poor sensitivity of wound healing outcome measure means smaller effects are not included
Rosenthal et al. (2003) Healing of advanced pressure ulcers by generic total contact seat: Two randomized comparisons with low-air-loss bed treatments	To compare a therapeutic seat with low-air-loss bed treatment for healing of G3+ pressure injuries	2x RCTs – prospective cohort, second study extension of first study but excluding one of the treatment arms Inclusion criteria - G3+ pressure injury on coccyx, trochanter or ischial tuberosity - able to sit in last 6 mths and still able to sit up with assistance Exclusion criteria - sacral pressure injury (not in contact with seat surfaces) - previous involvement in the study - on or shortly to be moved to LAL - skin graft planned within 1 wk - had an active sinus tract or fistula - albumin levels <3.0g/dL, indicating poor nutrition - antibiotics required for infection - Dx of osteomyelitis - weight <60kg - without hip/knee flexion of	Long term nursing homes in Los Angeles RCT 1 Group A: Total contact seat n=38 Group B: Therapulse low-air-loss mattress n= 38 Group C: medium density foam overlay with contour cube cutouts n= 38 RCT2 Group A: Total contact seat n= 47 Group B: Therapulse low-air-loss mattress n= 47	Participants were on bedrest except those assigned to the cushions Routine dressing changes Endpoints: - withdrawn if required surgery - 6 months on surface - pressure injury healed	PSSS completed weekly for 6 months. Week 4 score was used for comparison analysis (measure of wound healing). Number of participants fully healed Time to fully healed Secondary outcome measures: Interface pressures Functional outcome measured by seating tolerance (5 day average measured at Week 4) and Katz ADL score	<u>Interface pressure over time</u> Cushion – mean 14.3mmHg LAL – mean 35.5 mmHg Overlay – 64.7 mmHg Statistically significant results ($p<0.001$) for cushion compared with low-air-loss and compared with overlay <u>PSSS difference</u> At 4 weeks the PSSS improvement on the generic seat was significantly greater than that in the LAL or overlay ($p<0.001$) <u>Time to fully healed</u> Analysed from combined samples Cushion – median 3.33 ±0.12 months LAL – median 4.38 ±0.14 months Overlay – median 4.55 ±0.22 months Statistically significant results ($p<0.001$) for cushion compared with low-air-loss and compared with overlay No statistically significant difference when comparing LAL and overlay ($p=0.4$)	Results would be skewed from one group spending time SOOB as this changes load on pressure injuries, especially when sitting up in bed at 75° Overlay used is generally not recommended for treatment of G3+ pressure injuries The groups were dissimilar – Overlay group had more co-morbidities

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		90° min PEDro – 7/11 Power calculations completed but not reported				Not impacted by location Functional Outcomes Improved seating tolerance and ADL Scores on cushion compared with LAL or overlay	
Sanada et al. (2003) Randomised controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation	To examine the effectiveness of a new double-layer overlay for at-risk patients who require head elevation of 45 deg or more	RCT – single centre head elevation = 45 deg or more Inclusion criteria - Braden scale of <15 - bed bound - no pre-existing PIs - required head elevation >30 PEDro score = 8/11 Power calculations were not reported	General acute care ward in Japan n= 79 Intervention group 1 single layer alternating-air overlay (Air Doctor) n= 29 Intervention group 2 double-layer alternating-air overlay (Tricell) n= 26 Control group standard hospital mattress (Paracare) n= 27	Repositioning every 2 hours Special skin care to guard against friction and shear Nutritional intervention when deemed necessary (not all participants, unclear on when this was deemed necessary) Daily visual skin assessments Weekly measurements for BP, body temp, total protein, al End Points: Braden became >16 released from hospital, development of a PI	PI incidence K-Scale (Kanazawa University Pressure Ulcer Predictive Scale) Braden scale Braden conceptual schema	Intervention group 1 5 participants developed PIs (19.2%, 95% CI = 3.8-34.6%) PIs on coccyx (3) and heel (2) Intervention group 2 1 participant developed a PI (3.4%, 95% CI = 0-6.8%) PI on coccyx Control Group 10 participants developed PIs (37%, 95% CI = 18.4-55.6%) PIs on coccyx (5), sacrum (2), heel (2), trochanter (1) PIs were found at either G1 or G2 Sig difference in pressure injury incidence between groups (p<0.01) No significant difference between the groups for angle of head elevation (p=0.276) Comment made that 2-cell had less PIs as it prevented bottoming out when in head elevation	Small sample size for a three-armed trial – likely under-powered Assessors were not blind to treatments Excluded from analysis if head elevation was <=30
Branom & Rappl	To determine if	Quasi-RCT – pilot study	One acute facility and	General data collection for	Meeting the goals	Control group had larger %	Minimal

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(2001) "Constant force technology" versus low-air-loss therapy in the treatment of PUs	costs could be decreased by purchasing a less expensive mattress than a LAL while maintaining or improving patient outcomes	Inclusion criteria: - admitted as an inpatient to one of the two test sites - existing G3+ PU(s) on trunk or pelvis - bedridden, necessitating pressure distribution off bony prominence and ulcer Exclusion criteria not reported PEDro score – 4/11 Power calculations were not reported	one sub-acute facility, both in California, USA n=20 Mean age = 72 yrs Intervention group: Pressure Guard CFT air and foam static mattress replacement n=10 Control group: non-specified LAL mattress replacement n=8	group comparability included age, albumin or pre-albumin, g-tube and ventilator dependency, site of ulcer. Didn't assess PU risk level Participants were on assigned mattress for a maximum of 8 weeks Participants received the topical wound care protocol for the facility they were in (these were similar and included repositioning) Wound measurements (length, width and depth in cms) were taken at baseline, 3 weeks and end of study. They were also taken weekly when clinicians were able to	of wound treatment as determined by the team: each wound rated goal achieved, not achieved or exceeded. Rate of wound healing over time as a % of baseline, -at 3 wks - at conclusion (8wks max)	of ventilated participants (who are usually medically more fragile) and had less PUs on the trochanter Meeting wound treatment goal – 100% goals were either achieved or exceeded for the intervention group, compared with 63% for control group Rate of Wound Healing – wound closure at 3 weeks and at endpoint were approx double for the intervention group (14.4%, 9% respectively) as they were for the control group (7.4%, 5% respectively) Overall found study mattress to be more cost-effective and more efficient at G3+ PU treatment	statistical analysis reported Not properly randomised Pilot study so small sample size Study mattress was being tested on G3+ PUs however is supplier stated for low-medium risk Poorly described methodology and results
Gray & Smith (2000) Comparison of a new foam mattress with the standard hospital mattress	To compare PIs incidence and comfort perceptions with new foam mattress and standard hospital mattress	RCT – single centre Inclusion criteria: - emergency or list admission for bed rest or major surgery - weigh <160kg - skin intact - no existing skin conditions - not terminally ill Nil specific exclusion criteria mentioned PEDro score = 7/11 Power calculations were not	Surgical, orthopaedic and medical wards at a hospital in Aberdeen, UK n=100 Mean age = 65 yrs Intervention group: Transfoamwave pressure-reducing foam mattress n= 50 Control group: Transfoam pressure-	Data collection occurred on Days 1, 5 and 10 PIs were graded using Torrance scale rather than the now-standard NPUAP scale Skin assessment was completed by blinded assessors 25% of intervention group received pressure cushion 50% of control group received pressure cushion	PIs incidence Comfort perception (5 point scale from very comfortable to very uncomfortable)	PIs incidence was the same in both groups, with each group developing 2 new PIs Most participants found the support surfaces comfortable to some degree – no statistical analysis evident	Limited by small sample Uneven provision of pressure cushion for seating protocol may have made a difference to PIs incidence in favour of control group Blinding of subjects and

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		reported	reducing foam mattress n= 50	Both groups spent similar amounts of time sitting out of bed			therapists not specified
Gunningberg et al (2000) Effect of visco-elastic foam mattresses on the development of pressure ulcers in patients with hip fractures	To determine if a visco-elastic foam mattress is more effective and reducing PI incidence than a standard foam mattress	RCT – single centre Inclusion criteria were not described apart from: - aged over 65 yrs - existing hip fracture (defined) Exclusion criteria were not clearly defined by were inferred to include: skin assessment documented on arrival presence of existing PIs 51 eligible patients not identified for study and therefore excluded – thought to be due to atypical fracture presentation, heavy workload of staff and lack of communication PEDro score =6 Power calculations were reported – n=100 for a medium-large effect and power of 80%, 95% CI	A&E and orthopaedic ward in University Hospital, Uppsala, Sweden n= 101 Mean age = 84 yrs Intervention group: 10cm VE foam mattress in A&E then 7cm VE foam overlay + standard mattress after surgery n= 48 Control group: standard 5cm trolley mattress in A&E then standard mattress (defined) on ward n= 53	All participants were provided with a Lassekudden anti-decubitis heel protection device Skin checks each shift (3x daily) 30° head elevation in bed	Pressure injury incidence Number of interventions documented by ward nurses	Overall pressure injury incidence 29% (G1+) Experimental group - n=12 developed pressure injury - 8 G1, 2 G2 - incidence rate 8% Control group: - n=17 developed pressure injury - 9 G1, 7 G2, 1 G4 - incidence rate 15% No statistically significant difference, with statistical analysis data not provided for this outcome measure Nurses documented more interventions for the control group	Some (n=5, 10%) in the control group were given silicon fibre overlays which provide additional pressure reduction, skewing the results in favour of the control group Lower incidence than expected could mean the study is under-powered Poor reporting of statistical significance
Evans et al. (2000) A clinical evaluation of the Nimbus3 alternating pressure mattress system	To assess the clinical effectiveness of the Nimbus3 mattress on PIs healing and comfort in subjects ≥65yrs, with at least a G2 PIs and	RCT – 2 centres Inclusion criteria: - age ≥ 65 yrs - pre-existing G3 PIs - OR pre-existing G2 PIs and one or more of: difficulty repositioning and unable to tolerate 30º tilt, unable to	Acute setting and nursing home setting overall n= 32 hospital n= 12 nursing home n= 20 Mean age = 81.2 yrs	Wound surface area (WSA) recorded twice weekly by tracing outline of wound onto sterile cellophane. This was conducted by blinded assessors Weekly comfort rating	Primary outcome measure - Change in WSA (initial size – final size), calculated as reductions in WSA per day Only used the	Hospital Setting: No significant difference in WSA reduction (0.12cm2/day vs 0.08cm2/day, p=0.57) Intervention mattress more comfortable than controls (5 vs 4, p=0.006) Nursing Home Setting:	Small sample size, likely due to very strict inclusion and exclusion criteria Only looked at one PI per subject

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	mobility problems	move in bed, in bed for more than 20h in 24h, weight ≥ 108kg and bed-bound, undergone spinal anaesthetic Exclusion criteria - spinal metastases - exudating wounds that may lead to hygiene or infection control problems - weight >250kg PEDro score = 9/11 Power calculations were not reported	Intervention group: Nimbus3 alternating mattress replacement overall n= 17 hospital n= 7 nursing home n= 10 Nursing home residents had significantly more PIs at baseline Control group: Hospital – another alternating mattress (list provided in study) Nursing home – Alpha Xcell alternating mattress overlay overall n= 15 hospital n= 5 nursing home n= 10	Nurses followed their organisation's established practice for pressure care with a standardised wound dressing protocol used. Nil indication but possible that Torrance scale was used to grade PIs due to age of study	largest wound with the highest Grading per subject Secondary outcome measure – 5-point scale to measure comfort Additional tools: Modified APACHE score to determine illness severity Waterlow score	No significant difference in WSA reduction (0.11cm2/day vs 0.05cm2/day, p=0.131) despite participants in the intervention group having more ulcers Intervention mattress more comfortable than controls (5 vs 4, p=0.002)	Only looked at WSA and not volume as well (indication of depth of wound) Results not pooled so underpowered with differing control mattresses (wider variety for hospital setting than for nursing home setting)
Russell et al. (2000) Randomised controlled trial of two pressure-reliving systems	To determine differences between two pressure injury systems	RCT – single centre Inclusion criteria: - existing G2+ PI using Torrance classification Exclusion criteria: - non-consenting - randomised equipt not available - participated in trial during previous admission - weight > 159kg PEDro score = 6/11 Power calculations were	Acute setting – aged care ward in UK Group A: Huntleigh Nimbus3 mattress replacement + Aura cushion n=57 Group B: Pegasus Cairwave Therapy System + Proactive 2 Seating cushion n=55	Treated using a standard protocol developed by tissue viability nurses (not described), including remaining on alternating surface until either PI healed or discharge Participants repositioned according to manufacturers recommendations (4 hrly Group A, 8 hrly or more frequently as requested for Group B) Photographs taken of wounds weekly and coded	Visual assessment of wound, supported by weekly photographs Comfort using digital analogue scales (10 point scale which was then converted to a 5 point scale for comparison with other data)	12 mth follow up extended to 18 mths as statistical significance not attained No statistically significant difference in sacral pressure injuries (p=0.45) No statistically significant difference in heel pressure injuries (p=0.067) except when combined data for participants who had died as well as those still alive, when Group A was found to be superior to Group B (p=0.019)	Differing mattresses and cushions so hard to say if difference due to cushion or mattress or combination Groups not treated equally – Group A turned more frequently Errors in statistical reporting – used

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		reported – power 80%, n=200 (not achieved, despite extension)		so to be blindly assessed		No statistically significant difference regarding comfort of either support surface (mattresses or cushions) (p=reported not significant).	averages rather than medians for ordinal data Questionable conclusion regarding approaching significance after 18 mths of data collection, statistical significance only achieved if included participants who had died Insufficient power – required sample size not achieved – 39% drop-out Cushions used have either been discontinued or superceded

Acronyms: PIs – pressure injuries; LOS – length of stay; RCT – randomised, controlled trial; G1 – Grade 1; G2+ – Grade 2 or higher (similarly G3+ is Grade 3 or higher); LAL – low-air-loss; CLP – constant low pressure; AF – air-fluidised

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