

# Therapeutic effect of the new multilevel brace orthosis on cerebral palsy gait: a case report

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## Abstract

**Background.** Infantile spastic bilateral cerebral palsy (CP) is the most common form of CP. Diplegia (with ambulatory ability) is mostly a chronic condition that impairs the ability to walk. Standard orthotic management includes hip-knee-ankle-foot orthosis (HKAFO) as a primary conservative treatment option to contrast spasticity and stabilise gait through partial immobilisation of the body structure. Multilevel brace orthosis (MLB) (Registered Trademark) is a specific type of light HKAFO designed to improve functional alignment and dynamic gait stability without limb immobilisation. Aim of the case report is to verify the effects of the MLB on the diplegic gait cycle.

**Case.** A child with a bilateral spastic gait due to CP diplegia is described. Gait analyses were performed to investigate the therapeutic effects of the MLB on walking.

**Discussion.** The MLB improved the gross motor function measure of walking and gait temporal parameters (velocity), compared with barefoot condition. During the swing phase, we observed a reduction in plantar and knee flexion, and the orthosis increased the width and length of the step.

**Conclusion.** Use of this specific type of HKAFO in children with diplegia improved gait symmetry and stability. *Clin Ter 2024; 175 (1):11-16 doi: 10.7417/CT.2024.5027*

**Keywords:** Multilevel brace, diplegia, cerebral palsy, orthosis, rehabilitation

## Introduction

The Surveillance of Cerebral Palsy in Europe (SCPE) revealed that approximately two-thirds of pre/perinatal cerebral palsy (CP) cases are bilateral spastic and that white matter injuries are predominant in preterm (<31 weeks) born children (1). Predominant lower limb involvement (diplegia) is a complex developmental disorder with limitations on posture and movement, often leading to chronic impairment in the ability to walk. An impaired gait can be minimised using an orthotic device. Body orthosis helps to stabilise or to immobilise a body structure, improves alignment, prevents deformities, protects the body against injury, and/or assists

with motion function (2). In contrast to dynamic equinus, limb disalignment, and postural asymmetries, traditional ankle-foot orthoses (AFOs) and hip-knee-ankle-foot orthoses (HKAFO) offer biomechanical benefits to children with spastic diplegia (3; 4). Nevertheless, AFOs are not always well tolerated by the child; discontinuation of wearing the traditional orthosis has been described (5; 6). In traditional KAFOs, both knee joints are often locked in extension, and the ankles are supported in solid AFOs (sAFOs), blocking ankle motion so that the gait is inefficient. Many KAFOs' users are unable to generate the knee moments required to perform common mobility tasks such as sit-to-stand and stand-to-sit tasks (7). Moreover, afferent proprioception in muscles, tendons, and other tissues is restricted, further enhancing the need for visual and vestibular inputs to maintain balance (8). During the growth phase, clinical evidence suggests excessive movement limitation can cause reduced motor learning, initiative, and sports participation.

The literature supports the use of dynamic AFOs to correct skeletal misalignment and adaptive balance strategies in children with spastic diplegia (9).

New mechanical HKAFO devices (the advanced reciprocating gait orthosis "ARGO" and weight-bearing control orthosis WBCO) have been developed to improve balance and paraplegic patient gait. They induce ankle motion and assist dorsiflexion spatial-temporal parameters and the sagittal plane kinematic patterns of walking (4). Knee extension assist was developed as an implementation of the traditional KAFO to provide knee extension moment and free knee motion at all times (7).

The first walking stage is an efficient balance response training for children for the correct acquisition of independent walking (10). The Multi Level Brace (MLB® patent by dott. Cerioli) is a specific type of dynamic AFO that moves in this direction. It can be used as both a HKAFO and a KAFO, thanks to its "multilevel" configuration. MLB uses individually designed flexible structures (rubber bands and springs) corresponding to the hip, knee, and ankle joints to obtain a functional alignment that is different for each child. Postural adjustments in different body segments facilitate dynamic stability.

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This orthosis aims to facilitate a child's static (standing) and dynamic (walking) natural postural adjustments to increase limb alignment and equilibrium context/condition specificity.

The Gross Motor Function Measure (GMFM-88) (11) is a widely used instrument designed to detect changes in gross motor function over time or with interventions in children with CP (assessment and responsiveness to change). It was first developed in the late 1980s for use in the clinical and research settings (12). There was a significant correlation (estimated to be  $>0.60$ ) between the GMFM total change score over a 6-month time frame and parents', intervenors, and video rating judgements of change in motor function over that time, and a significant and positive correlation (estimated to be  $>0.40$ ) between each of the five dimensions of the GMFM and parents, intervenors, and video raters judgements of change in each dimension. The reliability, validity, and inter-rater reliability of this scale have been assessed in specific populations, such as those with brain injuries (13) and Down syndrome (14).

Using instrumental gait analysis (GA), biomechanical relationships can be analysed, and the differences between barefoot and orthosis walking can be compared.

This study aimed to compare patient walking without AFOs and with MLB, using GMFM and GA. A reduction in spastic equinus with a trend of ankle kinematics closer to the normal range for both feet was expected, with reduced ankle plantarflexion in the midstance phase of walking. Consequently, the reduction in knee flexion during the swing phase permitted better alignment of the segments.

## Materials and Methods

### Ethics

The research protocol for this single-case, non-profit, observational study was approved by the ethics committee (Lazio

1 Prot. 421/CE, 04/03/2019), and the family and participant provided written informed consent. The first two authors analysed the data.

### The device

The MLB is an orthosis comprising a circular pelvic belt to which the thigh is elastic with an extensor and abductor effect on the hip (see Fig. 1). There is one thigh grip on the left and one on the right, on which the elastics and thigh-leg springs are anchored: they are made of polypropylene and 10 cm high. Two springs on each side, one medial and one lateral, have an extensor function on the knee and are anchored to the thigh and leg sockets. They consist of small polypropylene tubes which contain eight harmonic steel rods with a diameter of 1.2 mm on the left, and seven on the right. The two springs on each side were connected by a round of tape placed anteriorly just above the kneecap, to allow coplanar movement of the two springs and enhance their extensor effect. The leg holds, one on the left and one on the right, carry an L-shaped leg-rear foot spring, pre-tensioned to favour the rearmost support of the heel during the step, comprised a  $15 \times 1$  mm spring steel. This spring moves from the leg hold to the foot hold, and the free space between the two holds (on which the elastic force of the spring depends inversely, in addition to its measurements,  $15 \times 1$  mm) is 8 cm on the right and 7 cm to the left. The ankle hinge limits plantar flexion but allows free dorsiflexion. A covering shoe was placed over the brace.

We will present the comparison between Barefoot, commercial shoes and MLB on February 2018 through the use of the video recorded GMFM-88; and the comparison between Barefoot and MLB through GA.

The GA of the left and right limbs during normal-speed walking was performed. We used instrumentation made available by Officine Ortopediche ITOP (BTS Motion Analysis Lab).

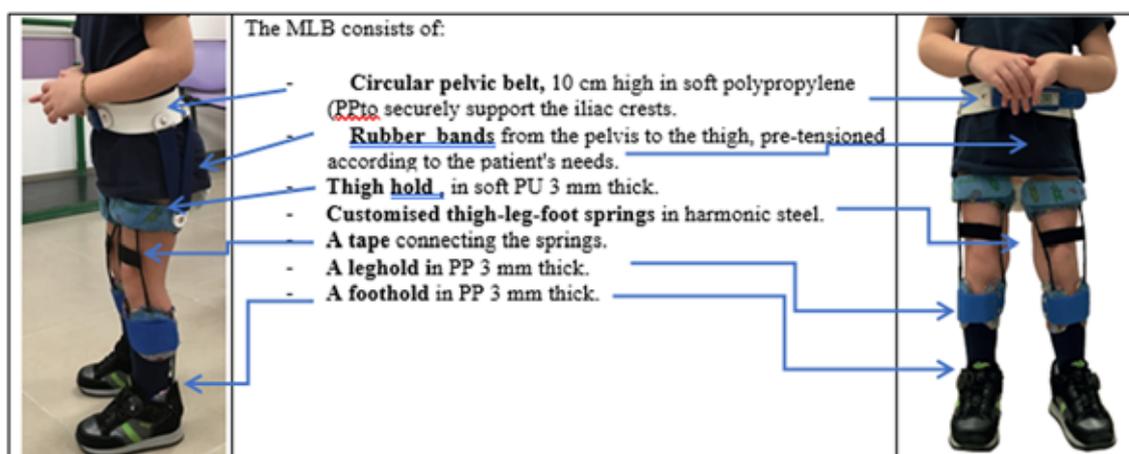


Fig. 1

## Patient Presentation

A 6-year-old female with CP, characterized by spastic diplegia and GMFSC Level II, was born preterm, at 29 weeks after a twin pregnancy. Birth weight was 1,019 kg, cranial circumference 26.5 cm.

Cerebral ultrasound at birth revealed periventricular hyperechogeneity, slight enlargement of the occipital horns, and lateral ventricle asymmetry enlargement to the right side.

Neurological examination showed hypertonia in the lower limbs, which was greater in the left lower limb. We reviewed her since first month of life onwards. At ten months the girl was unable to sit with support of the pelvis. On the ground with the lower limbs stretched, she had strong retroversion of the pelvis and dorsal kyphosis. She cried and became very irritated when she cannot reach objects and always wanted to be picked up to move toward them. Passive mobilisation showed ankle spastic equinus, worse on the left, with difficulty dorsiflexing the foot beyond 90° and flexion only possible with the knee flexed. At 12 months she began rehabilitation physiotherapy (corrected age) twice a week, in May 2014.

At twenty four months of corrected age she showed plantar grasping and extensor synergies of the two lower limbs during manipulation or speaking. Good fine motor manipulation and bimanual coordination were observed; she mainly used the right upper limb and had flexor synergies in the left upper limb when performing any activity. Adequate cognitive and language skills.

In June 2014 (25 months corrected age), she started using Nancy Hilton Afo, with poor results (QGSM55 8% with and without the Nancy HilthonT3). At 27 months she reached to stand alone and performed coastal navigation.

At 41 months (October 2015), here Gross Motor scores were as follows: Dimension A 96%; Dimension B, 88%; Dimension C, 69%; Dimension D, 12%; Dimension E, 14% (for long distances carried with a stroller), and she started the inoculation of botulinum toxin every six months (gemi muscles bilaterally and left semitendinosus) in order to reduce hypertone. First use of MLB at 3 years, after which she has been using it continuously.

## Results

One walking cycle was selected for comparison. Data analysis and motion kinematics of the sagittal, frontal, and transverse planes are reported. The data were averaged for both sides.

### Qualitative analysis

The effect of the MLB on GMFM Dimension E (walking, running and jumping) is depicted below (Table 1).

We calculated an increase in the Dimension E of 8% versus the increase of 3% with commercial shoes only. A slight increase in the GMFM total score was observed (from 87.7% to 89.4%).

A 14.3% increase in the mean walking velocity versus the barefoot condition, with a 16.7% improvement in cycle

Table 1

GMFM at 6 years old	Barefoot	Shoes	MLB
A. Supine/prone	100%	100%	100%
B. Sitting	100%	100%	100%
C. Crawling and kneeling	95.2%	95.2%	95.2%
D. Standing	71.7%	74.3%	76.9%
E. Walking, running, and jumping	66.6%	69.4%	75%
Gross motor quotient	86.7%	87.8%	89.4%

Note: Gross Motor Function Measure (GMFM) in three conditions; barefoot, commercial shoes and MLB. Gait evaluation with or without MLB in a single session, through clinical scales and GA, minimises bias related to the use of botulinum toxin.

length for both the right and the left limbs ;the gain in step width was 57.1% for the right foot and 41.3% for the left.

Using the MLB, there were significant improvements in sagittal plane kinematics at the level of the tibiotarsal joint, where it is possible to eliminate plantar flexion, knee joint, and hip joint, with reduction of flexion of the lower limbs approaching the normal range. Oscillations in the transverse and frontal planes were reduced, and the powers expressed by the joints in the sagittal plane were closer to normal. Finally, there was a significant improvement in the symmetry between the right and left limbs during walking.

### Joint angle profiles

All acquisitions analysed, both in the barefoot condition and with MLB, showed adequate consistency to confirm good gait pattern repeatability. In all planes, with the use of the MLB, there was a tendency toward symmetrisation of the kinematic parameters.

In the frontal plane, with the use of the MLB, the oscillations of the pelvis were reduced, with curves that closely approximate normality (Fig. 2). The hips appeared to have a trend closer to the norm and smaller angular excursions in abduction.

In the transverse plane the oscillations of the pelvis were reduced. In barefoot, the hips were intra-rotated, while with the MLB, the hips recovered external rotation within the normal limits in up to 30% of the gait cycle and in the swing phase.

However, the most interesting differences between the two conditions were recorded in the sagittal plane and are explained in detail below.

In the sagittal plane (Fig. 3), in barefoot, the first rocker was absent, as the foot rested in inversion. The second rocker was short and lasted up to 15% of the cycle, immediately followed by a significant increase in flexion, which was accentuated in the propulsive phase. The flexion reach values close to 15° during the swing phase.

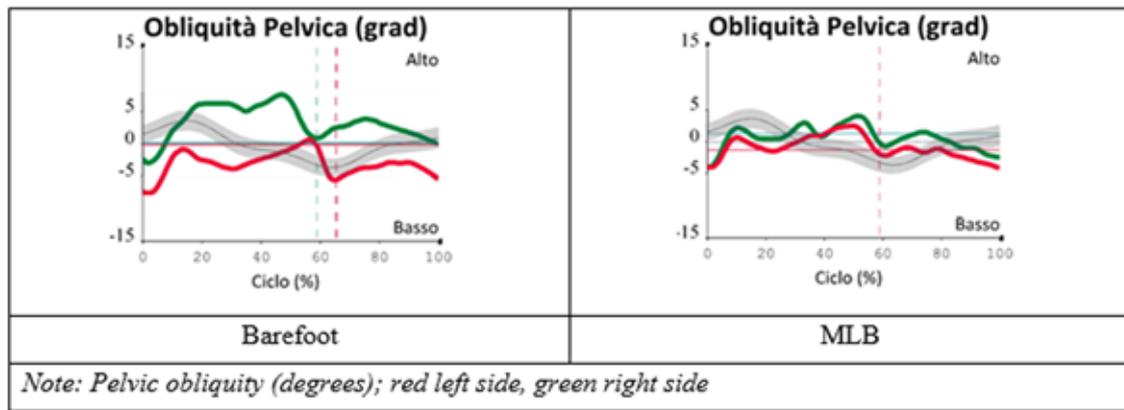


Fig. 2

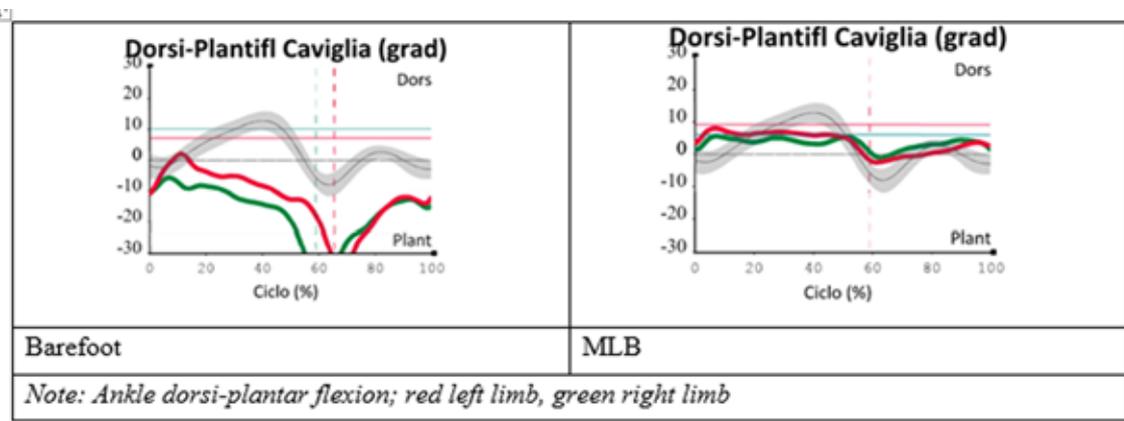


Fig. 3

Without the brace, plantar flexion was observed throughout the entire gait phase. With the brace, there was a repositioning of the tibiotarsal joint to values close to the normal range. Recovery of the first rocker, albeit for less time than normal, occurred. The midstance phase occurred with the ankle in slight dorsiflexion almost constantly, with slight oscillations around 5°. The third rocker was similar to normal but remained in an excursion range of approximately 10°. This angular excursion allowed the maintenance of a good ground clearance during the swing.

The flexibility of the materials and geometry of the brace allowed for a range of joint excursions of approximately 10°. The tibiotarsal joint was never engaged in excessive plantar flexion, keeping the angle of the ankle always within the dorsiflexion range.

Furthermore, in both the stance and swing phases, the brace allowed symmetrisation of the path between the right and left limbs.

Regarding the power generated/absorbed by the ankle in barefoot, there was an evident asymmetry between the right and left limbs, characterised by a succession of peaks of generated and absorbed power. With the MLB, there was significant levelling of the peaks, and the curves approached

the normal range. Better symmetrisation of the gait dynamics was observed.

In the sagittal plane, in barefoot, physiological flexion of the knee was missing in the acceptance of the load (Fig. 4).

The left knee began the stance phase with a flexion close to 30°, slightly less the right; subsequently moving into extension, remaining at the lower limits of the normal range.

The swing phase was performed with excess flexion to ensure that the necessary ground clearance was hindered by plantar flexion excess (noticeable in all gait cycles).

With MLB, the knees accepted load recovery, flexing physiologically at the moment of groundfoot impact. There was a reduction in knee flexion during the swing phase, with a peak below the normal range, presumably due to the extensor action of the thigh-leg elastic elements, which kept the knees less flexed throughout the swing phase. Compared with barefoot, there was symmetrisation of the path.

In barefoot (sagittal plane), the generation and absorption of power at the knee level, both on the right and left, occurred in an irregular manner, partially replicating the modality expressed for the other large joints of the lower limb.

With the MLB, the recovery of the power absorption capacity in the thrust preparation phase was evident bila-

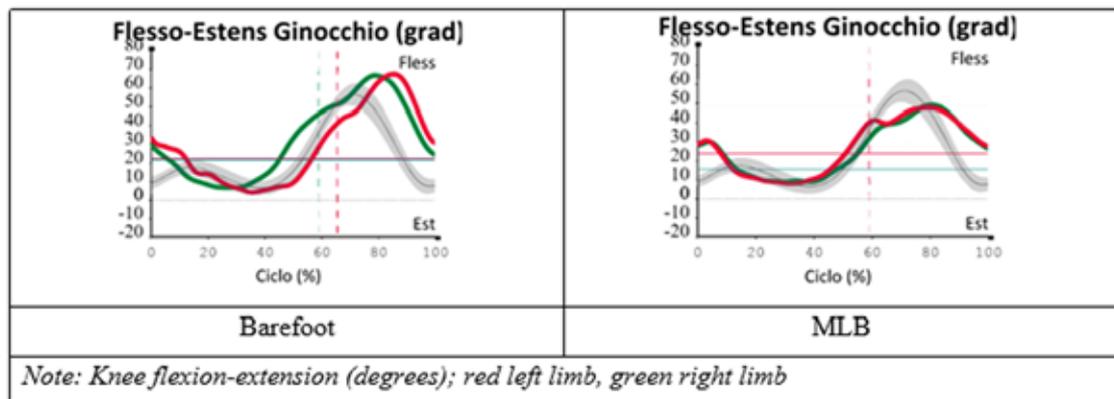


Fig. 4

terally. Furthermore, in this case, there was an important convergence between the representative curves of the powers expressed by the knee joint, demonstrating the symmetry of the path.

In the barefoot condition, the hips remained flexed at the lower limits of the norm in the first 20% of the gait cycle, subsequently and until the end of the stance phase, they remained at the upper limits of the norm, and never reached full extension (Fig. 5).

Hip flexion was also maintained in the subsequent swing phase, with an excess of flexion compared to the norm, precisely in correspondence with the excess of plantar flexion and the excess of flexion of the ankle and hip.

With MLB, excess hip flexion was reduced bilaterally, although it remained above the normal range on the right side. Again, there was a symmetrisation of the gait with the hip curves which tended to overlap.

In barefoot (dynamic analysis in the sagittal plane), as with the hip, the generation and absorption of power, both on the right and left, occurred irregularly, partially replicating the method expressed for the other large joints of the lower limb.

In particular, during the midstance phase both the right and left hips generate power when they should instead absorb it, demonstrating an excess of extensor activity.

With the MLB, the irregularity in the expression of the powers was reduced, and the curves approached (gait symmetrisation). In the second part of the stance phase, power absorption was restored.

The pelvis remained anteverted even with the use of the brace. However, the representative excursion of the “double bump” was reduced and the right and left side curves tended to overlap.

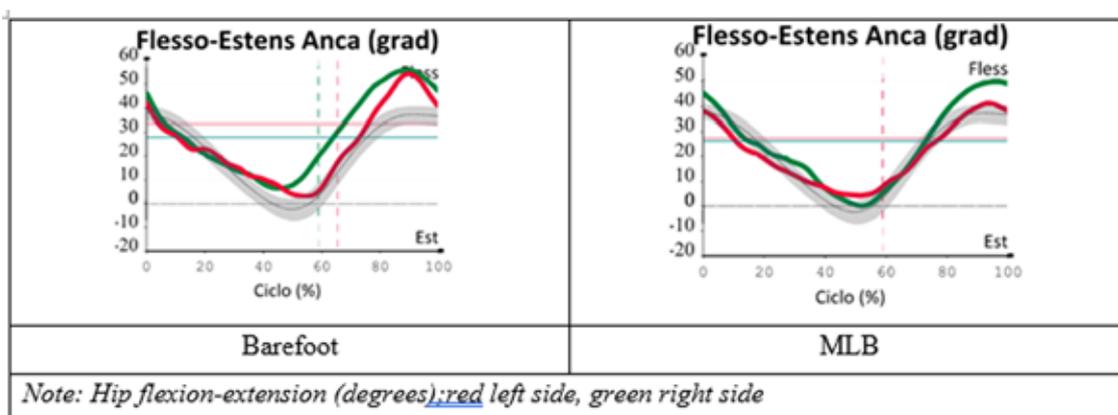


Fig. 5

## Discussion

In this case report on the use of MLB, we observed a slight increase in the GMFM global score, and a large gain in Dimension E specifically, when using the MLB. An increase in step width and length is described as the transition from slow to normal walking (15). The speed increased, and a better global alignment regarding the execution of each step was achieved.

Plantar flexion of the ankle below neutral alignment introduces functional errors in five of the eight gait phases: initial contact, midstance, terminal stance, midswing, and terminal swing (16). With the use of the MLB, we observed that ankle dorsiflexion at initial contact, midstance, and midswing showed a significant increase.

In our case report, using the MLB, compared to barefoot, demonstrated less knee flexion at initial contact, particularly in midstance; no significant change in the maximum knee flexion at swing was observed. It also effected the knee by reducing the plantar flexion and knee extension moment, as reported in other studies with AFO (17). It also effected pelvic stability during the stance phase (pelvis obliquity in barefoot resulted in a left downward and right upward movement) and reduced the flexion dynamics of the right knee. With the MLB, the oscillations in the frontal and transverse planes were reduced, and on average, an increase in the repeatability of the data and symmetry between the right and left limbs was recorded. Finally, the fact that there were no significant differences in the “standing” parameters between the “barefoot” and “MLB” conditions highlights how MLB exerts its effectiveness during walking.

These results need a repeated-measure follow-up to confirm this effect over a larger time span, considering the changes occurring with weight growth and repeated injections of botulinum toxin.

Another limitation regards the fact that we didn't compare the MLB with other traditional orthosis such as the Nancy Hilton Afo the girl used until age 3.

## Conclusions

MLB is useful in controlling the dynamic equinus deformity and stability obtained by reducing the compensation related to pelvic oscillation, with the effect of increasing its stability. The application of articular elements, adequately designed according to each patient, capable of accumulating and returning elastic potential energy in the form of moments of force capable of partially compensating those missing due to the pathology.

The MLB contributes to functional balance in the stance and permits better limb advancement in the swing phase. This orthosis can actively assist the patient's lower limbs by guiding them with a more efficient leg-walking pattern while allowing hip joint mobility.

## References

1. Arnaud C, Ehlinger V, Delobel-Ayoub M, et al. Trends in prevalence and severity of pre/perinatal cerebral palsy among children born preterm from 2004 to 2010: A SCPE collaboration study. *Frontiers in Neurology*, 2021; 12:624884. doi : 10.3389/fneur.2021.624884
2. Yamane A, Orthotic Prescription. In Webster J, Murphy, D. Atlas of orthoses and Assistive Devices. 2019; 5th ed. (Pp. 2-6). Elsevier
3. Carlson WE, Vaughan CL, Damiano DL, et al. Orthotic management of gait in spastic diplegia. *American Journal of Physical Medicine & Rehabilitation*, 1997; 76:219-225. Doi: 10.1097/00002060-199705000-00012
4. Bani MA, Arazpour M, Ghomshe FT, et al. Gait evaluation of the advanced reciprocating gait orthosis with solid versus dorsi flexion assist ankle foot orthoses in paraplegic patients. *Prosthetics and Orthotics International*, 2013; 37:161-167 Doi:10.1177/0309364612457704
5. Delvert C, Rippert P, Margirier F, et al. Use and tolerability of a side pole static ankle foot orthosis in children with neurological disorders. *Prosthetics and Orthotics International*, 2017; 41:134-140. doi: 10.1177/0309364616640946
6. Maas JC, Dallmeijer AJ, Oudshoorn BY, et al. Measuring wearing time of knee-ankle-foot orthoses in children with cerebral palsy: comparison of parent-report and objective measurement. *Disability and Rehabilitation*, 2016; 1–6. doi :10.1080/09638288.2016.1258434
7. Spring A, Kofman J, Lemaire E. [IEEE 2011 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society - Boston, MA (2011.08.30-2011.09.3)] 2011 Annual International Conference of the IEEE Engineering in Medicine and Biology Society - Knee-extension-assist for knee-ankle-foot orthoses, 8259-8262
8. Panwalkar N, Aruin AS. Role of ankle foot orthoses in the outcome of clinical tests of balance. *Disability and Rehabilitation: Assistive Technology*, 2013; 8:314-320
9. Burtner PA, Woollacott MH, Qualls C. Stance balance control with orthoses in a group of children with spastic cerebral palsy. *Developmental Medicine & Child Neurology*, 1999; 41:748-757. doi: 10.1111/j.1469-8749.1999.tb00535.x
10. Fedrizzi E, Facchin P, Marzaroli M, et al. Predictors of independent walking in children with spastic diplegia. *Journal of Child Neurology*, 2000; 15:228-234. doi:10.1177/088307380001500405
11. Russell DJ, Rosenbaum PL, Wright M, et al. The gross motor function measure (GMFM-88). Users manual. London, UK: Mac Keith Press. 2002
12. Russell DJ, Rosenbaum PL, Cadman DT, et al. The gross motor function measure: A means to evaluate the effects of physical therapy. *Developmental Medicine and Child Neurology*, 1989; 31:341-352. doi: 10.1111/j.1469-8749.1989.tb04003.x
13. Linder-Lucht M, Othmer V, Walther M, et al. Gross Motor Function Measure-Traumatic Brain Injury Study Group (2007). Validation of the Gross Motor Function Measure for use in children and adolescents with traumatic brain injuries. *Pediatrics*, 120:e880-886. doi: 10.1542/peds.2006-2258
14. Russell D, Palisano R, Walter S, et al. Evaluating motor function in children with Down syndrome: validity of the GMFM. *Developmental Medicine & Child Neurology*, 1998; 40:693-701. doi: 10.1111/j.1469-8749.1998.tb12330.x.
15. Archbold P, Mullarney B. The relationship between pedestrian loading and dynamic response of an FRP composite footbridge. *Bridge Structures* 2017; 13:147-157
16. Perry J. Gait analysis: Normal and pathological function. Thorofare NJ: Slack Inc 1992
17. Balan B, Yasar E, Dal U, et al. The effect of hinged ankle-foot orthosis on gait and energy expenditure in spastic hemiplegic cerebral palsy. *Disability and Rehabilitation*, 2007; 29:139-144. doi: 10.1080/17483100600876740