Clinical Literature Review

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| **Prepared By:** |
| Print Name | Position | Signature | Date(DD / MM / YY) |
| BEN SMITH | Product and Innovation Manager |  |  |
|  |  |  |  |
| **Reviewed By:** |
| Print Name | Position | Signature | Date(DD / MM / YY) |
| RAY BARDELL | Systems Manager (External) |  |  |
|  |  |  |  |
| **Approved By:** |
| Print Name | Position | Signature | Date(DD / MM / YY) |
| Mike Hutson | Managing Director |  |  |
|  |  |  |  |

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# 1. INTRODUCTION

Literature on Continuous Lateral Rotational Therapy (CLRT) has been reviewed to gain an understanding of its uses, it’s limitations and the best way to ensure that the product developed is acceptable for the intended use. Literature on pressure ulcers, specifically preventative solutions through Alternating Pressure Air Mattresses (APAMs), was not necessarily needed for this development project as this information is inherent to previous projects and is controlled by the NoDec Wizard software / control unit. The angle of the mattress is not software controlled and is integral to the air cell design, hence the review of specific CLRT literature.

The literature has been evaluated with the intention of analysing the clinical feasibility of the development project, the potential clinical risks and specific product requirements.

# 2. ROTATION THERAPY

## 2.1. Introduction to Continuous Lateral Rotational Therapy

Immobility impairs cough and mucociliary clearance in patients receiving mechanical ventilation, thereby promoting retention of secretions (Raoof et al, 1999). It is estimated that between 10% and 28% of patients admitted to intensive care unit (ICU) develop a nosocomial pneumonia related to being mechanically ventilated, also known as ventilator-associated pneumonia (VAP). Some studies show that this can incur an extra 28% in length of stay ~~a~~nd £6,000 - £22,000 in extra financial cost (Wanless and Aldridge, 2011).

It has long been recognised that turning the patient at various angles helps to treat acutely injured lungs, such as airway closure and atelectasis, and avoid pulmonary complications, such as ventilator-associated pneumonia (VAP), pooling and stagnation of secretions and lymphatic damage (Wanless & Aldridge, 2011, Clini & Ambrosino, 2004). Putting the patients at various lateral angles as opposed to supine helps improve gas exchange, mobilise secretions in the lungs and improve lymphatic damage. Typically, this involves, though technically difficult to do, placing the patients prone. This is quite aggressive turning therapy and, as found by Silpasupagornwongse et al (2006), very physically strenuous on the nursing staff – more than 85% of nurses developing lower back pain after starting work.

Less aggressive forms of turning include kinetic therapy, in which patients are rotated from side to side in a turn of at least 40° (80° total arc) and continuous lateral rotational therapy (CLRT), where patients are rotated from side to side in a turn of less than 40° (Ahrens et al, 2004).

Generally speaking, therapy with beds that intermittently or continuously rotate patients along their longitudinal axis by 30° or more have gained acceptance in the care of critically ill patients (Raoof et al, 1999). Certainly, Sahn’s (1991) findings that the early use of rotational therapy (7-14 days within admission) in immobile patients decreases the incidence of pneumonia are echoed by the National Institute for Clinical Excellence (NICE, 2008) in their published guidance on ventilation associated pneumonia (Wanless & Aldrige, 2011).

Early use of rotation therapy, i.e. 48 hours, which involves both manual postural changes and passive mobilization also reduces incidence of nosocial pneumonia / VAP with patients who have suffered with ischemic stroke (Cuesy, Sotomayor & Piña, 2010).

According to Uttarachon et al (2019), however, special turning / rotation beds are very costly and not always available in low – and middle – income countries (LMCs).

## 2.2. Clinical Benefits of CLRT

According to Anderson and Rappl (2004), specialised mattresses and beds for laterally rotating patients have been used for more than 30 years, mainly in the prevention and treatment of cardio-respiratory conditions in ICU patients.

The effect of CLRT on pulmonary outcomes is well-known in literature. Four studies from 1999 to 2012 demonstrate a statistically significant decrease in VAP rates when CLRT was implemented as compared to patients who were manually repositioned (Anderson et al, 2016). This being said, kinetic therapy has been investigated more frequently with more detailed studies. CLRT has been investigated in a manner similar to kinetic therapy, but with fewer studies with generally smaller sample sizes (Anderson and Rappl, 2004).

Wanless and Aldridge state that “Although the studies have small sample sizes and some methodological difficulties, most studies have reached similar conclusions. CLRT, when used appropriately, reduces the incidence of atelectasis, nosocomial pneumonia, time on the mechanical ventilator and length of stay in an ICU, making it beneficial and cost effective.” (2011)

Goldhill’s et al (2007) review and meta-analysis of the literature places the various benefits of into a comprehensible table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Study / Reference** | **Control** | **Intervention** | **Significant differences between treatment and control groups** |
| *Rotation* |
| Degrees | Per Hour | Hours / day |
| Kelley et al (1987)  | Turned a mean of 12 times a day | NR | 8 | NR | Risks of any infection (pneumonia or urinary tract infection or sepsis) 2.9 times less (pneumonia alone 28% vs 52%), risk of multiple infections 6.4 times less |
| Gentilello et al (1988) | Turned every 2 hours | NR | NR | 24 | Combines atelectasis and/or pneumonia (33.3% vs 65.8%) |
| Summer et al(1989) | Turned every 2 hours | NR | NR | 24 | Patients with sepsis and chronic obstructive airways disease had shorter ICU stay, patients with chronic obstructive airways disease had fewer days of mechanical ventilation |
| Demarest et al (1989) | Turned every 2 hours | NR | NR | 24 | Less atelectasis and/or pneumonia in those who started with normal findings on a chest radiograph (1/9 in treatment group vs 5/6) |
| Fink et al (1990) | No Comment | NR | NR | NR | Fewer lower respiratory tract infections (25.5% vs 58.3%), less pneumonia (13.7% vs 39.6%), shorter median hospital stay (20 days vs 37 days) |
| Clemmer et al (1990) | Turned every 2–4 hours | 72° | NR | 24 | No significant differences |
| Nelson and Choi (1992) | Turned every 2 hours | NR | NR | 20 | No significant differences |
| Shapiro and Keegan (1992) | No Comment | NR | NR | NR | No significant differences but mismatched groups; ISS controls 29, ISS rotation 45 |
| deBoisblanc et al (1993) | Turned every 2 hours | 45° | 8 | ≥18 | Pneumonia less (95 vs 22%) |
| Whiteman et al (1995) | Turned every 2 hours | 30° | 8 | NR | Fewer respiratory tract infections (36.4% vs 58.3%), and time to onset delayed |
| Traver et al (1995) | Turned every 2 hours | Up to 40° | 3 | NR | No significant differences |
| Raoof et al (1999) | Turned every 2 hours | 45° | 4 | ≥18 | Atelectasis resolved partially or completely (14.3% vs 82.3%), higher PaO2:FIO2 on days 3, 7 and 10 |
| MacIntyre et al (1999) | No comment | 32° | 8 | 24 | Fewer urinary tract infections (11% vs 27%) |
| Maclean (2001) | Turned every 2 hours | 45° | 2 | 18 | No statistical analysis |
| Kirschenbaum et al(1983-86) | Turned every 2 hours | 30° | NR | 18 | Lower prevalence (17.5% vs 50%), delayed onset of pneumonia (29 vs 12 days) |
| Ahrens et al (2004) | Turned every 2 hours | 40° | 2 | NR | Pneumonia less (14% vs 33%), lobar atelectasis less (16% vs 31%) |

Unfortunately, seven of the sixteen studies that Goldhill et al (2007) analysed did not include details on the degree of rotation. However, it quickly becomes obvious of the significant reduction in VAP when using rotational therapy as reported in 7 of the studies. Atelectasis, the collapse or closure of a lung which results in reduced gaseous exchange, was also mentioned in four of the studies with significant reductions compared to the control. Other clinical benefits where reduction in infections have been shown in studies include: Sepsis, urinary tract, chronic obtrusive airways, respiratory tract infections. Reduced length of stay in the ICU was also reported in a small number of studies (Goldhill et al, 2007).

Although not all of the studies mentioned the degree of rotation of turn, out of the nine studies, 4 would be classed as kinetic therapy (≤40°) as opposed to CLRT (>40°).

As concluded by Anderson and Rappl (2004), the optimal degree and frequency of rotation have not been determined by their review and study. Many studies reinforce this, where although 30° is generally accepted for pressure relief there is not a study that shows what degree gives the best care for helping to prevent VAP etc. Ahrens et al state “Research has been inadequate in evaluating frequency of turning, angle of turn, and duration of turn.” (2004)

## 2.3. Risks with CLRT

As with many medical devices there are contraindications involved with CLRT, any immobile patients with spinal cord injury, agitated patients and patients not receiving mechanical ventilation were unsuitable because of their inability to tolerate aggressive rotational therapy.

Due to the degree of the rotation, some patients who are awake find it difficult to tolerate CLRT, particularly at the higher degrees of rotation. Goldhill et al (2007) suggests that tolerance may be improved by administering a scopolamine patch, providing both antiemetic and sedative effects; but, in general, acute lateral rotation may be best suited to unconscious or sedated patients.

However, there can be a general reluctance with clinicians to sedate patients for kinetic therapy and the inability of some of the unsedated patients to tolerate kinetic therapy did limit the study findings of Ahrens et al (2004). In fact, patients randomized to the kinetic therapy group within their study, who, because of anxiety or physiological changes, could not tolerate the rotation during the first 24 hours were given an additional 24 hours to establish a tolerance. This was done by using the bed’s acclimation mode (Ahrens et al, 2004).

Ideally, neurologically depressed patients or patients sedated specifically for kinetic therapy should be considered for this type of treatment.

Supposed complications associated with rotational therapy also include disconnection of intravascular catheters and adverse effect of intracranial pressure and arrhythmias (Goldhill et al, 2007). Nevertheless, Gonzalez-Arias et al (1983) did find that in a study of 10 patients with head injuries, rotational therapy did not have any significant effects on intracranial pressure.

# 3. CONTINUOUS LATERAL ROTATIONAL THERAPY: A synergy to anti-decubitus devices

## 3.1. Reducing pressure ulcers using CLRT

According to Anderson et al (2016), hospital acquired pressure ulcers have a 4.77% incidence rate in critical care units while VAP has a reported incidence of 10–20% of all ventilated ICU patients and a mortality rate as high as 50–70%.

CLRT has been cited as a method to reduce incidence of both Hospital Acquired Pressure Ulcers and Ventilator Associated Pneumonia in hospitalized patients. In fact, in Goldhill et al’s (2007) conclusion, they state: “The beds considered in this review have other uses apart from the prevention and treatment of respiratory complications, *such as maintenance of skin integrity* and mobilization of secretions. These other uses must be considered when deciding whether to place a compromised patient on a therapeutic bed.”

Anderson and Rappl (2004) illustrated the potential healing effects on established pressure ulcers that CLRT may provide. Their study used a population which consisted of patients with a partial-thickness (Stage II) or full-thickness pressure ulcer (Stage III or IV) on the trunk of pelvis. Patients received the use of a powered support surface that included the CLRT modality (PressureGuard APM, Span-America), the mattress turned the patient in a 40-degree arc, 20 degrees to each side.

The results from their study were positive, 60% of the partial thickness wounds and 55% of the full thickness wounds closed in 12 weeks. Despite the small number of subjects in this study, according to Anderson and Rappl (2004) these results are similar to, or slightly better than, those recently reported by Bolton and McNees (2003) who found 61% of the patients with superficial or partial-thickness ulcers and 36% of full thickness ulcers healed in 12 weeks.

Although Anderson and Rappl (2004) are often cited for the reduction of pressure ulcers using CLRT, their study did not determine the optimal degree and frequency of rotation.

Moore & Cowman (2012) proved, in their randomised trial, that a 30° repositioning tilt helps maintain a level of perfusion over the weight-bearing areas. The control group were laterally rotated every six hours at 90° whereas the trial group were rotated at 30° every three hours. The incidence of pressure ulcers was 11% and 3% respectively, however it is important to stress this was manual repositioning using pillows and static wedges. 90° lateral tilt position has been reported to increasing the interface pressure over the greater trochanter – the bony prominence situated on the proximolateral side of the femur (Uttarachon et al, 2019).

Uttarachon et al, (2019) performed a study on a prototype mattress turning device that used inflatable bladders to laterally rotate the patient to 30°. They found that the peak pressure over the bony prominences was reduced significantly over the occiput and sacrococcygeal areas but increased over the scapula and trochanter as shown in the following table:

|  |  |
| --- | --- |
|  | **Peak Pressures (mmHg)** |
|  | *Supine* | *Lateral Tilt* |
| Occiput | 30.75 | 27.26 |
| Spine of scapula | 27.05 | 29.93 |
| Sacrococcyx | 35.99 | 27.26 |
| Greater trochanter | 0 | 30.29 |

This increase in pressure on the greater trochanter was deemed acceptable by Uttrachon et al (2019), however this still bears a risk to the patient and would need further investigation.

## 3.2. Associated Risks With Pressure Reduction Using CLRT

### 3.2.1. Nursing Intervention

Even if a CLRT bed provides a pressure redistribution surface, CLRT may not provide protection from pressure ulcers unless specific interventions for prevention are also instituted. (Wanless & Aldridge, 2011). Regardless of bed type, CLRT alone does not eliminate the need for manual repositioning of the patient (Nix, 2007), even if the CLRT is set for the maximum rotation the patient never breaks contact with the surface.

Anderson and Rappl (2004), although advocates for CLRT, state that CLRT mattresses do not replace the need for manual position and that despite the fact CLRT mattresses “rotate” the patient, their joints, muscles, organs require regular position changes for stimulation, stretch and function.

When manual repositioning, although being time consuming as stated by Moore & Cowman (2012), it does mean that the nurses can check the patient’s skin during the procedure. Nurses cannot depend on a kinetic bed to reposition the patient, they still need to intervene and inspect the skin frequently for signs of injury, especially over bony prominences (Black, 2006; Wanless & Aldridge, 2011).

Although Uttarachon et al (2019) hypothesis that low back pain in nurses will decrease with a turning mattress due to reducing the repositioning, they state that nurses “should be reminded that skin check is still necessary and should be done after every turn and repositioning especially in patients with physical impairments such as joint deformity as they will need additional manual repositioning”.

### 3.2.2. Shear Injuries

Black (2006) shows in their case study that although the subject was rotated to a 30-degree angle, but a patient must be positioned at 40-degrees laterally to relieve pressure on the sacrum. Because the patient wasn’t turned that far when the bed moved their body, the skin over the sacrum pressed against the bed surface while his body moved, creating a shearing injury.

Shearing injury to the sacrum commonly occurs when patients who are sitting up in bed slide down because the head of the bed is elevated. Laterally tilting the bed or mattress can put the patient at risk of a similar situation where the body slides down causing a shearing injury.

Anderson and Rappl (2004) hypothesise how the average rate of wound closure of Stage II was lower than the rates of full thickness pressure wounds due to the fact that partial-thickness or Stage II wounds are often due to friction or maceration. Therefore, they are easily re-opened by trauma, such as shearing forces. So, although they may close rapidly, they can also re-open rapidly, and can re-open several times while a CLRT mattress is in place (Anderson & Rappl, 2004).

Uttarachon et al (2019) address this risk of shearing forces during turning though the addition of a lateral small air bellow which, when inflated, supports and prevents a body from sliding down in their mattress turning prototype.

### 3.2.3. Pressure increased in certain areas

It was shown in numerous studies that CLRT does increase the pressure in the greater trochanter and sacrum (Black, 2006; Uttarachon et al, 2019).

Wanless and Aldrige (2011) also highlighted that heels must be protected from prolonged pressure which can still occur with CLRT, this could be through the use of a speciality therapy surface or by the use of positioning devices.

# 4. CONCLUSIONS

Reviewing numerous literature articles, it becomes apparent that there is not a specifically defined rotation amount to give the clinical benefits of CLRT. Although 30° is demonstrated as worthwhile and suitable when manually repositioning the patient for pressure reduction, this specific figure falls under the range of rotation amounts that have been studied for CLRT.

Ultimately 40° or more seems to have been accepted as significantly reducing incidences of VAP amongst other reduced incidences like: urinary tract, atelectasis and respiratory tract infections. However, this degree of rotation can be unnerving for conscious patients and they cannot tolerate such rotation amounts.

As shown in the table, there is still benefits with rotating the patient 30° as shown in Blacks (2006) case study in terms of reducing VAP and helping to mobilise secretions in the lungs. The case study highlighted the occurrence of pressure injuries to the sacrum when only rotating to 30°. This was confirmed by Uttarachon et al’s (2019) prototype where there was still pressure acting on the sacrum. From this it seems that the benefits of CLRT on pressure reduction do not extend to the sacrum and heels that are permanently in contact with the surface.

As the NoDec Wizard has both alternating pressure air mattress and the rotational features, any risks regarding pressure injuries should already be preventable from the upper alternating pressure deck of the mattress.

Like Uttarachon et al’s (2019) prototype, the former that is integrated in the mattress design will also support the patient and should prevent shearing forces.

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