

1 **Clinical Practice Guideline: Ankle Foot Orthoses**

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3 **Date of Implementation: February 18, 2016**

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5 **Product: Specialty**

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8 **GUIDELINES**

9 I. For AFOs Used During Ambulation:

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11 A. American Specialty Health – Specialty (ASH) considers ankle-foot orthoses
 12 described by **HCPCS Codes L1900 – L1971, L1990, L2108 – L2116, L4350,**
 13 **L4360, L4361, and L4386** to be medically necessary for the treatment of foot and
 14 ankle weakness or deformity according to the following criteria:

- 15 • For ambulatory beneficiaries who require stabilization for medical reasons,
 16 and have the potential to benefit functionally.

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18 AFOs and KAFOs that are custom-fabricated are covered for ambulatory
 19 beneficiaries when the basic coverage criteria listed above and one of the following
 20 criteria are met:

- 21 1. The beneficiary could not be fit with a prefabricated AFO; or
- 22 2. The condition necessitating the orthosis is expected to be permanent or of
 23 longstanding duration (more than 6 months); or
- 24 3. There is a need to control the knee, ankle or foot in more than one plane; or
- 25 4. The beneficiary has a documented neurological, circulatory, or orthopedic
 26 status that requires custom fabricating over a model to prevent tissue injury;
 27 or
- 28 5. The beneficiary has a healing fracture which lacks normal anatomical
 29 integrity or anthropometric proportions.

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31 If a custom fabricated orthosis is provided but basic coverage criteria above and the
 32 additional criteria 1-5 for a custom fabricated orthosis are not met, the custom
 33 fabricated orthosis will be denied as not medically necessary.

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35 B. **HCPCS codes L2210, L2220, L2230, L2232, L2250, L2270, L2275, L2280,**
 36 **L2320, L2330, L2340, L2360, L2755, L2760, L2275, L2820, and L2840**
 37 (additions to AFOs and KAFOs) will be denied as not medically necessary for
 38 ambulatory beneficiaries if either the base orthosis is not medically necessary, or
 39 the specific addition is not medically necessary.

1 II. For AFOs Not Used During Ambulation:

2 A. ASH considers ankle-foot orthoses described by **HCPSC Code L4396** to be
 3 medically necessary for the treatment of foot and ankle weakness or deformity **IF**
 4 **either all of criteria 1 - 4 or criterion 5 is met:**

- 5 1. Plantar flexion contracture of the ankle (see ICD-10 Diagnosis Code table
 6 below) with dorsiflexion on passive range of motion testing of at least 10
 7 degrees (i.e., a nonfixed contracture); and
- 8 2. Reasonable expectation of the ability to correct the contracture; and
- 9 3. Contracture is interfering or expected to interfere significantly with the
 10 beneficiary's functional abilities; and
- 11 4. Used as a component of a therapy program which includes active stretching of
 12 the involved muscles and/or tendons; and
- 13 5. The beneficiary has plantar fasciitis (see ICD-10 Diagnosis Code table below).
 14

15 If an L4396 is used for the treatment of a plantar flexion contracture, the pre-
 16 treatment passive range of motion must be measured with a goniometer and
 17 documented in the medical record. There must be documentation of an appropriate
 18 stretching program carried out by professional staff (in a nursing facility) or
 19 caregiver (at home).
 20

21 An L4396 and replacement interface (L4392/L4394) will be denied as not
 22 medically necessary if the contracture is fixed. Code L4396 will be denied as not
 23 medically necessary for a beneficiary with a foot drop but without an ankle flexion
 24 contracture. A component of a static/dynamic AFO that is used to address
 25 positioning of the knee or hip will be denied as not medically necessary because
 26 the effectiveness of this type of component is not established.
 27

28 If code L4396 is covered, a replacement interface (L4392/L4394) is covered as long
 29 as the beneficiary continues to meet indications and other coverage rules for the
 30 splint. Coverage of a replacement interface is limited to a maximum of one (1) per
 31 6 months. Additional interfaces will be denied as not medically necessary.
 32

33 **ICD-10 Codes and Descriptions applicable when medically necessary per the criteria**
 34 **listed above**

| ICD- 10 Code | Description |
|--------------|-------------------------------|
| M24.571 | Contracture right ankle |
| M24.572 | Contracture left ankle |
| M24.573 | Contracture unspecified ankle |
| M24.574 | Contracture right foot |
| M24.575 | Contracture left foot |
| M24.576 | Contracture unspecified foot |
| M72.2 | Plantar fascial fibromatosis |

1 ASH policy for ankle-foot orthoses codes L1900-L1971, L1990, L2108 – L2116, L2210,
 2 L2220, L2230, L2232, L2250, L2270, L2275, L2280, L2320, L2330, L2340, L2360,
 3 L2755, L2760, L2820, L4350, L4360, L4361, L4386, L4392 and L4396 are based
 4 primarily on Centers for Medicare and Medicaid Services (CMS) coverage policy on ankle-
 5 foot orthoses.

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HCPCS CODES AND DESCRIPTIONS

| HCPCS Code | HCPC Code Description |
|------------|---|
| L1900 | Ankle-foot orthosis (AFO), spring wire, dorsiflexion assist calf band, custom fabricated |
| L1902 | Ankle orthosis (AO), ankle gauntlet or similar, with or without joints, prefabricated, off-the-shelf |
| L1904 | Ankle orthosis (AO), ankle gauntlet or similar, with or without joints, custom fabricated |
| L1906 | Ankle foot orthosis (AFO), multiligamentous ankle support, prefabricated, off-the-shelf |
| L1907 | Ankle orthosis (AO), supramalleolar with straps, with or without interface/pads, custom fabricated |
| L1910 | Ankle-foot orthosis (AFO), posterior, single bar, clasp attachment to shoe counter, prefabricated, includes fitting and adjustment |
| L1920 | Ankle-foot orthosis (AFO), single upright with static or adjustable stop (Phelps or Perlstein type), custom fabricated |
| L1930 | Ankle-foot orthosis (AFO), plastic or other material, prefabricated, includes fitting and adjustment |
| L1932 | Ankle-foot orthosis (AFO), rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment |
| L1940 | Ankle-foot orthosis (AFO), plastic or other material, custom fabricated |
| L1945 | Ankle-foot orthosis (AFO), plastic, rigid anterior tibial section (floor reaction), custom fabricated |
| L1950 | Ankle-foot orthosis (AFO), spiral, (Institute of Rehabilitative Medicine type), plastic, custom fabricated |
| L1951 | Ankle-foot orthosis (AFO), spiral, (Institute of Rehabilitative Medicine type), plastic or other material, prefabricated, includes fitting and adjustment |
| L1960 | Ankle-foot orthosis (AFO), posterior solid ankle, plastic, custom fabricated |

| HCPCS Code | HCPC Code Description |
|------------|--|
| L1970 | Ankle-foot orthosis (AFO), plastic with ankle joint, custom fabricated |
| L1971 | Ankle-foot orthosis (AFO), plastic or other material with ankle joint, prefabricated, includes fitting and adjustment |
| L1980 | Ankle-foot orthosis (AFO), single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar 'BK' orthosis), custom fabricated |
| L1990 | Ankle-foot orthosis (AFO), double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar 'BK' orthosis), custom fabricated |
| L2108 | Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture cast orthosis, custom fabricated |
| L2112 | Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment |
| L2114 | Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment |
| L2116 | Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment |
| L2210 | Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint |
| L2220 | Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint |
| L2230 | Addition to lower extremity, split flat caliper stirrups and plate attachment |
| L2232 | Addition to lower extremity orthosis, rocker bottom for total contact ankle-foot orthosis (AFO), for custom fabricated orthosis only |
| L2250 | Addition to lower extremity, foot plate, molded to patient model, stirrup attachment |
| L2270 | Addition to lower extremity, varus/valgus correction (T) strap, padded/lined or malleolus pad |
| L2275 | Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined |
| L2280 | Addition to lower extremity, molded inner boot |
| L2320 | Addition to lower extremity, nonmolded lacer, for custom fabricated orthosis only |

| HCPCS Code | HCPC Code Description |
|------------|---|
| L2330 | Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only |
| L2340 | Addition to lower extremity, pretibial shell, molded to patient model |
| L2360 | Addition to lower extremity, extended steel shank |
| L2755 | Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only |
| L2760 | Addition to lower extremity orthosis, extension, per extension, per bar (for lineal adjustment for growth) |
| L2820 | Addition to lower extremity orthosis, soft interface for molded plastic, below knee section |
| L2840 | Addition to lower extremity orthosis, tibial length sock, fracture or equal, each |
| L4350 | Ankle control orthosis, stirrup style, rigid, includes any type of interface (e.g., pneumatic, gel), prefabricated, off-the-shelf |
| L4360 | Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise |
| L4361 | Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, off-the-shelf |
| L4386 | Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise |
| L4392 | Replacement, soft interface material, static AFO |
| L4394 | Replace soft interface material, foot drop splint |
| L4396 | Static or dynamic ankle-foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise |

| HCPCS Code | HCPC Code Description |
|------------|--|
| | customized to fit a specific patient by an individual with expertise |
| L4398 | Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf |

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BACKGROUND

Ankle-Foot Orthotics

An AFO extends well above the ankle to the top of the calf. It requires fastening at the lower leg, just above the ankle. This device may be used for ambulatory patients with weakness or deformity of the foot and ankle, which also require stabilization for medical reasons and when the patient has the potential to benefit functionally from use of the device. Commonly, AFOs are used to treat disorders including but not limited to ankle dorsiflexion, plantar flexion, inversion and eversion, spastic diplegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia in cerebral infarction. Certain neurologic and muscle control conditions such as stroke, neoplasms, hemiplegia, cerebral palsy, myelomeningocele and atrophic or dystrophic conditions may produce lower extremity spasticity or hyperactivity of muscles, hypotonicity of certain muscles and neuromuscular imbalances. Gait functioning, balance and foot/ankle positioning may be impacted. Custom-fitted and custom-molded foot orthoses and ankle-foot orthoses (AFOs) are used in ambulatory patients to control or correct foot joints, counteract internal deforming forces, compensate for weakness, correct or eliminate pathologic positioning, improve balance, improve gait functioning and reduce excessive plantar flexion.

The use of ankle-foot orthoses is one of the most common treatment approaches for ankle-foot weakness or deformity. An orthosis or “orthotic” is an orthopedic appliance or apparatus used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body. Orthoses can either be an over-the-counter orthotic (prefabricated) or a custom device derived from a three-dimensional representation of the member’s ankle and foot.

A *custom* fabricated orthosis is one which is individually made for a specific patient starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item. A *molded-to-patient-model* orthosis is a particular type of custom fabricated orthosis in which an impression of the specific body part is made by means of impression casting material and this impression is then used to make a positive model (of plaster or other material) of the body part. The orthosis is then molded on this positive model.

1 A *prefabricated* orthosis is one that is manufactured in quantity without a specific patient
 2 in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or
 3 otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is
 4 assembled from prefabricated components is considered prefabricated. Any orthosis that
 5 does not meet the definition of a custom-fabricated (custom-made) orthosis is considered
 6 prefabricated.

7
 8 Ankle-foot orthoses (AFOs) extend well above the ankle (usually to near the top of the
 9 calf) and are fastened around the lower leg above the ankle. In general, there are three types
 10 of ankle foot orthotic devices: passive devices, semiactive devices, and active devices.
 11 Passive AFO devices are not comprised of any electrical or electronic elements or any
 12 power sources. It may be comprised of mechanical elements like dampers or springs to
 13 control the motion of the ankle-foot complex. Semiactive AFO devices are capable of
 14 varying flexibility of the ankle joint by using computer control. Active AFOs contain an
 15 onboard power source, a control system, sensors, and actuators. Among these devices, a
 16 passive AFO is the most popular daily-wear device due to its compactness, durability, and
 17 simplicity of the design. Active and semiactive AFOs have the limited usage only for
 18 rehabilitation purpose due to the need of improvement of actuator weight, portable power
 19 supply, and general control strategy (Alam, 2014). AFOs can be constructed from metal,
 20 plastic, leather, synthetic fabrics, or any combination of these materials.

21 22 **Stroke and Ankle-Foot Orthoses (AFO)**

23 The main cause of musculoskeletal impairment is the weakness of plantar flexor and
 24 dorsiflexor muscles. Plantar flexor muscle weakness would result in reduction of push-off
 25 power and elevation in energy cost of patient as most of the power in walking is generated
 26 during ankle push-off. Plantar flexor muscles are not frequently affected; therefore, most
 27 of the ankle foot orthotic devices are designed for drop-foot prevention. Individuals with
 28 dorsal muscle weakness are not capable of lifting the foot adequately in midswing due to
 29 insufficient dorsiflexion; it results in toe-dragging, lowering walking speed, shortening of
 30 step length, elevation in walking metabolism, and high risk of tripping. “Foot-slap” and
 31 toe-dragging are the major complications of the patients having dorsiflexor muscle
 32 weakness. “Foot-slap” is the uncontrolled and rapid strike of foot on the ground producing
 33 distinctive sound at heel strike and “toe-drag” refers to dragging of forefoot during walking
 34 due to inadequate ground clearance during swing phase of the gait cycle (Alam, 2014).

35
 36 The traditional treatment for persistent drop foot is an AFO that holds the foot in a neutral
 37 position. The most common type of AFO is a solid plastic brace, although it may be made
 38 of metal or composite materials, with any number of modifications, including an articulated
 39 or hinged ankle joint. In general, AFOs have been found to support ankle dorsiflexion
 40 during swing phase and improve knee stability in early stance phase in individuals with
 41 drop foot (Kluding, 2013). Furthermore, AFOs have been shown to reduce the energy cost
 42 of ambulation in a wide variety of conditions (Brehm, 2008; Chen, 2008).

1 Van Swigchem et al. (2012) looked at use of an AFO compared to peroneal muscle
2 stimulation during gait with and without an orthotic device. During activities of daily
3 living, often individuals encounter obstacles during walking. For someone with foot drop,
4 these can be dangerous experiences that can lead to falls. This study aimed to identify
5 which intervention is more beneficial with respect to the ability to negotiate a sudden
6 obstacle. Twenty-four (24) community dwelling individuals with hemiplegia post stroke
7 participated in the study. These subjects used AFO bracing consistently. All twenty-four
8 (24) were fitted with a functional electrical stimulation (FES) device. Obstacle avoidance
9 ability was tested after 2 and 8 weeks. Thirty (30) obstacles needed to be avoided during a
10 treadmill walk. These objects were dropped in front of the affected foot while walking on
11 the treadmill with the AFO and then repeated with the FES. Obstacle avoidance rates were
12 calculated for each device. Success rates for avoidance were significantly higher among
13 the twenty-four (24) participants when they used FES compared to when they were wearing
14 the AFO; this was emphasized further when normalized for muscle strength of the lower
15 extremity.

16
17 Another study looked at the effects of dynamic AFOs in chronic stroke patients. Erel et al.
18 (2011) completed an RCT with 3 month follow up looking at the long- and short-term
19 effects of AFO use on function of patients with hemiparesis. Twenty-eight (28) patients
20 with chronic hemiparesis were randomly assigned to a study or control group. The control
21 group wore tennis shoes, and the study group wore the dynamic AFO after an initial
22 assessment with tennis shoes. For the initial assessment both groups had no differences
23 between outcome measures. After 3 months of AFO use, the subjects were retested. Timed
24 Up Stairs, gait velocity and physiologic cost index (measure of effort), showed significant
25 differences in favor of the study group. Functional reach and Timed Up and Go and Timed
26 Down Stairs did not show differences. Thus, patients with chronic hemiparesis may benefit
27 from using a dynamic AFO.

28
29 Tyson and Kent (2013) sought to determine the effectiveness of an AFO on mobility,
30 walking and balance in people with stroke. Randomized controlled trials of AFOs in people
31 with stroke, which measured balance, walking impairments, or mobility and were reported
32 in English, were selected. Thirteen trials with 334 participants were selected. The effect of
33 an AFO on walking activity ($P=.000-.001$), walking impairment ($P=.02$), and balance
34 (weight distribution) ($P=.003$) was significant and beneficial. The effect on postural sway
35 ($P=.10$) and timed mobility tests ($P=.07-.09$) was non-significant, and the effect on
36 functional balance was mixed. The selected trials were all crossover trials of the immediate
37 effects; long-term effects are unexplored. Authors concluded that an AFO can improve
38 walking and balance after stroke, but only the immediate effects have been examined. The
39 effects and acceptability of long-term usage need to be evaluated. Tyson et al. (2013)
40 systematically reviewed the evidence on the effects of an AFO on gait biomechanics after
41 stroke. Controlled trials of an ankle-foot orthosis on gait biomechanics in stroke survivors
42 were identified. Twenty trials involving 314 participants were selected. An ankle-foot

1 orthosis had a positive effect on ankle kinematics ($P < 0.00001-0.0002$); knee kinematics
2 in stance phase ($P < 0.0001-0.01$); kinetics ($P = 0.0001$) and energy cost ($P = 0.004$), but
3 not on knee kinematics in swing phase ($P = 0.84$), hip kinematics ($P < 0.18-0.89$) or energy
4 expenditure ($P = 0.43$). There were insufficient data for pooled analysis of individual joint
5 moments, muscle activity or spasticity. All trials, except one, evaluated immediate effects
6 only. Authors concluded that an ankle-foot orthosis can improve the ankle and knee
7 kinematics, kinetics and energy cost of walking in stroke survivors.

8
9 Daryabor et al. (2018) aimed at evaluating the efficacy of different designs of AFOs and
10 comparison between them on the gait parameters of individuals with hemiplegic stroke. A
11 total of 27 articles were found for the final evaluation. All types of AFOs had positive
12 effects on ankle kinematic in the first rocker and swing phases, but not on knee kinematics
13 in the swing phase, hip kinematics or the third rocker function. The articulated passive
14 AFO compared with the non-articulated passive AFO had better effects on some aspects
15 of the gait of patients with hemiplegia following stroke, more investigations are needed in
16 this regard though. Authors conclude that an ankle-foot orthosis can immediately improve
17 the dropped foot in the stance and swing phases. The effects of long-term usage and
18 comparison among the different types of AFOs need to be evaluated.

19
20 Daryabor et al. (2021) compared the effect of ankle-foot orthosis (AFOs) types on
21 functional outcome measurements in individuals with (sub)acute or chronic stroke
22 impairments. Overall pooled results indicated improvements in favor of AFOs versus
23 without for the Berg Balance Scale, timed-up and go test, Functional Ambulatory
24 Categories, 6-Minute Walking Test, Timed Up-Stairs, and Motricity Index. Heterogeneity
25 was non-significant for all outcomes except the Berg Balance Scale and Functional
26 Ambulatory Categories. Additionally, there was not sufficient evidence to determine the
27 effectiveness of specific orthotic designs over others. Authors concluded that an AFO can
28 improve ambulatory function in stroke survivors. Wearing an AFO in rehabilitation care
29 during the subacute phase post stroke may have beneficial effects on functional outcomes
30 measured.

31
32 Choo et al. (2021) conducted a meta-analysis to investigate the effectiveness of ankle-foot
33 orthosis (AFO) use in improving gait biomechanical parameters such as walking speed,
34 mobility, and kinematics in patients with stroke with gait disturbance. Experimental and
35 prospective studies were included that evaluated biomechanics or kinematic parameters
36 with or without AFO in patients with stroke. Gait biomechanical parameters, including
37 walking speed, mobility, balance, and kinematic variables, in studies involving patients
38 with and without AFO use were analyzed. A total of 19 studies including 434 participants
39 that reported on the immediate or short-term effectiveness of AFO use were included in
40 the analysis. Significant improvements in walking speed, cadence, step length, stride
41 length, Timed up-and-go test, functional ambulation category (FAC) score, ankle sagittal
42 plane angle at initial contact, and knee sagittal plane angle at toe-off were observed when

1 the patients wore AFOs. Stride time, body sway, and hip sagittal plane angle at toe-off
2 were not significantly improved. Among these results, the FAC score showed the most
3 significant improvement, and stride time showed the lowest improvement. Authors
4 concluded that an AFO improves walking speed, cadence, step length, and stride length,
5 particularly in patients with stroke. AFO is considered beneficial in enhancing gait stability
6 and ambulatory ability.

7
8 Johnston et al. (2021) authored a clinical practice guideline (CPG) to provide evidence to
9 guide clinical decision-making for the use of either ankle-foot orthosis (AFO) or functional
10 electrical stimulation (FES) as an intervention to improve body function and structure,
11 activity, and participation as defined by the International Classification of Functioning,
12 Disability and Health (ICF) for individuals with post stroke hemiplegia with decreased
13 lower extremity motor control. One-hundred twenty-two (122) meta-analyses, systematic
14 reviews, randomized controlled trials, and cohort studies were included. Strong evidence
15 exists that AFO and FES can each increase gait speed, mobility, and dynamic balance.
16 Moderate evidence exists that AFO and FES increase quality of life, walking endurance,
17 and muscle activation, and weak evidence exists for improving gait kinematics. AFO or
18 FES should not be used to decrease plantar flexor spasticity. Studies that directly compare
19 AFO and FES do not indicate overall superiority of one over the other. But evidence
20 suggests that AFO may lead to more compensatory effects while FES may lead to more
21 therapeutic effects. Due to the potential for gains at any phase post stroke, the most
22 appropriate device for an individual may change, and reassessments should be completed
23 to ensure the device is meeting the individual's needs. This CPG cannot address the effects
24 of one type of AFO over another for the majority of outcomes, as studies used a variety of
25 AFO types and rarely differentiated effects. The recommendations also do not address the
26 severity of hemiparesis, and most studies included participants with varied baseline
27 ambulation ability. According to authors, this CPG suggests that AFO and FES both lead
28 to improvements post stroke.

29
30 Daryabor et al. (2022) evaluated the efficacy of AFO types and comparison between them
31 on the energy expenditure metrics of walking in individuals who had suffered a stroke with
32 (sub)acute or chronic evolution. A total of 15 trials involving 195 participants were selected
33 for the final evaluation. All trials, except one, examined individuals in chronic phase.
34 Although the evidence from the selected studies was generally weak, the consensus was
35 that an AFO may have a positive immediate effect on the energy expenditure metrics
36 including energy cost, physiological cost index, mechanical work and vertical center of
37 mass trajectory on the affected leg, in both overground walking and treadmill walking in
38 adults with chronic stroke. There were insufficient studies to evaluate the medium term
39 efficacy of wearing an AFO combined with gait training on metabolic cost parameters
40 during ambulation. There were also insufficient studies for comparison among different
41 designs of AFOs. Authors concluded that an AFO can immediately improve energy
42 expenditure metrics of walking in stroke survivors. There is a need for further well-

1 designed randomized trials to evaluate long-term effect of gait training using AFOs and
2 comparison among the different types of orthoses.

3
4 Wada et al. (2022) evaluated whether ankle-foot orthosis (AFO) has a beneficial effect on
5 dorsiflexion angle increase during the swing phase among individuals with stroke and
6 patient-important outcomes in individuals with stroke. Studies reporting on AFO use to
7 improve walking, functional mobility, quality of life, and activity limitations and reports
8 of adverse events in individuals with stroke were included. Fourteen trials that enrolled 282
9 individuals with stroke and compared AFO with no AFO were included. Compared with
10 no AFO, AFO could increase the dorsiflexion angle of ankle joints during walking; (low
11 certainty of evidence). Furthermore, AFO could improve walking ability (walking speed);
12 (low certainty of evidence). No study had reported the effects of AFO on quality of life,
13 adverse events, fall frequency, and activities of daily life. Authors concluded that findings
14 suggest that AFO improved ankle kinematics and walking ability in the short term;
15 nonetheless, the evidence was characterized by a low degree of certainty.

16 **Orthotic Management in Cerebral Palsy (CP)**

17 AFOs have long been used for children with spastic CP to assist with gait and function.
18 Taking this a step further, Bahramizadeh et al. (2012) studied whether a specific floor
19 reaction type AFO (FRATO) would actually assist postural control in children with spastic
20 CP. A quasi-experimental design was used to test eight children with spastic CP against
21 eight matched control subjects. Posture control was assessed with and without the brace in
22 a standing position. Centers of pressure (CoP) were measured; standard deviations (SDs)
23 were included as an indication of excursion from center. The greater the lack of postural
24 control, the higher the standard deviation. Velocities of these SDs were also analyzed. It
25 appeared from the data that postural control was not significantly different between groups
26 and therefore the FRATOs did not affect postural control. The authors did note that
27 maximum knee extension was affected by the brace and could potentially positively affect
28 alignment of the knee.
29

30
31 Morris et al. (2011) published a result from an international consensus conference with
32 regards to orthotic management of cerebral palsy. Participants reviewed the evidence and
33 considered how these patients are treated on a day-to-day basis. They determined that many
34 of the papers were of low quality. Of interest is that substantial evidence suggests AFOs
35 which control the ankle and foot within the gait pattern allow for a more efficient gait in
36 those children who are ambulatory. Minimal evidence exists for the use of hip, spine, or
37 upper limb orthoses. Overall, the extent to which orthoses may prevent further deformity
38 was not established. Sees and Miller (2013) reviewed foot deformities and in children with
39 CP and treatments. Authors state that treatment for the young children should be primarily
40 with orthotics and manual therapy. Equinus is the most common deformity, with orthotics
41 augmented with botulinum toxin being the primary management in young children. Varus
42 deformity of the feet is often associated with equinus and can almost always be managed

1 with orthotics until 8 or 10 years of age. Planovalgus is the most common deformity in
2 children with bilateral lower extremity spasticity. The primary management is orthotics
3 until the child no longer tolerates the orthotic; then surgical management needs to consider
4 all the deformities, and all should be corrected.

5
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23 eight matched control subjects. Posture control was assessed with and without the brace in
24 a standing position. Centers of pressure (CoP) were measured; standard deviations (SDs)
25 were included as an indication of excursion from center. The greater the lack of postural
26 control, the higher the standard deviation. Velocities of these SDs were also analyzed. It
27 appeared from the data that postural control was not significantly different between groups
28 and therefore the FRATOs did not affect postural control. The authors did note that
29 maximum knee extension was affected by the brace and could potentially positively affect
30 alignment of the knee.
31

32
33 Morris et al. (2011) published a result from an international consensus conference with
34 regards to orthotic management of cerebral palsy. Participants reviewed the evidence and
35 considered how these patients are treated on a day-to-day basis. They determined that many
36 of the papers were of low quality. Of interest is that substantial evidence suggests AFOs
37 which control the ankle and foot within the gait pattern allow for a more efficient gait in
38 those children who are ambulatory. Minimal evidence exists for the use of hip, spine, or
39 upper limb orthoses. Overall, the extent to which orthoses may prevent further deformity
40 was not established. Sees and Miller (2013) reviewed foot deformities and in children with
41 Aboutorabi et al. (2017) conducted a systematic review of the literature and establish the
42 effect of treatment with various types of AFOs on gait patterns of children with CP. Authors

1 included 17 studies investigating a total of 1139 children with CP. In general, the use of
2 AFOs improved speed and stride length. The hinged AFO (HAFO) was effective for
3 improving gait parameters and decreasing energy expenditure with hemiplegic CP as
4 compared with the barefoot condition. It also improved stride length, speed of walking,
5 single limb support and gait symmetry with hemiplegic CP. The plastic solid AFO (SAFO)
6 and floor reaction orthoses (FRO) were effective in reducing energy expenditure with
7 diplegic CP. With diplegic CP, the HAFO and SAFO improved gross motor function.
8 Authors concluded that for children with CP, use of specific types of AFOs improved gait
9 parameters, including ankle and knee range of motion, walking speed and stride length.
10 AFOs reduced energy expenditure in children with spastic CP. However, further studies
11 with better quality are required for more conclusive evidence regarding the effectiveness
12 of AFOs in children with CP.

13
14 Lintanf et al. (2018) determined the effects of ankle-foot orthoses (AFOs) on gait, balance,
15 gross motor function and activities of daily living in children with cerebral palsy. Studies
16 of the effect of AFOs on gait, balance, gross motor function and activities of daily living
17 in children with cerebral palsy were included. Articles with a modified PEDro score $\geq 5/9$
18 were selected. Data regarding population, AFO, interventions and outcomes were
19 extracted. When possible, standardized mean differences (SMDs) were calculated from the
20 outcomes. Thirty-two articles, corresponding to 56 studies (884 children) were included.
21 Fifty-one studies included children with spastic cerebral palsy. AFOs increased stride
22 length and gait speed, and decreased cadence. Gross motor function scores improved
23 [Gross Motor Function Measure (GMFM) and Pediatric Evaluation of Disability Inventory
24 (PEDI)]. Data relating to balance and activities of daily living were insufficient to make
25 conclusions. Posterior AFOs (solid, hinged, supra-malleolar, dynamic) increased ankle
26 dorsiflexion at initial contact and during swing, and decreased ankle power generation in
27 stance in children with equinus gait. Authors concluded that for children with spastic
28 cerebral palsy, there is strong evidence that AFOs induce small improvements in gait speed
29 and moderate evidence that AFOs have a small to moderate effect on gross motor function.
30 In children with equinus gait, there is strong evidence that posterior AFOs induce large
31 changes in distal kinematics.

32
33 Firouzeh et al. (2019) described research on outcomes associated with early Ankle Foot
34 Orthosis (AFO) use, AFO use patterns, and parent and clinician perspectives on AFO use
35 among young children with cerebral palsy. Nineteen articles were included in the review;
36 14 focused on body functions and structures, seven on activity level outcomes and no
37 studies addressed participation outcomes. Evaluations of the effects of AFOs on gross
38 motor skills other than gait were limited. Overall, the body of evidence is comprised of
39 methodologically weak studies with common threats to validity including inadequate
40 descriptions of study protocols, AFO construction, and comparison interventions. Authors
41 concluded that research evaluating the effects of AFOs on age-appropriate, functional
42 outcomes including transitional movements, floor mobility and participation in early

1 childhood settings is needed to inform practice regarding early orthotic prescription.
2 Implications for rehabilitation. Lack of rigorous evidence about the effects of AFOs in
3 young children limits the ability of research to guide practice in pediatric rehabilitation.
4

5 Skaaret et al. (2019) evaluated changes in gait and impacts of AFOs one-year
6 postoperatively. In all, 33 children with spastic unilateral cerebral palsy (SUCP), 17 girls
7 and 16 boys, mean age 9.2 years (5 to 16.5) were measured by 3D gait analysis walking
8 barefoot preoperatively and walking barefoot and with AFOs one-year postoperatively.
9 Changes in Gait Profile Scores (GPS), kinematic, kinetic and temporal spatial variables
10 were examined using linear mixed models, with gender, gross motor function and AFO
11 type as fixed effects. The results confirm significant gait improvements in the GPS,
12 kinematics and kinetics walking barefoot one year after surgery. Comparing AFOs with
13 barefoot walking postoperatively, there was additionally reduced ankle plantarflexion by
14 an average of 5.1° and knee flexion by 4.7° at initial contact, enhanced ankle moments
15 during loading response, increased velocity, longer steps and inhibited push-off power
16 generation. Stance and swing phase dorsiflexion increased in children walking with hinged
17 AFOs versus children walking with ground reaction AFOs. Changes in the non-affected
18 limbs indicated less compensatory gait postoperatively. Authors concluded that major
19 changes were found between pre- and postoperative barefoot conditions. The main impact
20 of AFOs was correction of residual drop foot and improved prepositioning for initial
21 contact, which could be considered as indications for continued use after the one-year
22 follow-up.
23

24 **Achilles Rupture and AFO**

25 Given changes and advances in the care and immediate weight bearing status of Achilles
26 tendon rupture, Kearney et al. (2011) wanted to investigate the effects of an AFO with
27 varying heel wedges and how the results may impact management of these injuries. AFOs
28 and heel wedges are now being used for these immediate weight bearing protocols.
29 Researchers evaluated the plantar pressures and gait parameters on 15 healthy participants
30 using 3 different AFOs with 4 different levels of heel wedges inserted into the AFO.
31 Therefore, a total of 12 conditions were evaluated (randomly sequenced). Results
32 demonstrated that AFOs with a higher number of inserted heel wedges reduced forefoot
33 pressures, increased heel pressures, and also the time spent in terminal stance pre-swing
34 phases of the gait cycle. These results should be considered when determining weight
35 bearing and loading of an Achilles tendon rupture and use of an AFO with heel wedges.
36

37 The Orthopedic Division of the American Physical Therapy Association developed clinical
38 practice guidelines (CPG) for the treatment of plantar fasciitis (McPoil, 2008). The APTA
39 recommended night splints as an intervention for patients with symptoms greater than 6
40 months in duration. The desired length of time for wearing the night splint is 1 to 3 months.
41 The type of night splint used (i.e., posterior, anterior, sock-type) did not appear to affect
42 the pain/function outcomes. A walking boot is a rigid or semi-rigid device which may be

1 used to provide immobilization as treatment for an orthopedic condition or after orthopedic
 2 surgery. In the revised version of this CPG, recommendations are that clinicians should
 3 prescribe a 1- to 3-month program of night splints for individuals with heel pain/plantar
 4 fasciitis who consistently have pain with the first step in the morning (Martin et al., 2014).

6 PRACTITIONER SCOPE AND TRAINING

7 Practitioners should practice only in the areas in which they are competent based on their
 8 education, training and experience. Levels of education, experience, and proficiency may
 9 vary among individual practitioners. It is ethically and legally incumbent on a practitioner
 10 to determine where they have the knowledge and skills necessary to perform such services
 11 and whether the services are within their scope of practice.

12
 13 It is best practice for the practitioner to appropriately render services to a member only if
 14 they are trained, equally skilled, and adequately competent to deliver a service compared
 15 to others trained to perform the same procedure. If the service would be most competently
 16 delivered by another health care practitioner who has more skill and training, it would be
 17 best practice to refer the member to the more expert practitioner.

18
 19 Best practice can be defined as a clinical, scientific, or professional technique, method, or
 20 process that is typically evidence-based and consensus driven and is recognized by a
 21 majority of professionals in a particular field as more effective at delivering a particular
 22 outcome than any other practice (Joint Commission International Accreditation Standards
 23 for Hospitals, 2020).

24
 25 Depending on the practitioner's scope of practice, training, and experience, a member's
 26 condition and/or symptoms during examination or the course of treatment may indicate the
 27 need for referral to another practitioner or even emergency care. In such cases it is prudent
 28 for the practitioner to refer the member for appropriate co-management (e.g., to their
 29 primary care physician) or if immediate emergency care is warranted, to contact 911 as
 30 appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice
 31 guideline for information.

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