A review of current evidence for the use of the Repose® product range

KEY WORDS
- Heel protector
- Mattress
- Patient comfort
- Pressure ulcers
- Repose product range

The prevention and treatment of individuals with pressure ulcers requires the implementation of a range of strategies to include assessment of risk factors and the provision of appropriate interventions. Clinical approaches should comprise repositioning of the patient and also the use of pressure redistributing devices. There is a range of support surfaces available. This review focuses on the currently available evidence for the use of the Repose mattress overlay and foot protector device. The outcome of the review identified that there is a breadth of clinically relevant research available to demonstrate the utilisation and effectiveness of these specific products.

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Despite increasing knowledge regarding the aetiology of pressure ulcers (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel (EPUAP), Pan Pacific Pressure Injury Alliance, 2014) clinicians are still seeking effective preventative strategies to avoid tissue breakdown. Of equal importance is the requirement for cost-effective solutions for the prevention and treatment of pressure ulcers (Palfreyman and Stone, 2015). Approaches to prevention include early assessment of risk factors and the provision of appropriate interventions, such repositioning and support surfaces (including mattresses and cushions) (Chou et al, 2013).

Current guidance uses the term 'pressure redistribution' when describing mattresses, overlays, cushions and seating (National Institute for Health and Care Excellence, 2014), with manufacturers of such products proposing that these systems reduce the pressure exerted at the interface between the patient and the supporting surface. The purpose of this literature review is to provide a compendium of available research evidence to support the use of one such range of pressure-redistributing devices: Repose, which is produced by Frontier Therapeutics Limited.

HOW REPOSE WORKS

The Repose range of products is manufactured from a thermoplastic polyurethane film which is a multi-stretch, moisture vapour-permeable material that provides a non-allergenic, soft and smooth user interface which in an experimental situation has been shown to minimise friction and reduce shear (Wang et al 2015). It is comprised of a single air cell and is described as a reactive mattress, which means that small movements result in interface pressure being equalised across the entire surface. Repose is not suitable for persons weighing in excess of 139 kg or with unstable fractures, or where the person cannot be fully supported by the Repose product. *Box 1* summarises the range of products currently available.

REVIEW OF THE EVIDENCE

The Repose range has undergone significant advances over the past 18 years, with the original Repose mattress overlay being developed as a joint commercial initiative between the University Hospital of Wales and the Frontier Medical Group based in South Wales. The evidence base for the efficacy of the range of Repose products is increasing and, according to recent company estimates, its products have been used in the treatment or management of more than 3 million NHS patients to date.

One of the first randomised controlled trials to examine the effectiveness of the Repose mattress was undertaken by Price et al (1999). As the title of the subsequent publication suggested, it 'challenged

the pressure sore paradigm' as it highlighted the equivalency of a low-unit-cost inflatable mattress and cushion system (Repose) compared to a dynamic support mattress and an alternating pressure cushion. The sample included 80 patients with a fractured neck of femur who were randomised to the Repose mattress and cushion (Group A) or the dynamic mattress overlay and alternating cushion (Group B). All patients were assessed as being at very high risk of developing tissue damage according to the Medley scale, which was specifically designed for use with orthopaedic patients (Williams, 1992). The participants received standard best practice care, including regular repositioning. Assessment of skin damage was undertaken on four occasions: on admission, pre-operatively, 7 days post-operatively and at follow-up 14 days post-operatively. The data for the skin condition at the end of the 2-week follow-up period indicated that the majority of patients in both groups did not develop tissue damage (*Table 1*). The data shows that the majority of patient in both groups had a maximum score of zero (normal skin) at all assessment points. At the final assessment point, 9/50 patients had a higher score than zero (5 in Group A and 4 in Group B).

The authors examined patient-reported comfort ratings and showed that there was no statistically significant difference for either mattress. Price et al also examined the unit costs of the mattresses and identified that the 'low-tech' system was 50% cheaper than the alternating system (based on 1998 prices). In light of these findings, the authors suggested that the low-unit-cost Repose mattress overlay and cushions provided a viable alternative to the more high-tech/high-unit-cost pressure-relieving systems. At the time these findings questioned perceived opinions regarding the necessity for dynamic pressure-relieving systems.

Box 1. The Repose range

- Mattress Overlay
- Cushion
- Care-Sit™
- Foot Protector/Foot Protector Plus
- Wedge
- Trolley Mattress Overlay
- Babytherm
- Babynest
- Paediatric Mattress Overlay
- Companion
- Contur™

Subsequently, a study by Bale et al (2001) investigated the provision of support surfaces for the prevention of heel ulcers in patients within an acute hospital setting. This research was prompted by data identifying that heels were an increasingly common location for pressure ulceration. In phase 1 of the study, the authors undertook an audit to identify the types of devices being used. Bale et al found that the majority of patients (76.8%, *n*=289) were not provided with any foot support at all. In phase 2 the authors evaluated the use of the Repose Foot Protector in 100 consecutive patients. An assessment of the condition of skin on the heels using the 1999 EPUAP classification was undertaken. Data related to patient characteristics, clinical diagnosis, length of time between

Table 1. Maximum pressure sore score by assessment time and treatment group (Price et al, 1999)

Assessment	Group	Normal (Stage 0)	Persistent erythema (Stage 1)	Blister formation (Stage 3)	Superficial subcutaneous necrosis (Stage 4)	Number of patients with a pressure ulcer
Admission	Group A	26	12	1	1	14/40
	Group B	27	11	0	2	13/40
Preoperative	Group A	29	6	1	0	7/36
	Group B	29	4	1	3	8/37
7 days post surgery	Group A	26	3	2	1	6/32
	Group B	26	4	1	0	5/31
14 days post surgery	Group A	19	2	0	3	5/24
	Group B	22	2	1	1	4/26

Group A: Repose mattress and cushion system; Group B: dynamic support mattres and alternating pressure cushion

Declaration of interest
Supported by Frontier Therapeutics Limited.

admission and request for the device, ward type and patient comfort were collected on two occasions: the day the device was provided and day 10. The mean age of the sample was 70.5 (range 18–100 years), with the mean Waterlow score being 16.1 (standard deviation, 3.3). One-third of the participants came from an orthopaedic ward, with slightly fewer coming from the intensive care unit and surgical wards (31% and 22%, respectively). Overall the patients were relatively immobile, with 86% being either continuously in bed or only out of bed for short periods of time (*Figure 1*).

An assessment of each heel was undertaken on day 0, with the data showing that the majority of patients had grade 1 damage (left heel *n*=65 and right heel *n*=65, respectively). By day 10 an improvement in the grade of damage to the heels was evident (*Table 2*).

Similar to the previous study by Price et al, Bale and colleagues evaluated patient comfort as an outcome measure. Participants reported a higher level of comfort in the heel area after using the Repose Foot Protector ($p<0.0001$), see *Table 3*. They therefore concluded that by day 10 there was a significant improvement in patient comfort.

The study protocol precluded a longer-term follow-up but the findings did demonstrate improvements in the severity of tissue damage on the heel, as well as patient-reported comfort. This study raised the profile of the problem of heel pressure ulcers in patients with limited mobility, as well as suggesting that the use of a heel protector can have a positive impact on the condition of the skin over time.

A clinical evaluation of the use of the Repose Foot Protector was undertaken by Wilson (2002) in response to local data highlighting the problem of heel ulcer incidence in elderly patients who had sustained a fractured neck of femur. Appraisal of the use of the device took place over a 3-month period. During the study period, 38 patients wore the boots on both heels (*n*=76). Of these, 83% (*n*=63 heels) were assessed as having stage 1 pressure damage using the Stirling Pressure Sore Severity Scale (SPSSS). The author reported that deterioration occurred in a small number of patients but that the damage improved with continued heel protector use. While this is a small study, the results support the previous findings by Bale et al (2001) that the use of a heel protector can lead to improvements in early tissue damage.

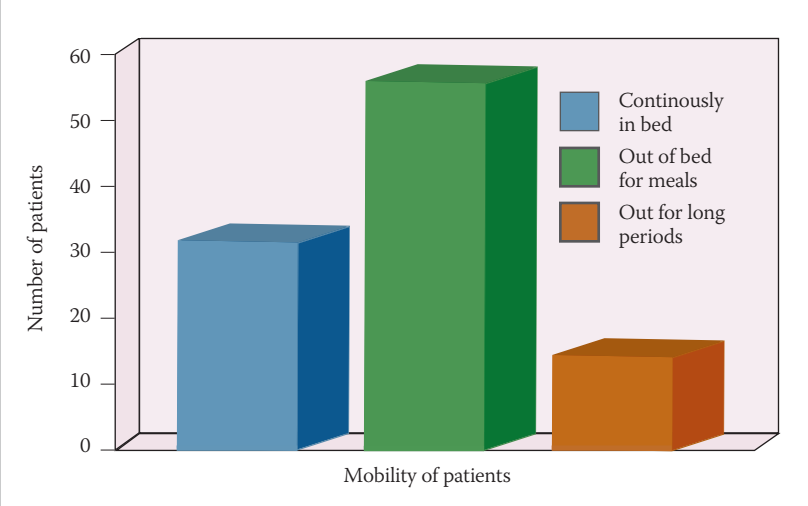

Figure 1. Mobility of patients included in the study evaluating the use of the Repose Foot Protector (Bale et al, 2001).

The observation that the use of the Repose Mattress Overlay appeared to have a positive effect on patient comfort prompted a 4-week prospective study by Price et al (2003) to examine the impact of using the mattress on reported levels of pain. The study included patients attending a rheumatology out-patient department who reported having chronic pain and sleep disturbance. Twenty patients were enrolled into the study, with data related to self-reported changes in sleep quantity and frequency of sleep disturbance being the primary outcome measures. Secondary outcomes were

Table 2. Condition of the skin on 100 consecutive patients' heels following allocation of the Repose Foot Protector (Bale et al, 2001)

Heel	Day	Healthy	Grade 1	Grade 2	Grade 3	Grade 4
Left (*n*=88)	0	11	65	12	0	0
	10	43	41	4	0	0
Right (*n*=91)	0	9	66	14	0	0
	10	45	32	13	0	0
Wicoxon signed rank z=-6.17, $p<0.0001$						

Table 3. Patient-reported comfort with use of the Repose Foot Protector. A five-point Likert-type scale was used; a low score denotes greater comfort (Bale et al, 2001)

Day	Mean	Standard deviation	Median	Minimum	Maximum
3	2.0	0.5	2	1	3
10	1.8	0.5	2	1	3
Wicoxon signed rank z=-3.71, $p<0.0001$					

Table 4. Changes in sleep and pain scores with use of the Repose Mattress Overlay (Price et al, 2003)

Week	Length of sleep in hours, mean (SD)[a]	Frequency of interruptions, mean (SD)[b]	Frequency of interruptions, mean (SD)[c]	Daytime pain, median (range)[d]	Night-time pain, median (range)[e]	Worst pain, median (range)[f]	Least pain, median (range)[g]
0 (baseline)	3.8 (2.1)	4.9 (2.1)	25.3 (13.6)	6 (4–9)	7 (3–9)	8.5 (6–10)	5 (3–6)
1	4.2 (1.7)	4.3 (1.8)	20.8 (13.6)	6 (3–8)	6 (3–8)	8.5 (6–10)	4.5 (3–6)
2	5.3 (1.5)	3.0 (1.4)	16.3 (13.6)	5 (3–7)	5 (3–8)	7.5 (5–10)	4 (3–6)
3	5.8 (1.6)	2.7 (1.5)	15.3 (9.6)	5 (3–7)	5 (3–7)	8 (5–10)	4 (3–6)
4	6.4 (1.7)	2.3 (1.3)	14.2 (9.8)	5 (3–6)	5 (3–7)	7 (4–10)	4 (3–5)

[a]ANOVA = 52.67, df = 4, $p<0.0009$; [b]ANOVA = 48.77, df = 4, $p<0.0009$; [c]ANOVA = 38.13, df = 4, $p<0.0009$; [d]ANOVA = 37.88, df = 4, $p<0.0009$; [e]ANOVA = 49.71, df = 4, $p<0.0009$; [f]ANOVA = 47.48, df = 4, $p<0.0009$; [g]ANOVA =12.18, df = 4, $p = 0.016$.
df = degrees of freedom; SD = standard deviation

self-reported changes in pain and use of analgesia. The authors described the data from 19 patients (all female) and reported statistically significant improvements in the mean length of sleep time, sleep interruptions and reduction of pain related to the use of the overlay mattress ($p<0.001$) (*Table 4*).

Price et al acknowledged that the sample was biased to the female gender and suggested that the inclusion of male participants was needed in future studies. The authors also recognised the potential impact of the Hawthorne effect on individuals who had lived with chronic pain and related sleep disturbances over many years, as the weekly home visits themselves may have resulted in improvements. However Price et al also reported a reduction in the consumption of analgesia for 13 of the 20 participants. The results of this small study suggested that the Repose mattress system had a positive impact on the quality and quantity of sleep for a sample of individuals with chronic pain.

In 2005, Osterbrink et al reported on a randomised, comparative study to evaluate the effectiveness of the Repose range of products including a mattress overlay, cushion, foot protectors and a wedge. The comparator was a small- or large-celled alternating mattress system. For this study participants had to have a grade 2 pressure ulcer as a minimum (pressure ulcer classification system not stated) and were drawn from hospital in-patients or nursing homes. Fifty patients were randomised to one of the mattress systems and were followed-up for 28 days, with data on wound healing parameters being collected. The results showed that the Repose system was better in terms of the numbers of wounds healed as well as time to wound healing ($p=0.009$). The Repose system demonstrated comparability to the large-cell mattress with regards to the same parameters. The authors also evaluated patient satisfaction in relation to the mattress they had been allocated, with the results showing that overall patients were more satisfied with the Repose system versus the other mattresses. These results are similar to the original study by Price et al (1999), which demonstrated the equivalency of a static pressure redistribution device compared to a dynamic system.

MacFarlane and Sayer (2006) undertook two independent clinical evaluations of the Repose range of products to determine the impact on pressure ulcer incidence, ease of use of the products and cost-effectiveness. The initial evaluation assessed the use of Repose Foot Protectors in a 24-bed orthopaedic unit. Data from a previous audit identified an incidence rate of 17% for all levels of tissue damage. Data collection took place over a 3-month period and all staff were trained in the use of the heel protectors. The authors collected data on pressure damage, Waterlow score and skin condition. The product was also evaluated by the nurses, who rated the product against key performance criteria, see *Figure 2* . During the audit period 44 patients took part in the evaluation, none of whom developed heel ulcers. Data from the user evaluation was positive in terms of ease of use.

In a second evaluation reported in the same publication, MacFarlane and Sayer described the results of a change in the provision of mattresses in a 460-bed hospital. The Repose overlay system was introduced as an intermediate step between the standard foam hospital mattress and the subsequent use of an alternating pressure mattress. In total, 136 overlays were used in selected units covering

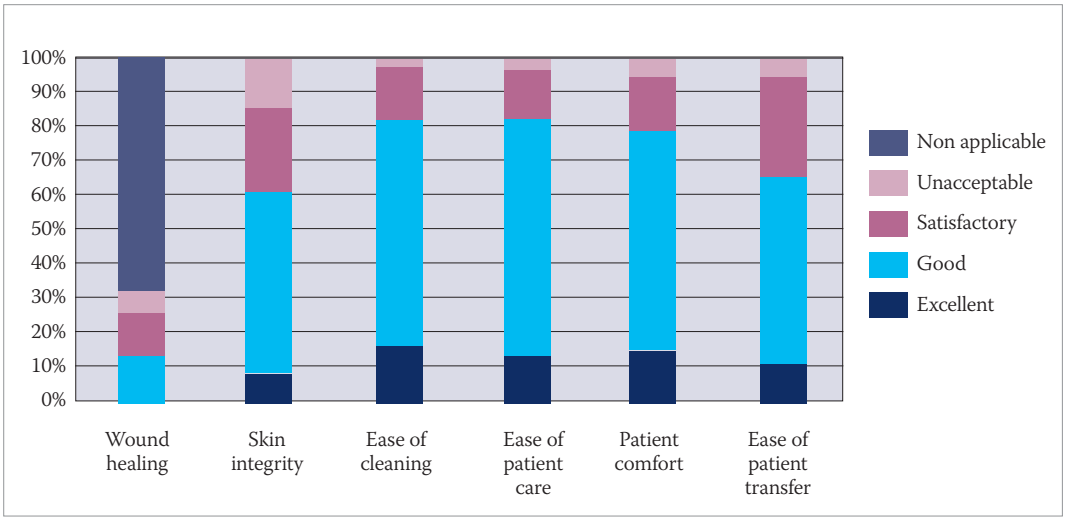

Figure 2. User evaluation of the Repose overlay mattress; key performance criteria (MacFarlane and Sayer, 2006).

acute admissions, intensive care, infectious diseases, oncology, rheumatology, respiratory, surgical, gastrointestinal and high dependency. The authors used the SPSSS to assess skin damage and reported that 78 out of a total 448 patients had skin damage, however the SPSSS includes blanching hyperaemia (grade 1), see *Table 5*. If these patients are excluded, the actual number of patients with more severe levels of tissue damage was 32.

MacFarlane and Sayer observed that in some patients (numbers not stated) the use of the overlay system resulted in an improvement in the grade of damage. Similar to previous studies, patients reported that the Repose overlay was comfortable. A rudimentary estimate of the potential cost savings of using the overlay during a 6-month period was £34,603. The authors acknowledged that a more accurate estimate of product cost effectiveness was required. Overall the evidence supported the notion that the use of Repose Foot Protectors and mattresses can help to reduce the prevalence of pressure damage, but also identified the role of the devices in improving skin condition where less severe damage is present.

Table 5. Prevalence of pressure ulcers at Western General Hospital, July 2000* (MacFarlane and Sayer, 2006)

Total patient population	448
Total pressure ulcers	78
Grade 1 blanching hyperaemia	6
Grade 2	25 (6%)
Grade 3/4	7 (2%)

*Grades measured using the Stirling scale

Fray and Hignett (2009) describe the use of a novel Repose device to assist with the transfer of patients in a lying position, i.e. from bed to trolley. Based on the Repose mattress system, the Repose Companion is a transfer device that is designed to remain with the patient following transfer. The authors included four experimental groups of devices: tube flat slide sheet, pair of single flat slide sheets, quilted tube flat sheet and the Repose Companion device. The participants (n=21, seven groups) were healthcare professionals with a high level of knowledge of patient handling, i.e. nurses, physiotherapists and back care advisors. In each group one of the participants acted as the 'patient'. The authors took a number of measurements to enable a detailed analysis of the task based on observations from video footage, the purpose of which was to identify aspects of the task that exposed the participants to force. The authors also examined the recording for compliance with the manufacturers' instructions. The final measure related to how long it took to complete the transfer. The security and comfort of patients was evaluated while tasks were performed.

The results showed that the participants ranked the Repose Companion device higher than the other products for forces, time taken, complexity and overall performance. The 'patient'-reported data indicated that the Repose device was the preferred option (*Table 6*), where a score of 1.00

Table 6. Comparison score and ranks for patient data relating to the use of four novel products (Fray and Hignett, 2009)

Item measured	Product average score (ranks 1-4, with 1 the preferred option)			
	Flat tube	Pair of flat sheets	Quilted tube	Repose Companion
Comfort on insertion	3.07 (3)	2.64 (2)	3.29 (4)	1.00 (1)
Comfort on transfer	3.14 (3)	2.71 (2)	3.14 (3)	1.00 (1)
Time taken	2.79 (3)	2.64 (2)	3.43 (4)	1.00 (1)
Security of transport	2.79 (3)	2.64 (2)	3.36 (4)	1.00 (1)
Overall performance	2.79 (=3)	2.79 (=3)	3.29 (4)	1.00 (1)

means the product was rated more highly. The data related to transfer time showed that the Repose surface was faster, as it did not require as many stages to complete the task; however in terms of force the Companion surface was not as efficient as the flat or quilted tube. The authors concluded that a benefit of the Repose Companion was that it reduced the number of tasks the users had to undertake to move the patient, which could provide an ergonomic advantage as well as being more comfortable for the patient.

In the most recent study examining the use of the Repose mattress, van Leen et al (2013) compared the use of a visco-elastic foam mattress on its own (Duosmart, Kabelwerk Eupen, Belgium) with the same mattress combined with Repose. This was a single-centre prospective study carried out in a nursing home. During the first 6 months, 41 patients aged 65 or more with a Braden score of 19 or lower with no existing pressure damage were randomised into two groups: 21 patients were placed on the foam mattress (control) and 20 patients were nursed on the foam mattress plus the overlay (intervention). In the second (crossover) 6 months of the study, 19 patients from the original cohort participated in each group, each acting as their own control. All patients were provided with a static air cushion when sitting out of bed. Patients were only repositioned at night if they developed non-blanchable erythema. The primary outcome measure for the study was the development of a category II, III, or IV pressure ulcer (using the EPUAP classification system). The baseline demographics showed that the average age of the control group (CG) patients was 80.8 and for the intervention group (IG) it was 79.1 years old. More than half of the participants in the CG and IG were female (18 versus 14, respectively) and had a diagnosis of dementia (18 versus 16). *Table 7* summarises the incidence of pressure ulcers during the 12-month study.

The results show that eight patients in the group who were nursed on the foam mattress developed a pressure ulcer. These were mainly category II ulcers and were more common on the heel. In the two cases where the patients developed a category III pressure ulcer, these individuals were transferred to a low air loss mattress. In the IG two patients developed a category II pressure ulcer during the 12-month period. This equates to a 22.2% risk of developing a pressure ulcer when using the foam mattress alone versus 5.2% with the combination, however this was not a statistically significant finding ($p>0.05$). This study highlighted a debate concerning the need for repositioning when using different support surfaces, something that the current joint 2014 National Pressure Ulcer Advisory Panel, EPUAP and Pan Pacific Pressure Injury Alliance guidelines address with regards to the use of overlays and mattresses for high-risk patients. Their recommendation is that overlays and mattresses should be considered where frequent manual repositioning is not possible.

Table 7. Incidence of pressure ulcers (category II and higher) per condition (van Leen et al, 2013)

	Visco-elastic foam mattress (n=40)*			Visco-elastic foam mattress with a static air overlay (n=39)§			*p*-value
Pressure ulcer	**Number**	**Location**		**Number**	**Location**		
Category:	8	Pelvic region	Heel	2	Pelvic region	Heel	
II	2	2	4	2	1	1	0.087
III	3	1	1	0	0	0	
IV	4	0	0	0	0	0	
Repositioning (at night)	8			1			0.014

*21 in the first 6 months and 19 in the second 6 months of the study; §20 in the first 6 months and 19 in the second 6 months of the study

SUMMARY

Placing the range research into a hierarchy of evidence such as suggested by Sackett et al (1996) shows that there is a breadth of clinically-relevant research demonstrating the utilisation and effectiveness of Repose products (*Figure 3*). The original randomised-controlled trial and subsequent clinical evaluations have demonstrated that the Repose Foot Protector can help to reverse less severe tissue damage (Price et al, 1999; Wilson, 2002; MacFarlane and Sayer, 2006). The majority of the evidence has indicated that benefits are also observed in terms of improved patient comfort (Bale et al, 2001) and, in patients with chronic rheumatology pain, use of the Repose mattress can improve sleep patterns and potentially reduce the requirement for analgesia (Price et al, 2003). In relation to moving and handling, one volunteer study demonstrated that the Repose Companion could help to make patient transfers faster (Fray and Hignett, 2009). Subsequent research has suggested that the use of a static air overlay mattress with a visco-elastic foam mattress may reduce the requirement for repositioning, even in high-risk patients (van Leen et al, 2013).

CONCLUSION

The prevention of pressure ulcers continues to be a significant challenge for clinicians. The provision of a support surface that redistributes pressure is a key element of an overall pressure ulcer prevention strategy. The evidence to support the use of the Repose range of products spans almost two decades and highlights the versatility of this static air overlay system with regards to the prevention and treatment of pressure ulcers. While there is often a focus on higher levels of evidence to support clinical practice, i.e. systematic reviews and meta-analysis, the strength of the research base to demonstrate the effectiveness of the Repose range of products lies in the provision of clinically-relevant forms of inquiry. WUK

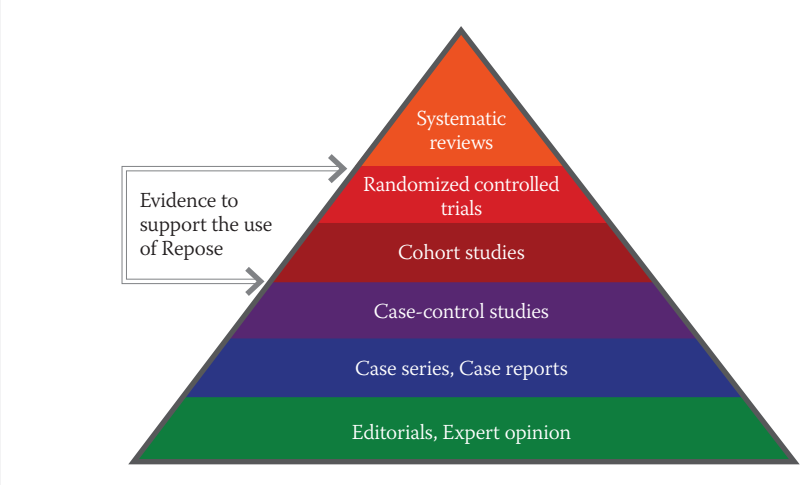

Figure 3. Levels of evidence to support the use of Repose (Sackett et al, 1996).

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