

Audit: Use of the Neo+ (formerly known as the 'IPS') by Daytot to produce a sustained supported flexed position in supine on neonatal surgical patients displaying abnormal postures: a retrospective audit and analysis of therapy selection and intervention.

Summary: Flexion is necessary for normal development. Early loss of physiological flexion combined with weakened abdominal muscles can occur with major birth defects requiring intra-abdominal or thoracic surgery during the neonatal stage of life. Reduced antigavity movements, which combined with a lack of handling during this critical period, can present with abnormal postures. This frequently leads to delay in early development skills, resulting in poorer outcomes.

Current practice for the post-term infant within a surgical neonatal intensive care unit is to position the infant using soft rolls in side lying and supine to promote flexion in midline, facilitate abdominal work and inhibit non-functional postures. Despite this, some infants continue to display abnormal postures and/ or muscle imbalance and subsequently a delay in the attainment of developmental milestones. These infants often require a greater degree of support. In an attempt to overcome these difficulties, a prototype Neo+ by Daytot Design was trialled; this ensured a greater degree of consistent positioning than that produced by the soft rolls.

Following the trial period, a retrospective audit of the 35 infants identified as having ongoing developmental difficulties requiring greater support was carried out. Analysis of the use of the Neo+ included identification of appropriate infants; mode of Neo+ application and evaluation of the developmental outcomes and length of time to achieve these outcomes.

The audit highlighted that the Neo+ was effective in maintaining a consistent flexed position reducing abnormal posturing and enabling the infants to re-establish normalised patterns of movement. This produced a more effective basis for building skill development.

Introduction.

Congenital birth defects are common, affecting up to 5% of neonates (Walker et al 2012) 95% of whom survive (Laing et al 2011). Birth defects can require abdominal or thoracic surgery during the neonatal stage of life in order for the infant to survive and this frequently leads to delay in attainment of early developmental skills (Laing et al 2011). Laing et al (2011) found that 26% of 118 infants who had abdominal or thoracic surgery had motor delay following the surgery during this critical period. There are a number of factors that can contribute to developmental delay in infants who require surgery during the neonatal period. Well documented problems for these infants in which physiotherapy has no direct influence include critical illness (Walker et al 2006); multiple surgical procedures (Simon et al 1993; Gischler et al 2009); length of ventilatory support (Friedman et al 2008); low birth weight (Fuller et al 2009; Kieviet et al 2009); poor nutrition (McGahren et al 1997); interrupted sleep patterns (Weisman et al 2011); attachment to medical appliances (Gischler et al); and long-term hospitalisation (Fuller et al 2009; van der Cammen-van Zijp et al 2010). It is recognised that surgical neonates can also have a problem with posture and stability, both of which are necessary for developmental progression (Bly 1983). Physiotherapy early intervention promoting supported postures can impact on this (Hunter 2010). Historically, current practice for the post-term infant within the surgical neonatal intensive care unit is to position the infant using soft rolls in side lying and supine to promote flexion in midline, facilitate abdominal work and inhibit non-functional postures. Despite this, some infants continue to display abnormal posture and/or muscle imbalance and subsequently there is a delay in the attainment of developmental milestones. These infants require a greater degree of support and/or inhibition than is currently provided by the soft rolls to address these abnormalities thereby assisting early skill development (Waitzman 2007).

A Neo+ designed by Daytot to provide enhanced sustained supine support for infants under the age of 1 year has been trialled in the neonatal unit at Glasgow Children's Hospital, Scotland between 2011 and 2013. Over 40 infants, having been identified as having additional positional needs, were selected by the highly specialised neonatal physiotherapist to use this system. The outcome of this trial needed to be evaluated.

Aims:

The aim of this evaluation was to analyse the current use of the Neo+ within the neonatal population in Glasgow Children's Hospital and to evaluate the selection criteria and therapeutic usage developed during the appraisal of this prototype piece of equipment.

Objectives:

The objectives of the evaluation were:

1. To identify any common links in selection criteria between the infants selected for Neo+ intervention.
2. To identify methods of Neo+ system usage.
3. To evaluate developmental outcomes following the intervention.

Method.

A retrospective audit was carried out by the Highly Specialised Neonatal Physiotherapist. The data collected was accessed through both electronic and paper health records. Gestational age and clinical data were collated. No personal identifiable data was retained.

Patients included in this audit used the Neo+ whilst inpatients at Glasgow Children's Hospital, Scotland (formerly Yorkhill hospital). Data was taken from babies born in 2011-2013. It was felt that the data from earlier years would be unreliable as the usage of the Neo+ before this time was in its infancy and use was sporadic. It was initially intended to be used as a sleeping system, however it quickly became apparent that the benefits of the Neo+ exceeded this passive application and could be used for a more active purpose. All infants born within these dates who used the Neo+ were included unless a consent form for sharing of data was not apparent in their physiotherapy notes. Three infants therefore had to be excluded. A total of 35 infants were audited.

Ethics

As this is a retrospective audit and evaluation of current practice within the neonatal unit no ethical approval was necessary.

A Risk Assessment carried out at this hospital identified a number of important facts to be considered before using the Neo+:

- Consent from parents/carers- recognising this product is in its prototype form.
- Position set up- in the hospital setting the infant's parents primarily were responsible for readjusting the Neo+ if it required remoulding when the physiotherapist was unavailable. Nursing staff were also available to support and assist this function once they had been trained in use of the Neo+ by the physiotherapist.
- Safety- as this product is a prototype and used for the under one year age group, it was deemed necessary all infants required an apnoea monitor when using the Neo+. (Back to sleep campaign, National Institute of Child Health, and Human Development 1994.)

Results.

Thirty-five infants were included in this audit (10 females and 25 males). All the infants were admitted to Glasgow as neonates for surgical support. It is common for these infants to have multiple morbidities but in order to categorize them their primary condition has been identified (Table 1).

Primary Condition	No. infants
Neurological	6
Preterm	6
Respiratory	5
Skeletal	2
Congenital	15
Metabolic	1

Table 1 Primary condition of infants who used the Neo+

Primary Presentations

All 35 infants selected to use the Neo+ presented with ongoing abnormal muscle function and /or postures despite supportive positioning as per standard practice in the neonatal unit.

Figure 1 provides information of the postural patterns with which the infants presented. Thirteen of the infants consistently displayed patterns of extension. Of these; nine were found to have low central stability, two had neurological high tone and a further two presented with normal stability but with habitual patterns of extension. A further nineteen infants, with flaccid postures, all had low central stability. Asymmetrical postures were identified with three infants, one of whom had high tone.

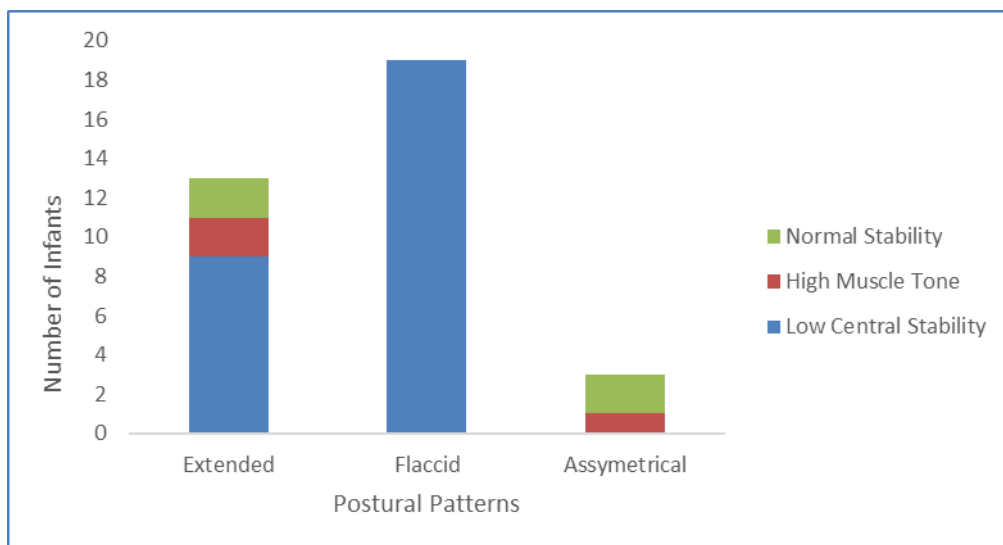


Figure 1 Postural patterns displayed by the infants

Although consistent abnormal posturing is a good indicator for using the Neo+ the aim of this audit was to identify any common selection criteria to assist the physiotherapist in prescribing appropriate support.

A number of factors were common to the infants which the physiotherapist was able to identify as markers likely to be indicative of ongoing developmental problems. The majority of infants displayed more than one marker. Figure 2 provides the frequency of the markers provided as selection criteria.

Selection criteria.

The selection criteria used to identify infants upon whom the Neo+ was appropriate for use was based on developmental milestones:

- Lack of spontaneous movement against gravity - upper and lower limb movement in supine.
- Head righting in prone - should be able lift head to preserve airway in this position.
- Supine: head to midline - position and hold centrally for a few seconds.
- Head lag at 6+ weeks- excessive head lag in supported sitting.
- Side lying- inability to maintain position when placed, extending back.
- Extended Supine- prolonged +/-or consistent patterns of extension when placed in supine.
- Poor head turning dissociation- inability to turn head from side to side without trunk rotation when in a supine position.
- Head turning preference- difficulty turning head to one side and maintaining turn to preferred position unless facilitated otherwise.
- Supine: Fix and follow- inability to consistently fix and follow in horizontal plane
- Skeletal deformities- problems skeletally causing alteration of normal postures e.g. scoliosis, shortened limbs.
- Frantic movements- infant unable to lie awake at rest without moving limbs.

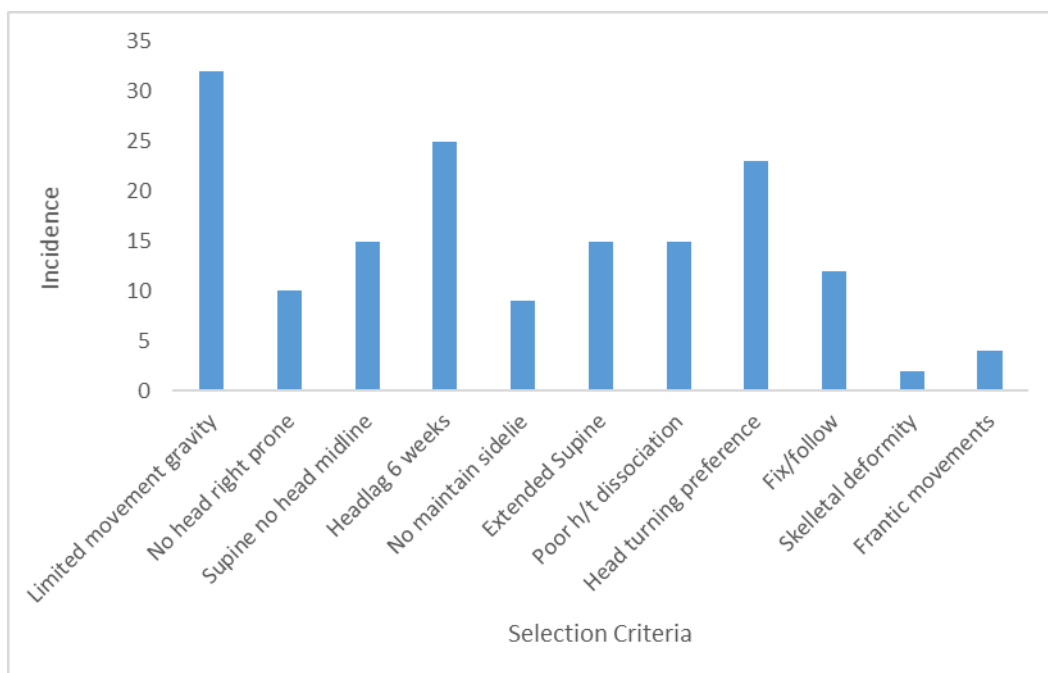


Figure 2 Incidence of selection criteria for infants requiring Neo+.

When this data was examined further it became apparent that infants requiring additional support generally displayed more than one of these identifying factors with the most common being lack of spontaneous movement against gravity (91%). Excessive head lag at 6 + weeks (71%) and head turning preference (66%) were also common presenting factors.

Selection criteria	2	3	4	5	6	7	8
Frequency	5	4	7	7	6	2	4

Table 2 Number of infants with multiple selection criteria

Of the 35 infants 30 (86%) displayed three or more factors identified for additional support (Table 2). All but 1 of the infants had at least 2 of the three common presenting factors.

Patterns of Use

All infants were placed in the Neo+ in a supine position. The Neo+ was used in the infant's cot exclusively.

Three different patterns of use were identified during analysis:

- In Neo+ whenever in his/her cot.
- In the cot, time out of the Neo+ with alternate side lying positions incorporated into the 24-hour period.
- Neo+ use two to three times daily, for up to an hour, whilst under a baby gym.

In all cases the parents/carers were encouraged to continue with normal handling and use of bouncy chairs as per standard practice throughout the day in addition to Neo+ use.

Infants who had an over-extended posture used the Neo+ over a 24-hour period whenever in their cot. Alternate side-lying was not incorporated until their pattern of extension had diminished and they were able to maintain a side lying position with a chin tuck.

Use of the Neo+ at night was not indicated unless the infant had a skeletal deformity or a pattern of overextension that required continuous inhibition of the over extension.

Progression for all the infants incorporated side lying using a soft roll to support and decreased use of the Neo+. Ultimately the Neo+ was used as a positioning aid for play under a baby gym to reinforce active abdominal work and midline.

All infants in this audit tolerated the Neo+, no direct contraindications were identified. The Neo+ was not appropriate for use with infants in incubators due to limited space available for Neo+ use. None of the infants in this audit used the Neo+ when they were preterm as current practice is to provide more restrictive boundaries to simulate intrauterine experience.

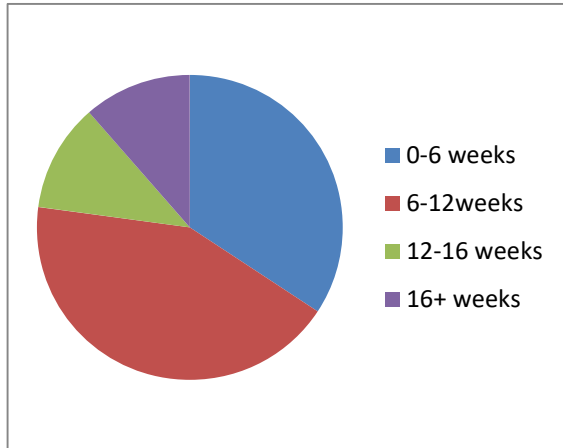


Figure 3 Age (corrected) of Infants requiring additional support:

The Neo+ was used at different stages of the infants' development (Figure 3). The ages given are corrected in the event of prematurity. Most of the infants required support in the 6-to-12-week category. Although there were a few (17%) who were not identified as requiring additional support until he/she was over 16 weeks.

Length of time of use of Neo+

The length of time that the infants required the additional support provided by the Neo+ varied from 1 week to in excess of 24 weeks (Table 3). This was influenced by a number of factors. Factors such as the medical condition of the infant; the cause of the abnormal posture; the compliance of use.

Weeks of use	1-6	6-12	12-24	24+
Number of infants	15	7	11	2

Table 3 Length of Neo+ use

Goals set:

These were individually set by the Highly Specialised Neonatal Physiotherapist working with the infants. They were dependant on both the infant's age and developmental level at the time of assessment for Neo+ use. The goals were based on motor milestones (Table 4).

Eleven (31%) of the 35 infants were either discharged home or transferred to their community hospital before all goals set were fully achieved. One infant died before discharge. The remaining 23 infants (64%) completed all their goals.

As this was a prototype product it was not available at other sites locally or given out for home use.

Table 4 provides information on the types of goals set for infants that required the additional support of the Neo+.

Milestones	Normal age achieved
Fix and follow	6-8 weeks
Head in midline	12 weeks
Head turn left and right	12 weeks
Spontaneous movement against gravity	From term
Head control in sitting	12 weeks
Head righting in prone	From term
Chin tuck in side lying	From Term
Hands to mouth	From Term
Hands to midline	12 weeks
Reach for toys	16 weeks

Table 4 Goals based on motor milestones

Time to goal achievement.

The data was analysed further to establish length of time required in the Neo+ to achieve the individual goals set for each infant (Table 5). Data from 12 infants who failed to complete usage due to early discharge or death were removed.

Condition	Neurological	Floppy Infant	Extended Infant
Goals Achieved (Average weeks)	18	5	17

Table 5 Average time of Neo+ use to achieve goals

This data indicates that infants displaying extended patterns of movement or a neurological impairment required additional support from the Neo+ for longer periods of time than those infants who displayed flaccid postures due to low central stability and/or muscle weakness.

The average stay in hospital was 108 days, with the shortest stay being 50 days and the longest 517 days (Figure 4)

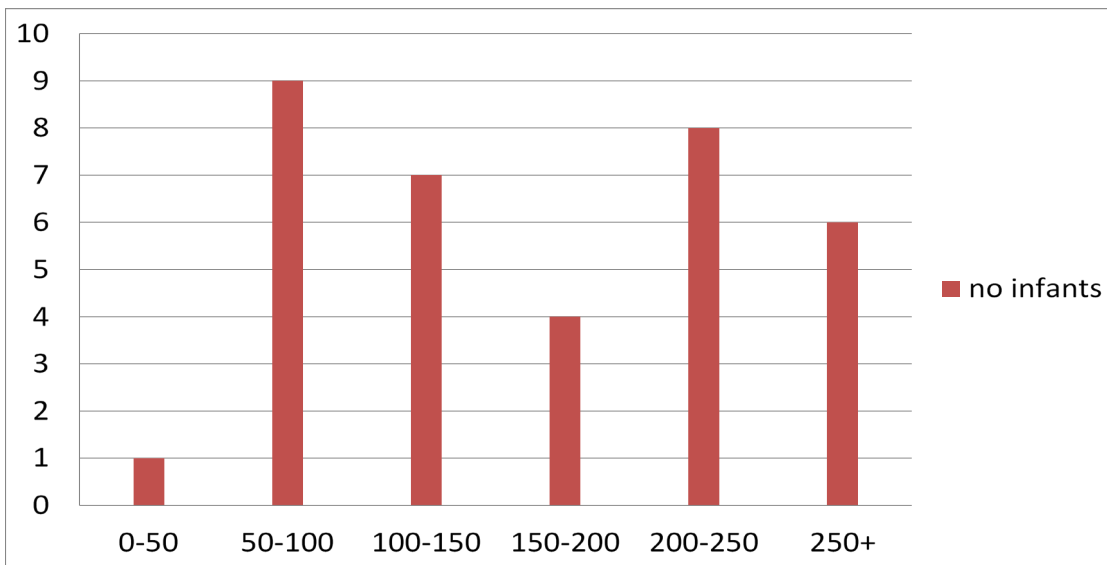


Figure 4 Time to discharge from hospital.

Of the 35 infants, two were still in hospital at the time of the audit completion although Neo+ intervention had been discontinued.

Onward physiotherapy referrals.

The number of infants referred to the community was high, 18 (51%).

A further 12 (34%) of the infants were seen at developmental follow up clinics as per pathways identified locally due to their prematurity or congenital abnormality.

Four (11%) required no further physiotherapy follow up, 1 infant died.

Summary of results.

There were a few similarities in the problems with which the children presented, there was no one criteria that was present in all the infants on whom the Neo+ was used. All of the infants had two or more of the criteria: 'limited movement against gravity'; 'excessive head lag at 6+ weeks' or 'head turning preference'. There was one infant who did not meet this, that is, the infant only had one of the three criteria, however this infant was seen when the Neo+ trial was in its infancy.

In general the Neo+ does not have to be used 24 hours a day however the desired outcomes were slower to achieve when it wasn't used consistently. There are some presentations that do require 24 hour usage: for those with skeletal deformities; and those infants who require inhibition of abnormal extensor posturing. The infant was in supine in the Neo+, as the infants development improved the time spent in the Neo+ decreased allowing alternate positioning to be introduced.

All infants responded positively to the Neo+ although some were more rapid than others in achieving his/her developmental goals.

Discussion.

The Neo+ by Daytot was used on more than 40 infants in Glasgow Children's Hospital between 2011 - 2013. This audit of the Neo+ usage has highlighted that infants who had more complex needs benefited from the additional support and more consistent flexed positioning provided by the Neo+. The reasons for use varied as did the time that the infants required the additional placement support. It was beneficial for all the infants upon whom it was implemented, this was irrespective of whether the underlying condition was neurological, musculoskeletal, respiratory or gastro-intestinal.

Primary Presentations

There were six identified primary conditions (Table 1) however the presentations of the infants with these conditions varied. This was directly influenced by his/her medical pathway and co-morbidities. There were three distinct presentations identified: the floppy infant without any neurological problems; the extended infant without any neurological problems; and the infants with neurological problems.

Selection Criteria

The Neo+ was not required for infants who only had one of the factors identified that could delay development (Table 2), however those infants with multiple factors that could impact motor development and therefore impact global skill development benefitted.

All but one of the infants had two or more markers. The infant who had one marker is the infant who was seen early on in the trial period who was included in this audit but who would now not be placed in the Neo+ as the infants' requirements would have been met with less support. If the same infant was to present now the Neo+ would not be used.

There were three primary markers identified: limited movement against gravity; excessive head lag at 6 weeks; and head turning preference. Thirty-four of the infants presented with at least two of these markers. Therefore, it can be postulated that infants that present with at least two of these three markers would benefit from use of the Neo+.

One of the primary selection criteria was a head turning preference. When positioned in flexion and midline in the Neo+ it was not necessary to block head movement to the preferred side in order to achieve the goal: head turn to left and right.

Patterns of use

It was noted that the most effective way to introduce the Neo+ in the hospital setting was to use it initially for a 24-hour period whenever the infant was placed in his/her cot. This allowed the infants' carers to establish regular usage and increased the understanding of the principle of use. When not used consistently progress was slower and was not appreciated as progress towards achieving developmental goals by parents and carers. Infants with skeletal deformities and patterns of over extension required to use the Neo+ over a 24-hour period, whenever in his/her cot in order to correct and inhibit the abnormal patterns of movement before developmental goals could be achieved.

The success of the Neo+ in achieving consistent flexion is dependent on the cooperation of the parents and carers in Neo+ use. Under the guidance of the Highly Specialised Physiotherapist, parents and carers became proficient in placing the infant in the Neo+ to ensure consistency in positioning the infant in flexion and midline. It was determined that the main value for the infant was when he/she was awake as it is an active system. Usage of the Neo+ encouraged muscle strength development, primarily in the abdominal

muscles by posteriorly tilting the infant's pelvis, supporting the infant in flexion and inhibiting extension. It maintained protraction of the shoulder girdle, encouraging hands to mid-line. By inhibiting thoracic extension and shoulder girdle retraction the infant was able to dissociate his/her head from trunk, thereby ensuring a head turning preference was minimised. Once postural stability had been achieved, the use of the Neo+ was progressed to reduced periods, with its primary objective to reinforce normal movement during play activities under the baby-gym.

Age of initial use

The majority of the infants (29/84%) who required the Neo+ were assessed as needing the additional support by 4 months corrected age (Figure 3). However, this was not a definitive age limit. Some infants were assessed as having additional positional needs later in his/her medical pathway; for instance, an infant who required multiple surgeries or an infant with late onset neurological difficulties where development of abnormal patterns of movement required to be inhibited. Immaterial to age, it was imperative to ensure the infant was medically stable as well as to ensure that the additional support was indeed required prior to introducing the Neo+ into the infant's care package.

Length of time using Neo+

It was encouraging that the pathology underlying the infant's morbidity did not impact the success of the Neo+ in promoting development, however some pathologies required a longer period of usage than others. Table 5 identifies the impact that these presentations had on the time to achieve developmental goals. This is not surprising as infants with neurological presentations and those with extended postures have established patterns of movement that are difficult to correct. These patterns have to be corrected before positioning in flexion can achieve the desired goals.

The length of time required for infants using the Neo+ to achieve his/her goals set varied greatly (1-24+ weeks - Table 3) and was influenced by many factors. If the underlying cause of the postural difficulty had a direct influence on the posture of the infant, this had to be resolved before the goals could be achieved and maintained consistently. This was the situation for infants who had gastric reflux and/or respiratory compromise. The length of time needed for Neo+ use was also influenced by the ongoing medical status, infants requiring multiple surgeries; repeated episodes of sepsis; medical setbacks; or infants who had less handling due to restrictions enforced by attachments to medical devices all took longer to achieve his/her goals and therefore required the Neo+ support for longer periods. As previously mentioned, compliance in use by parents and carers was fundamental in achieving goals and it was of great importance the instruction that parents in particular received was clear and consistent and incorporated joint goal setting.

Goals Set

The goals to be achieved from use of the Neo+ were based on the motor milestones for the developing infants and had to be set by the Highly Specialised Physiotherapist in conjunction with the infant's parents / carers. The goals had to be individualised to each infant, taking into consideration his / her pathology and medical pathway as well as the infant's age / corrected age and the expected motor achievements for that age. The number of goals to be achieved varied and was determined by the number of components of delay recorded as per the selection criteria (Figure 2).

Of the 35 infants on whom the Neo+ was used, 23 infants achieved all their goals. One infant died and 11 infants were discharged from Glasgow to home or back to the referring hospital before all goals had been achieved. As the Neo+ was a prototype and was being evaluated for beneficial effects in this population, it was not possible to have the Neo+ move with the infants who had yet to reach his / her goals. It is not possible to determine whether these infants would have reached their goals with the continued use of the Neo+ intervention. At this time, there is no facility in place for Yorkhill to routinely follow-up this cohort of infants to evaluate his / her motor development.

Time to goal achievement

When determining the amount of time it took of Neo+ usage to achieve the goals set, only those infants who achieved all their goals were included. Therefore, the data is only for 23 infants.

The amount of time it took for the infants to achieve age-appropriate motor development varied and was dependent on his / her underlying reason for Neo+ use (Table 4). Infants with low central stability and / or muscle weakness without any abnormal posturing (identified as 'floppy infants') responded very quickly to the Neo+ intervention and on average achieved all their goals within 5 weeks. Infants who displayed postures of extension with or without neurological components took significantly longer of 4 – 5 months of Neo+ support for all his / her goals to be met. This is not surprising as the majority of these infants had underlying medical conditions which significantly impacted their development. What was surprising was how quickly the 'floppy infants' responded to the intervention. This impacted the future requirement of these children for physiotherapy for developmental delay following discharge from hospital.

Time to discharge from hospital.

The infants who required the additional support of the Neo+ in general had extended periods of time in hospital (Figure 4). The longest period was 517 days (1 year 5 months). It is not surprising then that these infants had failed to develop given the constraints of the medical paraphernalia and the restrictions to normal movement and handling imposed by the hospital setting. Some of the infants were not medically stable or had staged treatment before abnormal posturing could be addressed, therefore the length of time in hospital was not an indication of the success of the Neo+.

Onward referrals

Many of the infants requiring the additional support from the Neo+ had complex disorders, consequently they required further physiotherapy intervention following discharge from the hospital as a matter of routine. The progress that these infants had made in motor development while in Glasgow provided them with a better developmental baseline and prognosis from which to proceed. The 'floppy infants' who previously would have required to be referred for continued physiotherapy from the community intervention team no longer needed to access this service. The use of the Neo+ has eliminated this cohort from further developmental physiotherapy.

Contraindication to the use of the Neo+

There were very few contraindications to the use of the Neo+ determined during the course of this trial.

It was determined that it was not feasible to use the Neo+ with preterm infants as it would not provide the correct boundaries required to simulate the intrauterine experience.

The Neo+ could not be used with infants who required to be placed in an incubator as there was insufficient space in the incubators for the equipment.

The Neo+ should not be introduced until the infant is medically robust enough to be able to tolerate the additional movements permitted as a consequence of the improved and sustained position the Neo+ provides. At times it must be recognised that in order for these infants to remain stable, abnormal postures need to be accommodated. For example, an infant with respiratory insufficiency may require to extend his / her thorax to facilitate their breathing. To correct this position may compromise the infant's survival. It is a team decision to determine when the point of being able to completely correct this abnormal posturing can be made. It is possible to accommodate abnormal posturing within the Neo+ while providing sustained support in other parts.

Limitations

A limitation to this audit was the way in which the data was recorded. As this was a trial of a prototype intervention it was not clear what information was needed beyond the normal physiotherapy record keeping. Over the course of the trial, it became clear that what was introduced as a sleep system had far greater benefits for vulnerable infants. Consequently, the data obtained from the use of the Neo+ was changed over the course of the 5 years.

Future Developments

Future developments for Neo+ use could consider positioning infants in postures other than supine lying, for instance side lying. It could also be explored if the Neo+ could be incorporated into a support mechanism to promote developmental play in infants with ongoing neurological difficulties.

The development of a recording keeping instrument also needs to be considered to ensure that the application of the Neo+ is consistent and meeting the needs of the infants who require the additional support.

The Neo+ overlay mattress currently is a one-patient use product. This could prove to be a prohibitive cost for the acute setting and a prohibitive cost for the primary care sector at £86 per infant.

It was also noted that it was quite easy to place the Neo+ incorrectly therefore it should be clearly labelled which way to place the product for proper and intended use.

It would not be ethically appropriate to carry out a randomised controlled trial to fully evaluate the impact that the Neo+ has on the development progress of infants requiring additional support. However, a retrospective audit of physiotherapy intervention and onward referral prior to the introduction of the Neo+ may provide stronger evidence for the support of this product.

Conclusion.

Post-surgical infants are at risk of developing non-functional patterns of movement that hinder the development of skills. It is recognised that flexion is necessary for normal skill development. Placing these infants in a consistently supported flexed position, inhibited extension and improved muscle balance between trunk flexors and extensors. This resulted in a positive impact on all aspects of the infants' development and reduced the need for follow-on physiotherapy intervention for developmental delay.

The introduction of the Neo+ has also enhanced the awareness and understanding of all staff to the developmental difficulties that these vulnerable infants may face following surgery and prolonged hospital admission. The staff training involved in introducing this product and the team working required to ensure the product's effectiveness has had a positive effect on positioning in general within the surgical unit in Glasgow.

At the start of this trial the underlying issues that were causing the delay in achieving motor milestones were not completely understood. As the trial progressed it became clear the impact the underlying core stability was a major factor, and that the early loss of physiological flexion was a key component in delay in the infant's development. Issues such as head turning preference were just accepted as an outcome of the medical journey and that the problem could not be addressed until further along the pathway when the consequence of something that is now so easily treated was much greater.

The Neo+ was found to be an effective tool in providing consistent postural support for the enhancement of motor development. Developmental delay following neonatal surgical intervention may now be more effectively treated in a greater number of these infants.

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Action plans: Sharing of Information: Daytot has a contract with Glasgow Children's Hospital allowing the consented transfer of patient data in the form of case studies to assist in on-going understanding of use for this product. The outcome of this audit will be shared with this company, but no identifiable data will be divulged.