Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic exploration report number:	TER312
Topic:	Dynamic elastomeric fabric orthoses for neuromuscular disease and central nervous system conditions
Summary of findings:	Dynamic elastomeric fabric orthoses are garments that consist of sections of compressive material, stitched together using specific tensions, and directions of pull. The orthoses are designed to help people with conditions that are characterised by limitations to sensory and proprioceptive abilities and movement by improving their functional ability. A number of guidelines have been published by the National Institute for Health and Care Excellence (NICE) on the use of orthoses in different conditions and age groups relevant to this TER. The majority of these do not make any specific recommendations about the technology that is the subject of the TER. However, guidelines do recommend orthotics for some conditions. A number of studies were identified for this topic. The majority of the evidence we found was for children with cerebral palsy. Whilst this evidence suggests that dynamic elastomeric fabric orthoses may improve functional abilities in children with cerebral palsy, the evidence was generally of low quality and heterogeneous in design, type of orthosis, sample size, study population, and outcomes measured. The only other secondary evidence we found was for developmental hip dysplasia, which also supported use of dynamic splint applications, but studies were heterogeneous for number of participants, age of population and grade of dysplasia. HTW researchers identified a few small randomised controlled trials (RCTs) for people with multiple sclerosis and those who have had a stroke. These RCTs did not show a significant benefit when using dynamic elastomeric fabric orthoses. Other identified studies relied on case series or non-randomised comparisons in conditions including autism and severe proprioceptive dysfunction, scoliosis, spasticity, brachial plexus palsy, and adult brain injury. We did not identify any economic evaluations. There is a high level of uncertainty on the effectiveness and varied findings. This may be due to the differences in the types of orthoses worn, manufacturers' designs, the variety of conditions orthoses are worn in, and outcomes measured.

Introduction and aims

Dynamic elastomeric fabric orthoses are garments that consist of sections of compressive elastic material, for example Lycra, of varying thickness stitched together using specific tensions and directions of pull. They are made-to-measure and can cover the whole body or a particular area. There are differences in the garments provided from different suppliers. The orthoses are designed to provide support and sensory information that will enable the user to 'feel' their body, arms and legs more and then use this sensory information to improve their functional ability. It can be used in conditions that are characterised by limitations to sensory and proprioceptive abilities and movement, including, but not limited to, cerebral palsy, stroke, multiple sclerosis, Parkinson's disease, spinal muscular atrophy, spina bifida, spinal cord injury, head injury, hypermobility, Ehlers-Danlos syndrome, scoliosis, autism, and attention deficit hyperactivity disorder. The topic proposer highlighted the Sensory Dynamic Orthosis, which provides dynamic compression to assist with management of postural control and abnormal tone.

Health Technology Wales researchers searched for evidence on dynamic elastomeric fabric orthoses for dynamic compression to increase sensory and proprioceptive feedback as well as provide musculoskeletal support for neuromuscular disease and central nervous system conditions. The only condition in which we applied date limits was for orthoses in children with cerebral palsy, where we used a cut-off date of November 2012 as this was the date of the search done by Health Improvement Scotland (Calvert and Kelly, 2013).

Evidence overview

Technology Assessments

Multiple guidelines have been published by NICE for the use of orthoses in different conditions and age groups relevant to this TER. The majority of these do not make any specific recommendations about the technology that is the subject of the TER. NICE recommends that orthotics should be considered, where appropriate, in: people at moderate or high risk of developing a diabetic foot problem; people with drop foot of central neurological origin; children and young people with spasticity; children or young people with cerebral palsy; adults with clear features of compression neuropathy of the radial nerve, common peroneal nerve or ulnar nerve and no features of a nerve root lesion; people with motor neurone disease; certain people after having a stroke (although wrist and hand splints should not routinely be offered to people with upper limb weakness after a stroke). NICE recommends that orthotics should not be offered to people managing low back pain, with or without sciatica, and that they are not usually used to treat children and adults with mobile flatfoot. NICE did not identify any evidence for orthotics in adults with cerebral palsy, but developed research recommendations (NICE recommendations can be found in the 'Literature Search Results' section of this TER, under 'Health Technology Assessments and Guidance').

Cerebral palsy

A scoping report by Health Improvement Scotland states that limited clinical and no cost-effectiveness evidence was identified for this topic, and no evidence was identified for adults with cerebral palsy. Two systematic reviews included in the scoping report found that splinting may improve functional abilities in some children with cerebral palsy, but the evidence base is limited in amount and in quality. The scoping report recommended that further research, with larger numbers, longer follow-ups and homogeneity in terms of type of garment and manufacturers' design, is required to determine the effects of splinting in cerebral palsy (Calvert and Kelly, 2013).

Systematic reviews

Cerebral palsy

HTW researchers identified three systematic reviews investigating suit orthoses in children and adolescents with cerebral palsy (Almeida et al, 2017; Martins et al, 2016; Karadağ-Saygı and Giray, 2019), published since the technologies scoping report by Health Improvement Scotland (Calvert and Kelly, 2013), and no studies for adults with cerebral palsy.

All three of these systematic reviews included RCTs, but the quality of the evidence was generally low and they mainly consisted of small numbers of participants, with total numbers ranging from 110 to 616 participants. Studies were heterogeneous in design, type of therapeutic suit, sample size, study population, and outcomes measured. Martins et al. (2016) found limited effects of suit therapy in gross motor function of children and adolescents with cerebral palsy, presenting small combined effect sizes (hedges' g: 0.46, 95% confidence interval [CI]: 0.10 to 0.82 for post-treatment, and hedges' g: 0.47, 95% CI: 0.03 to 0.90 for follow-up). Almeida et al. (2017) found that generally, the postural alignment and gait kinematic improved in children with cerebral palsy who wore the suit. Karadağ-Saygı and Giray (2019), who included the highest number of participants in their review, also found that wearing the suit along with conventional therapy improved proximal stability, gross motor function, and gait, but they used a narrative synthesis approach, as it was not possible to classify extracted and analysed data.

Developmental dysplasia of hip

Pavone et al (2021) conducted a systematic review evaluating dynamic splint applications (soft/fabric splints) and static splint applications for babies. Whilst it was found that dynamic splints were effective in cases of instability and dislocation, heterogeneity was high amongst included studies.

Primary studies

Stroke

HTW researchers identified two small RCTs investigating dynamic elastomeric fabric orthoses for use in people who were recovering from a stroke (Morris et al, 2019; Giray et al, 2020). Neither RCT demonstrated a significant clinical benefit to using dynamic elastomeric fabric orthoses. A longitudinal study (Gracies, 2000) and another small study (McPherson et al, 1985) with people with hemiparesis following stroke supported the use of dynamic elastomeric fabric orthoses, as did a small cross-sectional study of people with hemiplegia (Kumar, 2019).

Multiple sclerosis

We identified an RCT of 21 adults with multiple sclerosis and upper limb tremor who received a sensory dynamic orthosis sleeve or a non-compressive sleeve (placebo) that they wore eight hours a day, for nine weeks. There was no significant difference between groups for the Fahn-Tolosa-Marin Tremor Rating Scale. The performance subscale demonstrated significant improvements for the placebo group compared with the treatment group. There was no between-group differences in the satisfaction subscale (Miller et al, 2015).

Autism and severe proprioceptive dysfunction

We identified one small retrospective analysis of 14 children with autism and severe proprioceptive dysfunction, where compression garments appeared to show beneficial behavioural and postural improvements (Guinchat, 2020).

Scoliosis

Two case studies were found which investigated the use dynamic elastomeric fabric orthoses in the treatment of scoliosis in children. Both studies suggested that dynamic elastomeric fabric orthoses can have long term corrective outcomes (Matthews and Bridges, 2012; Matthews and Crawford, 2006).

Spasticity
Two children diagnosed with cerebral palsy and two children with an acquired brain injury were assessed for quality of upper limb movement while wearing and not wearing an upper limb Lycra splint. The results suggest that the effectiveness of Lycra splints was highly variable between individual children with spasticity (Corn et al, 2003).

Brachial plexus palsy
A case study of a child with obstetric brachial plexus palsy found that the Dynamic Movement Orthosis supported the shoulder during functional task and optimised active strength distally in the wrist and elbow (Yasukawa et al, 2011).

Adult brain injury
A single case study found that a Lycra orthosis may have some beneficial effects on upper limb function late after brain injury (Watson et al, 2007).

Economic evaluations
We did not identify any cost-effectiveness studies for dynamic elastomeric fabric orthoses for neuromuscular disease and central nervous system conditions.

Ongoing studies
We identified one ongoing systematic review analysing the effects of dynamic suit orthoses on the spatio-temporal parameters of gait in subjects with cerebral palsy. The anticipated completion date was 30 July 2019, but we were unable to find it online (Belizón et al).

Areas of uncertainty

HTW researchers identified a systematic review analysing the key characteristics of published evidence on compression garments, joint supports and dynamic-movement orthoses. The systematic review highlighted a need for more robust study designs in patient populations and accurate description of interventions (Snowdon et al, 2018). This supports the outcome of our search, with the majority of evidence identified coming from small case studies/non-randomised studies. Assessment of the literature is difficult due to the differences in the types of orthoses worn (e.g. glove/body suit), manufacturers' designs, the variety of conditions orthoses are worn in, and outcomes measured. It is also unclear what the comparator(s) would be in Wales due to the number of conditions and types of treatment.

Literature search results

Health Technology Assessments and Guidance

Multiple NICE guidelines/guidance were identified for use of orthoses in different conditions and age groups relevant to this TER. The majority of these do not make any specific recommendations about the technology that is the subject of the TER.

- NICE guideline (NG59) (2016, last updated December 2020). Low back pain and sciatica in over 16s: assessment and management:

https://www.nice.org.uk/guidance/ng59

Do not offer belts, corsets or foot orthotics for managing low back pain with or without sciatica.

- Interventional procedures guidance (IPG305) (2009). Sinus tarsi implant insertion for mobile flatfoot:

https://www.nice.org.uk/guidance/ipg305

Orthotics and physiotherapy are normally used to treat children and young adults.

- NICE guideline (NG19) (2015, last updated October 2019). Diabetic foot problems: prevention and management:

https://www.nice.org.uk/guidance/NG19

For people at moderate or high risk of developing a diabetic foot problem, the foot protection service should assess the biomechanical status of the feet, including the need to provide specialist footwear and orthoses.

- Interventional procedures guidance (IPG278) (2009). Functional electrical stimulation for drop foot of central neurological origin:

https://www.nice.org.uk/guidance/ipg278

Patients may use ankle-foot orthosis

- Clinical guideline (CG145) (2012, last updated November 2016). Spasticity in under 19s: management:

https://www.nice.org.uk/guidance/cg145

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; preventing or slowing hip migration; relieving discomfort or pain; preventing or treating tissue injury, for example by relieving pressure points.

Whilst some of the recommendations for orthoses were not specified as rigid/dynamic, these were:

Consider rigid wrist orthoses to prevent contractures and limit wrist and hand flexion deformity.

Consider dynamic orthoses to improve hand function (for example, a non-rigid thumb abduction splint allowing some movement for a child or young person with a 'thumb in palm' deformity).

- NICE guideline (NG62) (2017). Cerebral palsy in under 25s: assessment and management:

https://www.nice.org.uk/guidance/NG62

Ensure that the child or young person with cerebral palsy can enable access to other services within their local or regional network as appropriate, including orthotics and rehabilitation services.

Recognise that the most common condition-specific causes of sleep disturbances in children and young people with cerebral palsy include night time interventions, including overnight tube feeding or the use of orthoses.

- NICE guideline (NG119) (2019). Cerebral palsy in adults:

https://www.nice.org.uk/guidance/ng119

There was no evidence identified on the effectiveness of orthotic devices for adults with cerebral palsy. The committee discussed that there is variation in how orthoses are used in current practice and decided that further research in this area is a priority. Orthotic devices, such as splints, are used to help improve positioning and function. They can be used alongside other treatments or separately. The committee developed a research recommendation to determine the effectiveness of different splinting regimens in improving and maintaining posture or functional abilities in the upper limb.

- NICE guideline (NG127) (2019). Suspected neurological conditions: recognition and referral:

https://www.nice.org.uk/guidance/ng127

For adults with clear features of compression neuropathy of the radial nerve, common peroneal nerve or ulnar nerve and no features of a nerve root lesion, refer to orthotic services for a splint.

- NICE guideline (NG42) (2016, last updated 2019). Motor neurone disease: assessment and management:

https://www.nice.org.uk/guidance/ng42

If a person needs orthoses to help with muscle problems, they should be referred to orthotics services without delay, and the orthoses should be provided without delay.

- Clinical guideline (CG162) (2013). Stroke rehabilitation in adults:

https://www.nice.org.uk/guidance/cg162

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).

Consider ankle-foot orthoses for people who have difficulty with swing-phase foot clearance after stroke (for example, tripping and falling) and/or stancephase control (for example, knee and ankle collapse or knee hyper-extensions) that affects walking.

Healthcare Improvement Scotland. Best practice statement, use of ankle-foot orthoses following stroke (2009): https://www.healthcareimprovementscotland.org/previous_resources/best_practice_statement/ankle-foot_orthoses_stroke.aspx

The use of ankle-foot orthoses should be considered in the management of patients with mobility problems following stroke.

NHS Quality Improvement Scotland: An evidence note in 2005 (EN11) examined the effectiveness of dynamic splinting for children with cerebral palsy. We were not able to access this evidence note, as it has been removed from the NHS Quality Improvement Scotland website, but it is described in the technologies scoping report by Health Improvement Scotland (Calvert and Kelly, 2013).

Calvert J, Kelly J (2013). What is the clinical and cost effectiveness of dynamic elastomeric fabric orthoses (DEFOs) for cerebral palsy? https://database.inahta.org/article/13476

Evidence reviews and economic evaluations

Pavone V, de Cristo C, Vescio A, et al. Dynamic and Static Splinting for Treatment of Developmental Dysplasia of the Hip: A Systematic Review. Children (Basel). 2021;8(2)doi:10.3390/children8020104, 10.3390/children8020104

Individual studies

Esra Giray, Kardelen Gencer Atalay, Nurullah Eren, Osman Hakan Gündüz & Evrim Karadag-Saygi (2020) Effects of dynamic lycra orthosis as an adjunct to rehabilitation after botulinum toxin-A injection of the upper-limb in adults following stroke: A single-blinded randomized controlled pilot study, Topics in Stroke Rehabilitation, 27:6, 473-481, DOI: 10.1080/10749357.2019.1704371

Morris JH, John A, Wedderburn L, Rauchhaus P, Donnan PT. Dynamic Lycra® orthoses as an adjunct to arm rehabilitation after stroke: a single-blind, two-arm parallel group, randomized controlled feasibility trial. Clinical Rehabilitation. 2019;33(8):1331-1343. doi:10.1177/0269215519840403

Ongoing research

Natalia Belizón, Carlos Luque. Effects of dynamic suit orthoses on the spatio-temporal parameters of gait in cerebral palsy: a systematic review. PROSPERO 2019 CRD42019139339 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019139339

Topic proposer

Cerebral palsy (children)
Almeida KF, ST; Figueiredo,PRP; Aquino,AA; Mancini,MC. Effects of interventions with therapeutic suits (clothing) on impairments and functional limitations of children with cerebral palsy: a systematic review. Brazilian Journal of Physical Therapy. 2017;21(5):307-20

Cerebral palsy (adults)
Karadag-Saygi EG, E. The clinical aspects of effectiveness of suit therapies for cerebral palsy: a systematic review. Turk J Phys Med Rehab. 2019;65(10):1-18

Upper limb spasticity (children)

Corn, K., Imms, C., Timewell, G., Carter, C, Colllins, L., Dubbeld, S., Schubiger, S. and Froude, E. (2003). Impact of Second Skin Lycra® splinting on the quality of upper limb movement in children. British Journal of Occupational Therapy, 66(10), pp. 464–471.®

Autism

Guinchat, V., Vlamynck, E., Diaz, L., Chambon, C., Pouzenc, J., Cravero, C., Baeza-Velasco, C., Hamonet, C., Xavier, J. and Cohen, D., 2020. Compressive Garments in Individuals with Autism and Severe Proprioceptive Dysfunction: A Retrospective Exploratory Case Series. Children, 7(7), p. 77.

Paediatric scoliosis

Matthews, M. and Bridges, S., 2012. Does the use of dynamic elastomeric fabric scoliosis suits provide an improved and more user friendly option for early intervention in childhood scoliosis? Scoliosis, 7(S1).

Matthews, M. and Crawford, R., 2006. The Use of Dynamic Lycra® Orthosis in the Treatment of Scoliosis. Prosthetics & Orthotics® International, 30(2), pp. 174–181

Brachial Plexus Palsy

Yasukawa, A., Martin, P., Guilford, A. and Mukherjee, S., 2011. Case Study: Use of the Dynamic Movement Orthosis to Provide Compressive Shoulder Support for Children With Brachial Plexus Palsy. JPO Journal of Prosthetics and Orthotics, 23(3), pp.159–164.

Multiple sclerosis adults

Miller LVW, F; Lamont,L; Preston,J; Hair,M. Sensory dynamic orthoses in mild to moderate upper limb tremor in multiple sclerosis: A mixed methods feasibility study. Clinical Rehabilitiation [Internet]. 2015 16/10/2015:[1-14 pp.]. Available from: cre.sagepub.com

Stroke
Gracies JM, Marosszeky JE, Renton R, Sandanam J, Gandevia SC, Burke D. Short-term effects of dynamic lycra splints on upper limb in hemiplegic patients. ArchPhysMedRehabil. 2000;81(12):1547-55.

Kumar, P., 2019. The Effects of Lycra® Arm Sleeve on Glenohumeral Subluxation in Poststroke Hemiplegia—A Preliminary Study. *JPO Journal of Prosthetics and Orthotics, 31*(1), pp. 70–75.

McPherson, J., Becker, A. and Franszczak, N., 1985. Dynamic splint to reduce the passive component of hypertonicity. *Archives of Physical Medicine and Rehabilitation, 66*(4), pp. 249–252.

Adult brain injury

Watson, M., Crosby, P. and Matthews, M., 2007. An evaluation of the effects of a dynamic Lycra® orthosis on arm function in a late stage patient with acquired brain injury. *Brain Injury,* 21(7), pp. 753–761.

dm orthotics website (a manufacturer of dynamic orthoses)

Cerebral palsy

Martins EC, R; Oliveira,R; Latras,S; Lourenco,S; Pereira,I; Ferros,A; Lopes,I; Silva,CR; Marques,M. Efficacy of suit therapy on functioning in children and adolescents with cerebral palsy: a systematic review and meta-analysis. DevMedChild Neurol. 2016;58:348-60.

Rehabilitation and function

Snowdon NS, D; Potia,T; Wheat,J; McLean,S. Compresssoin garments and fabric orthoses for rehabilitation and function: a systematic mapping review. International Journal of Therapy and Rehabilitation. 2018;25(12):655-64.

Date of search:	*September 2021*
Concepts used:	Dynamic elastomeric fabric orthoses, Lycra garment