Lycra Orthoses for Neurological and Musculoskeletal Conditions

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Summary

- Lycra orthoses consist of sections of Lycra with strategically positioned reinforcement panels providing specific areas of resistance to stretch and aid corrective alignment of the body. They are made to measure and range from a glove for improved hand / upper limb function to a full body suit for whole body involvement.

- They are predominantly used in children with cerebral palsy but are also advocated for other neurological and musculoskeletal conditions such as muscular dystrophy, multiple sclerosis, stroke, scoliosis, and head injury.

- The orthoses are presumed to work by increasing sensory and proprioceptive awareness as well as producing a mechanical compressive effect. This in turn leads to reduction in abnormal tone, improved proximal stability, posture, movement and functional performance.

- Advantages of Lycra orthoses include the flexibility and breathability allowing freedom of movement, intimate skin contact and user comfort over conventional rigid/semi-rigid orthoses.

- The evidence base for the clinical effectiveness of Lycra orthoses in the management of cerebral palsy and other neurological and musculoskeletal conditions is limited. Available studies which have mostly been in children with cerebral palsy tend to be lacking in quality and have many limitations (e.g. small patient numbers, mostly case studies/series, non-standardised and/or subjective outcome measures and short duration).

- Limited evidence suggests that wearing Lycra orthoses may improve stability, movement and function in some children with cerebral palsy in the short term. However the available evidence is overall inconclusive; while some studies have demonstrated a beneficial effect, others have shown no effect or a detrimental effect.

- The limitations of the evidence make it difficult to characterise whether there are patient groups that may benefit more than others and which if any benefits are sustained in the long term.

- Adverse effects reported in studies with various types of Lycra orthoses (full body suits, vests, shorts) include vomiting, cyanosis, hyperthermia, muscle weakness, inhibition of voluntary movement, respiratory compromise, constipation, friction sores and erythema. Long term safety is not known.

- Practical difficulties with putting on and taking off the orthoses, feeling hot and/or restricted and toileting have been reported. Careful assessment of the patient’s need and designing the orthosis accordingly e.g. addition of extra zips may address these issues.

- No published cost-effectiveness studies were identified, Cost varies depending on the type of orthosis required and the manufacturer. Standard costs for more commonly used orthoses range from about £90 to £3200.

- The orthoses have an average life span of about 12 months, but may need to be replaced more often in children as they grow. Alterations may be possible with some orthoses to make them bigger so that they don’t have to be replaced as quickly.
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Introduction and background

Lycra orthoses are a type of orthotic device - an externally applied artificial device or appliance used to support, align, prevent, or correct deformities or to improve musculoskeletal function.\(^1\) They have been available for around 15 years and were originally developed as a treatment modality for improving movement, posture and function in children with cerebral palsy. They have since been employed in the management of other neurological and musculoskeletal conditions affecting movement and posture such as muscular dystrophy, multiple sclerosis, stroke, scoliosis, and head injury.\(^2-4\)

Lycra orthoses are made to measure to conform to the shape of the wearer. They are made up of strategically positioned reinforcement panels, using specific tensions and directions of pull, which provide specific areas of resistance to stretch to aid corrective alignment of the body.\(^5, 6\) Plastic boning can be added to provide extra support if necessary.\(^7\) The extent to which the orthosis covers the body depends on the requirements of the individual and designs range from a glove for improved hand / upper limb function to a full body suit for whole body involvement.

In contrast to conventional orthoses which tend to be rigid or semi rigid, Lycra orthoses are breathable and flexible, allowing freedom of movement. Hence they are referred to as dynamic. They may be referred to as dynamic Lycra orthoses, dynamic Lycra splints or Dynamic Elasto\-meric Fabric Orthoses (DEFOs).\(^5, 8, 9\)

The mechanisms by which Lycra orthoses are presumed to work are a combination of physiological and biomechanical effects. The areas of high pressure provided by the close, tight fit of the Lycra orthosis are thought to increase sensory and proprioceptive awareness, and produce a mechanical compressive effect. This in turn leads to reduction in abnormal tone, improved proximal stability, posture, movement and functional performance.\(^7, 9-11\)

The style and design of the Lycra orthosis is based on the individual’s specific functional objectives. Detailed measurements are taken by a physiotherapist, occupational therapist or orthotist specifying the reinforcement that is required. The orthoses are also fitted and reviewed by the therapist/orthotist. The wearing time is usually increased gradually until the patient reaches their recommended wearing time which can be throughout the day in some cases. Night time wear is not advised unless specifically prescribed.\(^3, 12, 15\)

The orthoses have an average life span of about 12 months but may need to be replaced more often in children as they grow;\(^5\) although at extra cost, some orthoses may have the possibility to get altered e.g. by adding panels to make them bigger so that they don’t have to be replaced as quickly.\(^14\) Patients typically receive one orthosis\(^14\) which can be washed according to the manufacturer’s care instructions.\(^3, 12, 15\) Washing around twice weekly is usually recommended.\(^3, 12\)

The length of time that the orthosis will have to be worn varies between patients. For some people, wearing the orthosis for a few years may result in permanent functional improvement, whereas for others reduction in use may result over a period of time. In general, it is usual to wear the orthosis for a number of years.\(^3, 16\)

Patient and carer commitment and motivation, and adherence to treatment are deemed to be essential components of treatment success.

In the UK, the main manufacturers of dynamic Lycra orthoses appear to be DM Orthotics Ltd, Jobskin and Second Skin. Orthoses from these manufacturers are CE marked.\(^17-19\) Specific construction and prescription varies between manufacturers.\(^8\)
The NICE guidance on spasticity in children and young people with non-progressive brain disorders - last updated in November 2016 states that orthoses may be considered for children with spasticity based on their individual needs, and aimed at specific goals. However, there are many different types of orthoses and the guideline does not specifically address Lycra based orthoses.\(^{(1)}\)

The NICE guidance on stroke rehabilitation in adults – published in June 2013 gives recommendations on the use of orthoses for the upper limb but again, this guideline does not make a specific mention of Lycra based orthoses.\(^{(20)}\)

Lycra orthoses have been developed as another form of orthotic treatment. Their flexibility and breathability allowing freedom of movement, intimate skin contact and user comfort, are viewed as advantages over conventional rigid/static orthoses.

**Clinical Evidence**

The vast majority of studies investigating Lycra orthoses have been carried out in children with cerebral palsy. Hence, this has resulted as the main focus of the literature review. Many of the studies are case series/case reports with small numbers of patients. At the time of the original NTAG review, only one published randomised controlled trial (RCT) on the effectiveness of Lycra orthoses was identified. There has since been an additional RCT assessing different outcomes which is discussed in the evidence in a later section.

**Lycra orthoses for cerebral palsy**

**Systematic reviews**

Two systematic reviews on the effects of Lycra orthoses in patients with cerebral palsy were identified at the time of the original NTAG review.

The first by Blackmore et al in 2006 was a systematic review of the effects of soft splinting (splints made of soft, pliable material such as neoprene and Lycra) on upper limb function in people with cerebral palsy. Five studies were included (all using Lycra), most of which were case series. One study included matched controls. All of the studies had small sample sizes (n= ≤24), included patients with different types of cerebral palsy and were mostly of short duration (<12 months). The review found that the evidence regarding soft splinting is very weak. The only study with matched controls found no significant differences in muscle strength (grip strength and abdominal strength) between children who had worn the Lycra splints and those who hadn’t. This study was considered methodologically weak due to its small sample size, a heterogeneous population (with no distinctions between types and severity of cerebral palsy), and inappropriate outcome measures. The conclusion was that there was no evidence to support the use of upper limb soft splinting in people with cerebral palsy and the need for high quality RCTs was highlighted.\(^{(10)}\)

The second was a rapid review published in 2010 investigating whether Lycra orthoses improve function and movement in children aged 0-18 years with cerebral palsy. A total of eight studies were included, many of which were also included in the review by Blackmore et al. Most were case series/case studies and no RCTs were identified. Several methodological limitations were noted such as small patient numbers, inclusion of children with different types of cerebral palsy, and lack of objective outcome measures. The authors stated that the available data suggest Lycra orthoses help to improve proximal stability and function in children with cerebral palsy, but the evidence is limited. The review concluded that more research is needed before an evidence based approach to using Lycra orthoses in the management of children with cerebral palsy can be implemented.\(^{(21)}\)
Randomised controlled trial

The first RCT investigating Lycra orthoses for children with cerebral palsy was published in 2011. The Australian study was a randomised parallel group trial with waiting list control. A total of 16 children aged 8-15 years were randomised to either 3 months of wearing a Lycra arm splint combined with goal directed training (n=8) (group 1), or 3 months of goal directed training only (n=8) (group 2). After 3 months, group 2 then received 3 months of wearing the Lycra arm splint combined with goal directed training. The Lycra splints were worn during school hours, approximately 6 hours per day, 5 days per week. The goal directed training involved 25 minutes of daily active practice of task specific activities related to the child’s functional goals. Assessments were done at baseline, initial splint application, 3 months after wearing the splint and immediately after removing the splint.

The results of this RCT were published in two separate papers. The first publication focused on the fluency of movement following Lycra splint wear. Fluency in this context was defined as the ability of the movement to flow smoothly and freely without jerkiness or tremor. All participants completed the fluency section of the Melbourne Assessment of Upper Limb Function at each assessment session. This assessment involved performing 16 common upper limb tasks which a typically developing child of 5 years can easily complete. Additionally, movement substructures of the motion of the wrist joint centre (WJC) were analysed.

There was no change in movement fluency based on the Melbourne assessment between baseline and 3 months of splint wear for the entire cohort (p=1.00). There were significant improvements in 5 out of 6 of the movement substructures analysed including movement time, percentage of time in primary movement, normalised jerk, percentage of jerk in primary movement and percentage of jerk in the secondary movement. The conclusion was that children’s movements were faster, more efficient and required less secondary corrections following splint wear, and Lycra splinting has the potential to improve movement outcomes for children with cerebral palsy.

The second publication focused on the effects of the combination of Lycra splinting with goal directed training, compared with goal directed training alone. The Goal Attainment Scale (GAS), a tool used to detect discreet changes in movement performance of importance to the child was administered to all children at each assessment. Additionally, using 3D motion analysis, maximum joint movement and range of movement (RoM) were assessed in three or four joints during four different upper limb tasks including reach forwards to an elevated position, reach sideways to an elevated position, supination/pronation and hand to mouth.

Following 3 months of splint wear and goal directed training, 7/8 children achieved the expected level (for 3 months of training) of change in goal attainment (a change in GAS score ≥ 50), while only 1/8 receiving goal directed training alone achieved this level. When the entire cohort had received training and splint wear, 15/16 children achieved their movement related goals after 3 months and on average, achieved a 25% increase in movement proficiency related to their goals (statistical analysis not performed).

A total of 28 assessments of maximum joint movement/RoM were completed. Immediately upon splint wear, there were significant improvements in only 4/28 assessments. After wearing the splint for 3 months combined with goal directed training, significant improvements were observed in 11 assessments across three of the upper limb tasks. No significant improvements were observed in the pronation/supination task, although there was a trend towards improvement. Few improvements (4/11) were evident upon immediate removal of the splint.
It was concluded that Lycra splints combined with goal directed training can result in the achievement of movement goals and have a positive effect on selected maximum range of movement and joint kinematics in children with cerebral palsy. The splints were found to be most effective when worn although there may be small carry over improvements in movement compensations following splint removal.

Non-systematic reviews

A number of non-systematic reviews on the effectiveness of Lycra orthoses for cerebral palsy have also been published. In 2002, the National Horizon Scanning Centre (NHSC) published a review on “Lycra Garments for Cerebral Palsy and Movement Disorders” which included five primary studies. Overall the review concluded that there may be some short term benefit from the use of Lycra splints, however there was no evidence to determine long term benefit or whether there are patient groups that may benefit more than others.\(^{(1)}\)

A 2004 review by Attard and Rithalia including nine primary studies concluded that Lycra orthoses are useful in improving proximal stability in children with cerebral palsy leading to improved functional abilities particularly when combined with a multidisciplinary team approach. However noted that further research was required to learn more about how they work.\(^{(8)}\)

An evidence note by NHS Quality Improvement Scotland (QIS) in 2005 (EN11) mainly based on the reviews by NHSC, and Attard and Rithalia concluded that Lycra orthoses may improve functional abilities in the short term in some children with cerebral palsy. However, suitability needs to be decided on a case by case basis and further research is required to determine the long term effects and if there are patient groups or specific disabilities that may benefit more than others.\(^{(8)}\)

A Technologies Scoping Report by Healthcare Improvement Scotland in 2013 was published as an update to EN11 looking at the clinical and cost effectiveness of dynamic Lycra splinting for cerebral palsy. This review found that the evidence base is limited both in quantity and quality with little development since the publication of EN11 and concluded that further research, with larger numbers, longer follow ups and homogeneity in terms of type of orthosis and manufacturers’ design, is required to determine the effects of Lycra splinting in cerebral palsy.\(^{(5)}\)

Also in 2013, the Peninsula Cerebra Research Unit reviewed the evidence on Lycra orthoses for cerebral palsy and made similar conclusions to previous reviews stating that there haven’t been enough well conducted studies of the same garment in groups of children with the same condition to be able to say that the evidence clearly shows that they do work. Also, the lack of long term studies makes it impossible to provide dependable advice about any lasting benefit once the orthosis is no longer worn.\(^{(2)}\)

It is worth noting that these reviews include or refer to many of the same studies as each other as well as the systematic reviews discussed earlier.

A research project evaluating the effects and functional outcomes of Lycra orthoses to the upper limb in children with cerebral palsy supported by Jobskin is ongoing at Keele University.\(^{(18)}\)

Lycra orthoses for other conditions

The use of Lycra orthoses in other conditions has been studied to a much lesser extent.

There are few reports on the use of Lycra orthoses for treatment and/or prevention of scoliosis. Lycra orthoses are considered to offer the advantage of deformity correction...
Lycra Orthoses for Neurological and Musculoskeletal Conditions

without the bulk and discomfort of rigid braces conventionally used for scoliosis. A recent retrospective audit of clinical notes obtained from five NHS paediatric physiotherapy departments was used to ascertain current orthotic management of children with neuropathic scoliosis. Of the total sample (n=180), 77 had confirmed scoliosis 39 of whom used a Lycra orthosis, and 43 had a spinal curve developing 22 of whom used a Lycra orthosis. The remaining 60/180 had no report of spinal curvature but used a Lycra orthosis as a preventive measure. Cobb angles (a standard measurement used to determine and track the progression of scoliosis) were regularly monitored in 26 children. Scoliosis improved in 6/26 children, 3 of which no longer required intervention. These 3 were managed with Lycra suits.

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In a further 5 children who wore Lycra suits, there was no progression of their scoliosis over an average of 1 year 4 months. The data suggested that Lycra orthoses are currently used in the management of mild to moderate scoliosis due to a range of neuromuscular conditions, predominantly in cerebral palsy; and may have a potential role in prevention and/or treatment of neuropathic scoliosis but further robust research is needed in this area. (6)

A case study involving a 7 year old with thoracic scoliosis reported that wearing a Lycra scoliosis suit reduced the Cobb angle by half from 33° to 15° and subsequent X-rays showed that the curve was maintained at 20°C for 30 months even without the suit being worn. (24) A case series involving 7 patients with scoliosis due to various conditions including spinal injury, cerebral palsy, and agenesis of the corpus callosum reported that improved alignment and reduction in Cobb angle were observed with Lycra suits. This was available only as a conference abstract with no further details regarding the magnitude of effect. (25)

A small study (n=8) published as a conference abstract examined whether Lycra sleeves are effective for glenohumeral subluxation (GHS) which is reported to occur in up to 81% of patients post stroke. Patients wore the sleeve for 7 hours a day on 7 consecutive days. GHS was assessed by ultrasound prior to application of the sleeve, immediately after application on day 1, and on day 8. A reduction in GHS was observed on both day 1 and day 8 by 0.21 cm and 0.28 cm respectively (statistical significance not reported). Three patients experienced decreased pain, 3 found the sleeve easy to wear and 4 reported that the sleeve was beneficial. (26)

One case study evaluated the effects of a Lycra glove on arm function in a 70 year old man with late stage acquired brain injury. Although improvements in some measures were seen, the results were equivocal and some changes were noted irrespective of introduction of intervention. Therefore it was unclear whether the Lycra glove was entirely responsible for the changes seen. (27)

Another case study found improvements in movement and coordination skills in a 5 year old with developmental coordination disorder who wore a Lycra body suit for 12 weeks which was sustained after removal although no measurable effect on proprioception was observed. The authors noted that the improvement could have been the result of natural maturation through the normal development process and it was difficult to differentiate between this and the effect of the Lycra suit. (28)

Jobskin is currently supporting University of West of England in Bristol in evaluating effects of Lycra sleeves on upper limb in patients after stroke. (18)

Summary of clinical evidence

There is limited evidence on which to base the clinical effectiveness of Lycra orthoses in the management of cerebral palsy and other neurological/musculoskeletal conditions. Several factors make it difficult to draw solid conclusions including:
Lack of high quality studies – mostly case studies/ case series; only one RCT was identified
- Small patient numbers
- Inconsistent outcome measures – many studies used non-standardised assessments with some creating their own, and many did not use objective outcome measures, making comparison difficult
- Variation in the types and severity of cerebral palsy treated
- Variation in the types and design of orthoses used (e.g. glove, body suit)
- Lack of adequate comparator
- Short duration

Overall, the limited data available suggest that wearing Lycra orthoses may improve stability, movement and function in some children with cerebral palsy in the short term, but are not conclusive. The limitations of the evidence make it difficult to characterise whether there are patient groups that may benefit more than others and which if any benefits are sustained in the long term. Furthermore, it is not known the extent to which any benefits obtained may impact the patient’s quality of life. All reviews agree that there is a need for well-designed RCTs to properly evaluate the effectiveness of Lycra orthoses.

Clinical Evidence Update February 2020

Since the original NTAG review, there have been some developments in the study of the use of Lycra orthoses particularly for the management of cerebral palsy. Key publications since the original review investigating use of Lycra orthoses for cerebral palsy include three systematic reviews and one RCT published as two publications looking at different outcome measures. A non-randomised controlled study was also published.

Systematic reviews

The systematic reviews evaluated the effect of suit/garment therapy on functioning in children and adolescents with cerebral palsy. While none of the reviews focused specifically on Lycra orthoses, these are included within each review.

The first review by Almeida et al (2017) aimed to evaluate the evidence on the effects of therapeutic suits in the treatment of impairments and functional limitations of children with cerebral palsy. (29) It included 13 studies of various suit therapies, of which three specifically investigated the effects of orthoses made from Lycra. It is worth noting that these studies were included in earlier reviews discussed above at the time of the original NTAG review. Two of these were repeated measures case studies and investigated a full body Lycra suit worn for 6 hours a day for 6 weeks used alongside usual rehabilitation treatment in children with various types of cerebral palsy. One of the studies (n=11) found significant increases in self-care and mobility skills from baseline (30) while the other (n=7) found no effect in any Paediatric Evaluation of Disability Inventory (PEDI) scales or on proximal and distal stability during walking. (31) The third study was a single case experimental design (SCED) study investigating Lycra leggings worn for an average of 6.9 hours a day for 6 weeks alongside usual rehabilitation sessions in children with spastic diplegic cerebral palsy. Results showed significant improvement in walking speed in 5/8 children. (32) Some difficulties/ side effects were reported with the orthoses across the studies such as issues with donning and doffing, problems with toileting, excess heat, circulation difficulties (e.g. blue fingers), friction sores and difficulty in keeping the orthosis clean. (29-32)

Methodological evaluation found the quality of all three studies to be very low due to methodological limitations e.g. inconsistencies in the intervention, lack of adjusting for confounding, etc. Similar to previous reviews, the authors concluded that the quality of the
Evidence for suit therapies in improving body structure, function and activity in children with cerebral palsy is low to very low. Studies lack information about which children with CP will benefit from different types of suits. Authors concluded that the low quality of evidence suggests caution in recommending the use of these therapeutic suits. (29)

The second review by Wells et al (2017) evaluated whether garment therapy improves motor function in children with cerebral palsy. (33) The primary outcome of interest was movement related function and secondary outcomes included impairment, participation, parental satisfaction and adverse outcomes of garment wear. Fourteen studies were included with study design ranging from RCTs to repeated measures case studies. The three studies mentioned above in the systematic review by Almeida et al were included in the review. In addition, the first RCT discussed earlier and three further studies included in at least one review discussed in the original NTAG appraisal were also included. Of these three studies, one was a repeated measures study (n=24) investigating the "UP-suit" prescribed to the individual's needs and worn for an average of 6.5 hours daily for 53 days. Improvements in postural stability and dynamic function, reduced involuntary movements, and increased confidence to attempt motor tasks were reported. (34) Another repeated measures study (n=4) found that wearing a full body Lycra suit for >4 hours daily for 4 weeks alongside routine rehabilitation therapy resulted in improved function in 3 patients and reduced function in one patient. (35) Finally a multiple single subject study (n=4; 2 patients with cerebral palsy, 2 patients with acquired brain injury (ABI)) found that long term upper limb Lycra splint wear for up to 6.5 hours each day while at school was associated with either no change or significant decreased in quality of movement in the children with cerebral palsy. In the children with ABI (non-long term splint users), one initially showed significant improvement in quality of movement which was not maintained over time while no significant difference was observed in the second child. (36) Similar difficulties/ side effects to those mentioned above were reported. The authors note several limitations that limit the conclusions that can be drawn from the studies reviewed including low methodological quality and inconsistent findings, lack of homogeneity between cerebral palsy subtypes/ severity and suit types, and variability in wear time and duration. They conclude that whilst there is some evidence for the use of garment therapy, it is not sufficiently robust to recommend their prescription instead of, or as an adjunct to conventional therapy options. (33)

The most recent systematic review by Karadag-Saygi and Giray (2019) aimed to evaluate the clinical aspects and efficacy of suit therapy for patients with cerebral palsy and included a total of 29 studies. (37) The review included two additional studies specifically investigating Lycra orthoses in children with cerebral palsy that were not included in either of the reviews by Almeida et al or Wells et al. These are among three main publications since the original NTAG appraisal as mentioned earlier and will be discussed in detail below. Similar to previous reviews, the authors of this review also found limitations in the available evidence and applicability to clinical practice. Studies were heterogeneous in design, sample size, study population, and outcomes measured. The limited evidence makes it impossible to draw any firm conclusions about which children with cerebral palsy may benefit more than others from suit therapies or what suit designs or wearing time regimens are most effective. (37)

Randomised Controlled Trials

Giray et al., 2018

The first RCT published since the original appraisal study was a Turkish single blind study investigating the effect of a Lycra orthosis known as a stabilizing pressure input orthosis (SPIO) vest on trunk posture and hip lateralization in children with cerebral palsy. The study also compared effects between two hour and 6 hour daily wear. (38)
The study population comprised of 24 children aged 3 to 9 years old with mild to moderate diplegic or tetraplegic spastic cerebral palsy (Gross Motor Function Classification System (GMFCS) III-IV) who had impaired trunk control. The children were randomised to one of three groups: i) the control group who received only conventional exercise therapy, ii) the SPIO 2-hour group who wore the orthoses during 2 hours of daily therapy and the SPIO 6-hour group who wore the orthoses an additional 4 hours to the 2 hour wear during therapy. The SPIO vest was made up of a front part with a double or triple layer of Lycra fabric attached to a Velcro sensitive neoprene back panel, providing adjustable compression around the shoulder, trunk pelvis and hips.

All patients were hospitalised for 2 weeks during which they received conventional exercise therapy for 2 hours per day and wore the orthoses for 2 or 6 hours. The patients were then discharged and followed up for 6 months. During the follow up period, both SPIO groups continued wearing the orthoses at home (wear time determined by weekly phone calls) and all children continued their regular therapies for one hour a day twice a week.

The outcomes measured included the sitting assessment scale (SAS) used to assess posture and balance during sitting, the Cobb angle (CA) and kyphotic angle (KA) used to determine the effect of the orthosis on trunk posture and the Migration Index (MI) used to evaluate the effect on hip lateralization. All assessments were conducted before treatment and after 6 months and measured without the orthosis in the SPIO groups. Investigators were blinded.

Baseline characteristics were generally similar across the groups. At 6 months there was statistically significant improvement in the SAS scores for all groups compared to baseline but the improvement was significantly less in the control group compared to the SPIO groups. A lower KA was observed in all groups but the change in the SPIO groups was significantly greater than that seen in the control group. The changes in the CA and MI after treatment did not significantly differ among groups. There were no significant differences between the SPIO 2-hour and SPIO 6-hour groups in any of the variables assessed. The study concluded that the SPIO vest in combination with conventional exercises improved kyphotic posture but not CA and hip lateralization.

Whilst the randomised single blinded design of this study as well as the use of a homogenous sample of children with cerebral palsy may be considered strengths, there are some important limitations worth mentioning. The initial setting of the study where patients received intensive exercise therapy alongside wearing the vest during a 2 week hospital admission may not be representative of how patients would be managed in the real world setting. The intensive exercise therapy may have influenced the results observed and a different management protocol may yield different results. The authors state that since no differences were observed between the SPIO 2-hour and 6-hour groups, a wear time of 2 hours can be recommended for patients with low compliance. However, while the 2-hour and 6-hour wear time were stipulated in the 2 week hospital admission phase, wear time could have differed during the 6 month post discharge phase. The average wear time of the vest after discharge from hospital was not reported.

The main aim of the study was to assess the effect of the orthosis on trunk posture by measurement of CA and KA. While statistically significant improvements in KA were observed with the orthosis, this was not the case for CA. The clinical significance of the study results in relation to trunk posture is unclear. The study did not evaluate the effect on the vest on the patient’s activity or participation. Potential adverse effects don’t seem to have been addressed but this was done in a separate publication. The authors recognised that the small sample size of the study makes it difficult to draw any conclusions about the efficacy of the SPIO vest and conclude that further large-scale studies are needed to confirm the findings.
Giray et al., 2018

The second RCT publication was by the same group of researchers and appears to have used the same population, intervention and methodology described in the study above. The primary outcome measure was the SAS to evaluate posture and balance during sitting. Secondary outcome measures included the sitting dimension of the Gross Motor Function Measure (GMFM), the Box and Block Test (BBT) to measure gross manual dexterity, and a parent satisfaction survey. The assessments were performed before treatment, at the end of the 2 week hospital stay, after 1 month and after 3 months of wearing the orthosis. The SAS and the BBT were also applied immediately after wearing the orthosis.

The study found that there were statistically significant improvements in the SAS scores, sitting dimension of the GMFM and the BBT scores for all groups at all follow-up points compared to baseline. All groups demonstrated similar improvements except for the control group demonstrating significantly less improvement in the SAS than the SPIO groups. The SAS and BBT scores increased immediately after putting on the orthosis. Patient satisfaction survey scores were higher in the SPIO groups than the control group after 1 month of treatment but there were no differences between the groups at 3 months. There were no differences between the SPIO 2-hour and SPIO 6-hour groups between for any of the assessments at any of the follow-up time points. No adverse effects were observed.

The study results demonstrated that when used with conventional exercise therapy, the orthosis was effective in improving sitting balance as demonstrated by the SAS scores. The authors note that better sitting position has been shown to result in better upper extremity function in children with CP. However it is important to highlight that improvement in sitting balance was also observed in the control group who used conventional exercise therapy alone. This as well as the similar improvements observed across all groups for the other outcome measures i.e. the sitting dimension of the GMFM and the BBT makes interpretation of the study results difficult and raises questions about whether the improvements could have been the result of factors other than the intervention e.g. the exercise therapy since this was received by all groups, or the child’s development. The authors however note that the sample size calculations were performed based on the primary outcome and the study was insufficiently powered to detect differences in the secondary outcomes of the sitting dimension of GMFM and BBT. Other limitations noted by the authors were that kinematic assessment of posture and upper extremity could not be performed and the outcome measures could not assess patient activity and participation. They concluded that further studies with a larger number of children with cerebral palsy at different functional levels, with kinematic assessment of posture and upper extremity, and assessment of activity and participation are required before any firm conclusions can be drawn.

Non-randomised trial

Romeo et al., 2018

A non-randomised controlled trial (n=10) assessed the efficacy of a Lycra suit worn 4 hours daily for 6 months in improving motor function and static balance in children aged 4-8 years with spastic diplegic or spastic quadriplegic cerebral palsy with GMFCS level II-V. The suit had shoulder, trunk and pelvis coverage with the possibility of adding reinforcing panels or derotation bands. All children were also receiving regular physiotherapy (2-3 times a week). Static balance was assessed by a “seated stabilometry exam” with and without the suit at baseline and after 6 months. Motor function was evaluated using GMFCS and the GMFM which were measured without the suit at baseline and after 6 months.

At baseline there was no significant difference between study and control groups for the static balance measurements. After 6 months, the study group showed significantly better scores than the control group only in one of the static balance measurements (centre of
pressure (CoP) velocity on the anterior-posterior axis [AP-vel]) both on the assessments performed with and without Lycra suit.

For the motor function assessment there was improvement in all dimensions of the GMFM in the study group compared to baseline but the difference only reached significance for the total score. There were however no significant differences between the study and control group at baseline and after 6 months. No significant differences from baseline were observed in the GMFCS within or between the study and control groups. All parents reported more stability in sitting with less fear in maintaining the position. No specific adverse effects were reported but parents reported difficulty with putting on the suit and occasionally, skin chaffing over joint lines.

The results suggest that the Lycra suit improved certain parameters of static balance but showed no significant difference in motor function compared to control. The results must be interpreted with caution given the small sample size. On the whole, this study adds little to the evidence already available on the effectiveness of Lycra orthoses.

**Single case experimental designs**

Children with cerebral palsy form a very heterogeneous group due to a wide variety in clinical presentation, site and severity of impairments and activity and participation limitations. It has been acknowledged that research using group RCT designs in this small and heterogeneous population may be associated with challenges in conducting, interpreting and applying. RCTs in this specialty tend to have small sample sizes and the narrow selection does not reflect the wide diversity in presentation of children with cerebral palsy, limiting the generalizability of the results. Moreover, the variability in treatment effect can be masked and the results may not be valid when applied to a specific patient. Additionally, it would be difficult to obtain large homogenous samples of subjects with similar disorders in this population.\(^{(41, 42)}\)

The single case experimental design (SCED) has been advocated as an alternative to traditional group research methodology and has become increasingly used in rehabilitation research. The SCED is a within subject design where the participant serves as their own control. It involves repeated measurements collected before the intervention to establish a baseline and continued during the intervention and any subsequent phases. The systematic and repeated collection of data through one or more baseline and intervention phases is a key requirement for SCEDs. There are various designs of SCEDs, the most basic being an AB design where A is the baseline phase and B is the intervention phase. Others include the withdrawal design (ABA) and multiple baseline design.\(^{(41-43)}\)

Three SCED studies evaluating the efficacy of Lycra orthoses in children with cerebral palsy were identified. These have been included in at least one of the systematic reviews discussed earlier.

**Corn et al., 2003**

The first assessed the effectiveness of Lycra splints to improve the quality of upper limb movement in children with spasticity.\(^{(38)}\) The study included 4 children aged 8-16 years; 2 with cerebral palsy who had already been wearing a Lycra splint for at least 12 months and 2 with acquired brain injury (ABI) sustained more than 5 years previously who were new users of the Lycra splints. The splints were worn for up to 6.5 hours each day while at school. Details of the design of the splint were not given other than that they were upper limb Lycra splints and that there was a glove component. Quality of upper limb movement was assessed using the Melbourne Assessment of Unilateral Upper Limb Function.
The study used multiple single subject design consisting of a series of AB designs. The long-term splint users were first assessed over several weeks while wearing the splint (intervention phase) and then over subsequent weeks without the splint (baseline phase). The new users were assessed first without the splint (baseline phase) and then while wearing the splint (intervention phase). Children were assessed twice a week during school hours.

Results showed that long term use of the splint in the children with cerebral palsy was associated with a significant decrease in the quality of upper limb movement in one child and no change in quality in the other child. In the children with ABI, there was significant improvement in one child initially but this did not persist over time, while no change was seen in the other child. The study does not appear to have evaluated potential adverse effects of the splint. There were some limitations which influenced the data gathering process e.g. absence from school due to school holidays and sickness, and delays while the new users awaited their splints. The authors state that the results must be viewed with caution and cannot be generalised to a wider population.

Matthews et al., 2009

The second study assessed the effects of DEFO Lycra leggings on the gait of 8 children aged 3-13 years with spastic diplegic cerebral palsy. The study was a multiple single subject study using the ABA design involving a baseline phase, an intervention phase, and a withdrawal phase where the intervention was removed. Each phase was said to last for 6 weeks. The leggings were expected to be worn for approximately 8 hours per day. Outcome measures included the ten metre walking test (10MWT), visual analogue scale (VAS) scoring of perceived gait changes; physiological cost index (PCI) - a derived quotient of energy expenditure during gait; functional mobility changes using Patient Specific Functional Scale (PSFS) and subject/carer perceptions recorded in daily diaries. The 10MWT and VAS scoring were performed weekly, while the PCI and PSFS were performed at various time points during the study.

The results showed there was significant improvement in walking speed in 5/8 children between the baseline and intervention phase. A reduction in walking time suggests that the subject is more controlled. Walking time increased in some children in the withdrawal phase but this pattern was not consistent. PCI values were lower and less variable at the end of the intervention phase compared to the end of the baseline phase. The values worsened slightly at the end of the withdrawal phase but were still less variable than the previous phases. Statistical analysis was however not performed for this measurement. All 5 patients who received a PSFS assessment were judged by their physiotherapists to have improved in their ability to perform their identified functional task. Review of daily diaries suggested improved gait and confidence and changes in fatigue level. There were some complaints regarding soreness to thighs from increased heat and difficulty in don and doff of leggings. The mean wear time of the leggings was 6.9 hours per day.

Although the authors mention that the daily activities of each child over the period of study were not constrained in any way it is unclear if the children were also receiving routine rehabilitation therapy during the study. The authors acknowledge the possibility that the observed results were influenced by expectation and motivation. With regards to the study design, the number of data points collected for each phase of the study for the 10MWT is not clear. It is stated that this outcome was measured weekly however the graphical data suggests that there were two data points per phase and the time interval between data points recorded on the graph is also not clear. Guidelines for carrying out SCEDs recommend that a phase must have at least three (preferably at least five) data points to qualify as an attempt to demonstrate an intervention effect. Furthermore, inter-rater reliability which is key in ensuring consistency of the findings was not reported. The authors...
described their study as an exploratory study to establish “proof of concept” of the effect on the intervention and propose that further research is required to provide definitive results. Power calculations supported the feasibility of a larger, controlled study.

Lewis et al., 2016

The most recent SCED study examined the effectiveness of Lycra orthoses for the management of shoulder subluxation (partial dislocation of the shoulder joint) in children with severe cerebral palsy. This study is available only as a conference abstract. The study included 3 children between the ages of 6 and 11 years old with GMFCS level IV-V. A multiple baseline AB design was used. Outcome measures included the distance from the tip of acromion process to humeral head (mm), shoulder passive range of motion, participant/parent evaluation (rating scale), care and comfort hypertonicity questionnaire and a diary log of compliance. Patients continued with their routine care including botulinum toxin-A (BTX-A) injections. No details regarding the design of the orthosis or wear time were given. Three measurements were collected for the baseline phase. The intervention phase was to last for 12 months with measurements collected after 3, 6, 9 and 12 months of treatment. There was improvement in pain and discomfort at rest or during activity while wearing the orthosis particularly around the time participants received BTX-A injections, and two children showed improved shoulder enlocation during periods of consistent wearing. None of the children completed the 12 month intervention phase. The reasons included not wearing in summer months due to heat and rubbing, complex medical issues and deep brain stimulation implantation surgery. It is not possible to draw conclusions from this incomplete study on the effect of the orthosis on the patients’ condition. The authors recommend further rigorous study with larger sample sizes and less medically complex patients.

Overall the data from these SCED studies do not represent a strong evidence base for the use of Lycra orthoses in children with cerebral palsy. A rule of thumb has been proposed for the amount of replication needed to have confidence that the effect of the intervention will be seen in everyday practice: a minimum of 5 SCED research papers examining the intervention that meet quality standards, conducted by at least three different research teams in three different geographical locations with a combined number of 20 single cases across the papers. Available data from SCEDs on the effect of Lycra orthoses for the management of cerebral palsy or other musculoskeletal/neurological conditions do not meet this criteria.

Repeated measures studies

Another study design that has been used in this area is the repeated measures study design where measurements are taken at baseline and then repeated after a specified time period of using the intervention so that the patient still serves as their own control. These however do not meet the standards for SCEDs which require systematic repeated collection of measurements across distinct experimental phases.

Summary of clinical evidence update

In summary, a review of the additional data published since the original NTAG appraisal as well as available SCEDs did not find compelling evidence for the effectiveness of Lycra orthoses in children with cerebral palsy. The conclusion therefore remains that the evidence base is limited and inconclusive.
Safety

Similar to clinical effectiveness, limited data are available regarding the safety of Lycra orthoses.

Contraindications to Lycra orthoses documented in the literature include absence/unavailability of adequate monitoring and supervision, compliance and behavioural issues, severe epilepsy, chronic respiratory problems, and intractable peripheral cyanosis associated with hypoactivity.\(^{(7-11)}\) Since patient motivation is considered to be a major influence on the success of the orthosis, it has been suggested that the wearer needs to have a capacity for purposeful intent and participation in daily activities for optimum benefit.\(^{(9, 11)}\)

Adverse effects that have been reported in studies with various types of Lycra orthoses (full body suits, vests, shorts) include vomiting, cyanosis, hyperthermia, induced muscle weakness, inhibition of voluntary movement, respiratory compromise, rubbing, constipation, friction sores between legs and at zip sites and erythema.\(^{(10)}\)

Studies have reported practical issues with the orthoses. Some experience difficulties with putting on and taking off the orthoses. Temperature can also be an issue leading to feeling hot and restricted in the orthosis. There may be problems with toileting, and some may find it difficult to breathe with full body suits. In some studies, the discomfort and inconvenience were bad enough to affect adherence or lead to discontinuation.\(^{(2, 8, 13, 21)}\)

These problems may be alleviated to some extent by considering the needs of the child during assessment. For example, more zips can be added to relevant areas and/or reinforcements/boning can be altered, and the wearing regimen can be altered during hot weather.\(^{(9)}\)

The long term effects of wearing Lycra orthoses remain unknown. Reviewers have recommended further research to determine whether the pressure being applied to the skin can be harmful in the long term, whether it can cause muscle fatigue or atrophy, what other physiological changes are taking place at the interface between the patient and the orthosis, and whether circulation is being affected.\(^{(9)}\)

Relevant Guidance

The NICE clinical guideline CG145 on the management of spasticity in under 19s (2012) gives recommendations on the use of orthoses, but does not specifically mention Lycra based orthoses. The guideline recommends the following:\(^{(1)}\)

- Consider orthoses for children and young people with spasticity based on their individual needs and aimed at specific goals, such as: improving posture, improving upper limb function, improving walking efficiency, preventing or slowing development of contractures or hip migration, relieving discomfort or pain and preventing or treating tissue injury.

- When considering an orthosis, discuss with the child or young person and their parents or carers the balance of possible benefits against risks. For example, discuss its cosmetic appearance, the possibility of discomfort or pressure sores or of muscle wasting through lack of muscle use.

- Assess whether an orthosis might cause difficulties with self-care or care by others, difficulties in relation to hygiene or be unacceptable to the child or young person because of its appearance.
• Ensure that orthoses are appropriately designed for the individual child or young person and are sized and fitted correctly. If necessary seek expert advice from an orthotist within the network team.

• Be aware when considering a rigid orthosis that it may cause discomfort or pressure injuries in a child or young person with marked dyskinesia. They should be monitored closely to ensure that the orthosis is not causing such difficulties.

• The network team should review the use of orthoses at every contact with the child or young person. Ensure that the orthosis is still acceptable to the child or young person and their parents or carers, remains appropriate to treatment goals, is being used as advised, remains well fitting and in good repair, and is not causing adverse effects such as discomfort, pain, sleep disturbance, injury or excessive muscle wasting.

The guidance also gives recommendations on specific uses of orthoses, including which types of orthoses may be used to achieve specified objectives.

The NICE clinical guideline CG162 on stroke rehabilitation (2013) gives the following recommendations on the use of orthoses for the upper limb (without specifically mentioning Lycra):(20)

• Do not routinely offer wrist and hand splints to people with upper limb weakness after stroke.

• Consider wrist and hand splints in people at risk after stroke (for example, people who have immobile hands due to weakness, and people with high tone), to:
  - maintain joint range, soft tissue length and alignment
  - increase soft tissue length and passive range of movement
  - facilitate function (for example, a hand splint to assist grip or function)
  - aid care or hygiene (for example, by enabling access to the palm)
  - increase comfort (for example, using a sheepskin palm protector to keep fingernails away from the palm of the hand).

In 2011, consensus recommendations on the orthotic management of cerebral palsy were published by an international multidisciplinary group of healthcare professionals and researchers convened by the International Society for Prosthetics and Orthotics. The group reached the following conclusion regarding Lycra orthoses:(13)

Several types of Lycra based orthoses have appeared in the last ten years, with designs ranging from full body suits to smaller garments such as sleeves/gloves and leggings. Some children with cerebral palsy appear to experience functional gains by using Lycra based orthoses; however, others experience difficulties with donning and doffing, feel hot and/or restricted, have problems with toileting in full suits, or experience compromised respiratory function. Synthesis of evidence from studies evaluating Lycra based orthoses is made difficult by the heterogeneity of the orthoses investigated, the various types of cerebral palsy treated and outcomes measured. Hence the characteristics of people who may benefit from using Lycra garments are not well defined in the literature. The effectiveness of Lycra based orthoses to improve function is not established, and should be evaluated carefully, in a research context.

A number of NHS commissioning group policies on the use of Lycra orthoses were identified from an online search. The recommendations of some of these are summarised in the table below:
### Table 1. Summaries of selected NHS commissioning group policies on Lycra orthoses

<table>
<thead>
<tr>
<th>Group</th>
<th>Recommendation</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scarborough and Ryedale CCG</strong>&lt;br&gt;Lyra Dynamic Splinting for Children with Neurological Impairment&lt;sup&gt;45&lt;/sup&gt;</td>
<td>- Requests for funding will only be considered on an individual patient basis by the CCG Individual Funding Request (IFR) Panel.&lt;br&gt;- The referral needs to come from a local lead specialist physiotherapist or occupational therapist. The expected benefits for that patient over other treatments must be clearly quantified.&lt;br&gt;- Provision of subsequent garments will depend on clear, quantifiable demonstration of benefit for the individual patient which has been set upfront.</td>
<td>December 2015 (Was due to be reviewed in 2017, but has not yet been reviewed)</td>
</tr>
<tr>
<td><strong>Gloucestershire CCG</strong>&lt;br&gt;Lyra splinting for paediatric patients with cerebral palsy/movement disorders&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Lyra splinting services is commissioned for paediatric patients who meet the following criteria:&lt;br&gt;- children aged between 3 and 18 years* with a diagnosis of cerebral palsy or other neurological condition&lt;br&gt;- following multidisciplinary team assessment by the Occupational Therapist and Physiotherapist and support from a Consultant Paediatrician that the child is likely to achieve an improvement in (or maintain) functional abilities regarding balance or movement control&lt;br&gt;- where the child and family/carers are motivated to support the introduction and maintenance of use of the intervention.&lt;br&gt;Regular monitoring at appropriate intervals by the multidisciplinary team (including Physiotherapist, Occupational Therapist and Consultant Paediatrician) to assess progress or maintenance of functional ability is required. Use of the splint will be discontinued if benefits cease to be achieved or maintained. *Replacement splints will be funded automatically to the age of 16. Requests for new or replacement splints for children aged 17-18 will be considered by the Effective Clinical Commissioning Policies Group.</td>
<td>October 2015 (Was due to be updated in 2017. Update not yet done)</td>
</tr>
<tr>
<td><strong>Greater Manchester Shared Services</strong>&lt;br&gt;Greater Manchester EUR Policy Statement: Lyra Body Suits&lt;sup&gt;47&lt;/sup&gt;</td>
<td>- Lycra body suits (sometimes referred to as lyca orthoses) are not routinely commissioned.&lt;br&gt;- Clinicians can submit an individual funding request outside of this guidance if they feel there is a good cause for clinical exceptionality. Requests on the grounds of clinical exceptionality should be submitted with all relevant supporting evidence which must be provided with the request.</td>
<td>May 2017</td>
</tr>
<tr>
<td><strong>East and North Hertfordshire CCG</strong>&lt;br&gt;Lyra Dynamic Splinting for Children with Neurological Impairment&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Requests for funding should only be considered on an individual patient basis by exceptional treatment panels. The referral needs to come from a local lead specialist physiotherapist or occupational therapist. The expected benefits for that patient over other treatments must be clearly quantified. Provision of subsequent garments will depend on clear demonstration of benefit for the individual patient.</td>
<td>February 2016</td>
</tr>
<tr>
<td><strong>Mid and South Essex Sustainability and Transformation Partnership CCG Joint Committee</strong></td>
<td>Dynamic Lycra Splinting is provided for a small cohort of people with cerebral palsy as part of some commissioned community health care services, but is not funded separately.</td>
<td>April 2018</td>
</tr>
<tr>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td><strong>Midlands &amp; Lancashire CSU Criteria Based Clinical Treatments 2018-19 covering the following CCGs:</strong></td>
<td></td>
<td>February 2018</td>
</tr>
</tbody>
</table>
| NHS Halton, NHS Knowsley, NHS Liverpool, NHS Southport and Fromby, NHS South Sefton, NHS St Helens, NHS Warrington | • Lycra Suits are not normally commissioned for postural management of cerebral palsy. Evidence does not support routine commissioning of Lycra suits in management of cerebral palsy.  
• Any application for exceptional funding should include a comprehensive assessment of the child’s postural needs with clear outcome goals and time frames. | |
| **Wakefield CCG** | Given the lack of clinical evidence available, particularly for adults, and the issues identified with patient compliance it is felt that referrals should be considered on a case by case basis through IFRs. It is recommended that Lycra garments are not commissioned for new adult referrals. | March 2014 (Policy Expired. New policy issued with recommendations valid for Wakefield, Huddersfield, North Kirklees and Calderdale – see below) |
| **Wakefield CCG** | **Criteria for Funding** | |
| **Criteria for Funding** | • Patient registered with local GP.  
• Patient must be on local physiotherapy/occupational therapy/orthotics caseload and must have been referred by one of these.  
• Patient should have cerebral palsy or similar condition with significantly abnormal postural muscle tone.  
• There are no contraindications present.  
• Referral should identify the specific significant benefits offered by the therapy for this patient.  
• Evidence provided that other therapies have been considered but were deemed to be insufficient.  
• Evidence of the patient/carer’s willingness to comply with treatment (e.g. signed agreement or previous successful use).  
• If the patient is over 18, successful previous use of Lycra garments and benefits evidenced.  
• Requests for replacement garments should include a user or professional evaluation of benefits to add to the evidence base on this technology. | |
| **NHS Greater Huddersfield, NHS North Kirklees & NHS** | Lycra garments are not routinely commissioned. Cases may be considered on an exceptional basis for example: | June 2018 |
### Calderdale Commissioning Policy for Individual Funding Requests

- The patient should have cerebral palsy or similar condition
- There are no contraindications present (contraindications stated within the policy)
- Referral should identify significant benefits offered by the therapy for this patient
- Evidence provided that other therapies have been considered but were deemed to be insufficient
- Evidence of the patient's / carer's willingness to comply with treatment (e.g. signed arrangement or previous successful one)
- If the patient is over 18, successful previous use of Lycra garments and benefits evidenced
- Requests for replacement garments should include a user or professional evaluation of benefits.

Funding requests for replacement garments will be required to evidence on-going clinical benefit. Funding for a replacement garment will not normally be agreed within:

1. 12 months from last approval for children aged up to 18 or
2. 12 months to 2 years from last approval for patients aged 18+

### Specialist opinion

Specialists with experience in using Lycra orthoses based at The Newcastle upon Tyne Hospitals NHS Foundation Trust were in agreement that the evidence base is limited. They reported no change in practice and prescribing of Lycra orthoses since this document was first published. However, therapists reported that they have witnessed improvements in patients’ function as a result of wearing Lycra orthoses, and positive feedback is often received from patients and their families. It was suggested that from experience, Lycra orthoses may be beneficial for children with truncal weakness (poor core strength) to improve trunk stability and fine manipulative skills; children with dystonia to limit the range of involuntary movements at joints and improve joint stability; and for joint positioning (e.g. at the wrist, thumb or elbow).\(^{(53)}\)

### Cost Analysis

No published evidence on the cost-effectiveness of Lycra orthoses was identified. As noted by the NHSC review, a detailed cost-effectiveness study is needed before any cost savings can be quantified with regards to increased mobility and reduced care needs.\(^{(11)}\)

The cost varies depending on the type of orthosis required. Prices and product range can also vary between manufacturers. The following table lists the standard prices of selected orthoses from the three main manufactures identified. The suppliers more commonly used in the region seem to be DM Orthotics or Jobskin.\(^{(14)}\)
Table 2. Prices of selected Lycra orthoses from three main manufacturers

This report contains data that are confidential to the NHS and commercially sensitive, and should not be disclosed to third parties outside of NTAG. Please contact the Professional Secretary if further information is required.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>COST (Prices listed below are exclusive of VAT and postage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM Orthotics</td>
<td></td>
</tr>
<tr>
<td>All in one suit (excluding gloves)</td>
<td>£545.59</td>
</tr>
<tr>
<td>Vest with sleeves</td>
<td></td>
</tr>
<tr>
<td>Glove/gauntlet with sleeve</td>
<td></td>
</tr>
<tr>
<td>Shorts to knee</td>
<td></td>
</tr>
<tr>
<td>Leggings</td>
<td></td>
</tr>
<tr>
<td>Dorsiflex sock</td>
<td></td>
</tr>
<tr>
<td>Postural scoliosis suit</td>
<td></td>
</tr>
<tr>
<td>Structural scoliosis suit</td>
<td></td>
</tr>
<tr>
<td>Shoulder orthosis</td>
<td></td>
</tr>
<tr>
<td>Jobskin</td>
<td></td>
</tr>
<tr>
<td>Body suit</td>
<td>£485.30 - £556.30</td>
</tr>
<tr>
<td>Vest with sleeves</td>
<td></td>
</tr>
<tr>
<td>Below knee sock</td>
<td></td>
</tr>
<tr>
<td>Gauntlet to elbow</td>
<td></td>
</tr>
<tr>
<td>Glove to elbow</td>
<td></td>
</tr>
<tr>
<td>Pants with leg</td>
<td></td>
</tr>
<tr>
<td>Second Skin</td>
<td></td>
</tr>
<tr>
<td>Body splint</td>
<td></td>
</tr>
<tr>
<td>Postural splint</td>
<td></td>
</tr>
<tr>
<td>Arm/gaitor splint</td>
<td></td>
</tr>
<tr>
<td>Hand/gauntlet splint</td>
<td></td>
</tr>
<tr>
<td>Foot splint</td>
<td></td>
</tr>
</tbody>
</table>

*Cost does not include a measurement fee of £75 for a body garment and £40 for a lower limb or a upper limb garment. Jobskin recommends suits should be changed every 6 months.

*Cost covers measuring, fitting and one review appointment within the life of the splint which is recommended to be 1 year.

Other aspects to consider regarding the cost include how often the orthosis will be replaced and the duration that the orthosis will be worn. On average, orthoses last for around 1 year, but this may vary depending on growth. At additional cost, alterations may be possible with some orthoses to make them bigger and last longer. The duration of wearing the orthosis will vary for each individual and may depend on their clinical presentation, functional goals and progress.

There is a lack of robust information from which to deduce the number of patients that would be eligible for Lycra orthoses in the NTAG region.

Between November 2016 and May 2017, a total of 22 IFR applications were made for Lycra orthoses to various CCGs based in North East England, except Darlington CCG. Out of these, 13 (59%) IFRs were approved. Individual CCG data is included in table 3 below.
Table 3: Lycra Orthoses IFR Approvals and Refusals Nov. 2016 to May 2017

<table>
<thead>
<tr>
<th>CCG</th>
<th>Approved</th>
<th>Declined</th>
<th>% of approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Durham</td>
<td>2</td>
<td>5</td>
<td>28%</td>
</tr>
<tr>
<td>Durham Dales, Easington and Sedgefield</td>
<td>2</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>Hartlepool and Stockton</td>
<td>2</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>South Tees</td>
<td>1</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Sunderland</td>
<td>3</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Darlington</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>South Tyneside</td>
<td>3</td>
<td>1</td>
<td>25%</td>
</tr>
</tbody>
</table>

Approvals and total applications figures for Newcastle Gateshead CCG, North Tyneside CCG and Northumberland CCG are not available between November 2016 and May 2017.

Between June 2017 and July 2018, a total of 166 IFR applications were made for Lycra orthoses to various CCGs based in North East England. Out of these, 154 (92%) IFRs were approved. Individual CCG data is included in table 4 below

Table 4: Lycra Orthoses IFR Approvals and Refusals May 2017 to July 2018

<table>
<thead>
<tr>
<th>CCG</th>
<th>Approved</th>
<th>Declined</th>
<th>% of approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Durham</td>
<td>7</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Durham Dales, Easington and Sedgefield</td>
<td>9</td>
<td>1</td>
<td>90%</td>
</tr>
<tr>
<td>Hartlepool and Stockton</td>
<td>7</td>
<td>4</td>
<td>63%</td>
</tr>
<tr>
<td>South Tees</td>
<td>0</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Sunderland</td>
<td>7</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Darlington</td>
<td>0</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>South Tyneside</td>
<td>1</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Newcastle Gateshead</td>
<td>59</td>
<td>2</td>
<td>96%</td>
</tr>
<tr>
<td>North Tyneside</td>
<td>19</td>
<td>4</td>
<td>82%</td>
</tr>
<tr>
<td>Northumberland</td>
<td>44</td>
<td>0</td>
<td>100%</td>
</tr>
</tbody>
</table>

Points to consider

- The overall clinical benefit of Lycra orthoses is difficult to estimate based on the available evidence.
- Available studies are mostly case studies/series with small numbers of patients and have a number of limitations. Synthesis of the evidence is made difficult due to the differences in the types of orthoses worn (e.g. glove/body suit), manufacturers’ designs, types of cerebral palsy treated and outcomes measured in studies.
• To date there have been two published RCTs evaluating the effect of Lycra orthoses for different outcomes (total n=40). These studies do not provide conclusive evidence on their efficacy.

• Single case experimental design (SCED) studies have been proposed as a better suited research design than traditional RCTs due to the small and heterogeneous nature of the population of children with cerebral palsy. However the data available from SCED studies do not represent a strong evidence base for the use of Lycra orthoses.

• Overall, the available evidence is inconclusive; some studies have demonstrated a beneficial effect on stability movement and function, but others have shown no effect or a detrimental effect.

• It is not clear from the available data whether there are some patients that will benefit more than others and whether any benefits are sustained in the long term. Long term safety is also not known.

• Practical issues with putting on and taking off the orthosis, feeling hot and/or restricted and toileting have been reported in studies.

• Patient and carer commitment and motivation, and adherence to treatment are deemed to be essential components of treatment success.

• No published evidence on the cost-effectiveness of Lycra orthoses was identified and so any cost savings with regards to increased mobility and reduced care needs cannot currently be quantified.

• NICE guidelines on spasticity in children and young people and stroke rehabilitation in adults give recommendations on the use of orthoses but do not specifically address Lycra based orthoses.

• A number of other commissioning groups have issued recommendations on the use of Lycra orthoses. Many of these do not routinely commission Lycra orthoses but consider funding on an individual basis through individual funding requests.

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References