LOWER EXTREMITY ORTHOSES

INTRODUCTION

This chapter provides guidelines for equipment and orthoses used to augment or replace lower extremity (LE) function affected by spinal cord injury or dysfunction. It addresses both external devices such as standers which patients can be placed into, as well as orthoses which are worn to improve positioning and upright mobility. Orthoses can be used to help with ambulation at the therapeutic, household, and/or community level. Patients may require assistive devices such as crutches or a walker, even with the use of lower extremity orthoses.

Functions of Orthosis

1 Reduce energy cost of ambulation
2. Pain reduction and provide comfort
3. Deformity correction and prevention (Solid AFO prevents equinus deformity of foot, KAFO for preventing Genu Recurvatum)
4. Support/stability of joints (Eg. KAFO provides mediolateral stability)
5. Assist action of weak muscles (assist motion)
6. Spasticity control (tone reducing orthosis)
7. Restriction of range of motion of hyperflexible joints
8. Pressure redistribution (helps in prevention of joint deformity and pressure sores)

GENERAL CONSIDERATIONS

A multidisciplinary approach incorporating the patient, caregivers, physician, physiatrist, physical and occupational therapists and certified prosthetist-orthotist is essential for orthotic decision making. Orthotic options are determined by the strength of both key and non-key muscles of the lower extremity assessed using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI). Non-key muscles include hip extensors, knee flexors, and gastrocnemius assessed in traditional manual muscle testing positions. In addition, sensation, skin integrity, range of motion, blood pressure and fluid status should be assessed. The patient should be evaluated for cognitive ability to understand the wear/care of orthotic use. The patient should be deemed a candidate based on expected compliance and/or a support network.[1]

Further evaluation for orthotic use should include upper extremity strength as an assistive device, such as crutches or a walker, may be required for mobility even with the application of lower extremity orthoses. In addition, a thorough orthopedic evaluation for scoliosis, kyphosis, pelvic obliquity, hip subluxation/dislocation, lower extremity fractures or amputation, and evaluation of biomechanics, kinematics of gait, proprioception, and spasticity should be completed to determine indications and contraindications of orthotic care.

Orthoses must fit and function well and re-assessment is necessary to ensure continued fit and appropriateness. A client who receives an orthosis must receive education regarding its use and maintenance in order to prevent changes in skin integrity as well as maintain optimal effectiveness of the orthosis.

Table 1. Considerations for Orthotic Use

Strength of lower and upper extremity musculature
Orthopedic impairments (scoliosis, pelvic obliquity, hip subluxation/dislocation, lower extremity fracture, amputation)
Spasticity
Joint contractures
Proprioception
Biomechanics in upright positioning and kinematics of gait
Orthostatic hypotension
Endurance/energy expenditure requirements

LOWER EXTREMITY ORTHOSES

Three primary goals for the use of orthotics for persons with spinal cord injury (SCI) are:

1. protect and/or maintain bone and joint integrity
2. assist with function/ mobility while substituting for muscle strength, and
3. to encourage normal orthopedic development in children[1].

Lower extremity orthoses range from off-the-shelf products, which do not require modification, to custom-fit off-the-shelf products and custom-made orthoses. They can be worn unilaterally, bilaterally, and in some cases are connected and encompass both limbs within one orthosis. In general, a custom-made orthosis is indicated for anatomical abnormalities, heavy-duty/obese patients, patients presenting with weakness throughout the limb, and/or long-term repeated use.

Table 2. Common materials/components used in Lower Extremity[4] Orthotics

Carbon Fiber	Lightweight, durable, and has energy storing/returning properties Consider for heavy duty users, obese patients Possibly indicated for edematous patients as total contact can be reduced
Metal	Traditional style often indicated for legacy patients with similar exisiting braces Possibly indicated for edematous patients as total contact is reduced Increased durability but also increased weight and bulk Steel, aluminum and titanium configurations possible
Plastic	Custom orthoses can be configured for more or less contact and more or less stiffness
Padding	Can be added to most custom braces Indicated for edematous, insensate, and sensitive patients Various durometers/types of padding possible
Joint Options	Various hip, knee and ankle joints exist to help restore function and/or prevent deformities Activity level, ROM, desired outcome, patient strength and weight should all be considered

Orthoses can be made from various materials such as metal, plastic, and/or carbon fiber. Orthoses may contain mechanical joints which help assist or prevent certain motions at the level of the hip, knee, and ankle or contrarily may be unjointed if no motion is desired. One may want to consider padding if a patient presents with poor sensations and/or volume fluctuations to prevent skin breakdown. Please see flowchart below to determine which materials may be indicated depending on your patient's condition.

The following are descriptions of lower extremity orthoses typically used with persons with SCI:

Stander: commercially available and usually includes a seat that the user transfers into or a pelvic strap which allows the patient to stand directly from the wheelchair. A manual, hydraulic or electric lift is used to bring the individual to standing. Lower extremity, trunk, chest, and upper extremity supports are available as needed.

A stander is beneficial for multiple body systems affected by spinal cord injury including cardiometabolic, bowel/bladder function, as well as the prevention of skin, bone, and joint complications. Standers also encourage increased participation level in activities in an upright position (i.e. school, social activities.[14]

Ankle Foot Orthosis (AFO): When used for upright mobility, this type of lower extremity orthosis provides ankle and foot support for the user as well as influence for hip and knee mechanics. An AFO can allow improved foot clearance during swing phase of ambulation and/or provide stability of the ankle/knee in stance phase of gait. They can improve safety during transfers by preventing unwanted motion, as well as standing and mobility by providing ankle and foot support.

AFOs may be off-the-shelf or custom-made depending on the patient's indication. There are both articulating and non-articulating versions available depending on the patient's presentation. See Table 2 for design considerations.

For AFOs the general options are as follows:

- Solid AFOs which control motion at ankle in sagittal, coronal and transverse planes. Generally indicated for someone with profound weakness throughout foot and ankle. This design can be used both as a positional AFO for standing/ transfers, as well as for ambulation.
- Semi-solid AFOS which are trimmed to the midline of the malleoli to allow for more motion at the ankle than a solid AFO. Indicated for someone primarily with sagittal plane foot drop and fair strength in coronal/transverse plane at the foot and ankle.
- Posterior Leaf Spring AFOs are trimmed posterior to the malleoli and allow for more sagittal motion at the ankle. Indicated for someone primarily with sagittal plane foot drop and good strength in coronal/transverse plane at the foot and ankle.
- Ground/Floor reaction AFOS(GRAFOS or FRAFOS) have an anterior component of the AFO which extends below the knee. GRAFOs are generally indicated for people who need knee extension assistance and/or have plantar flexion weakness. It promotes knee extension through mid-late stance and assists with plantar flexion in late-stance.
- Articulating AFOS are jointed at the ankle level which can be used to limit, allow, and/or assist with certain motions. For example, a joint can block plantar flexion but assist with dorsiflexion. There are several joint types and configurations which can be used based on the patient's presentation so be sure to consult with your local specialist.
- Stretching AFOS are used to increase/ maintain ROM at the ankle and foot. There are OTS options which can be purchased to control purely sagittal motion but if a patient has severe contractures and/or contractures in more than one plane(ex: equinovarus) a custom-made orthosis is likely indicated. It is even possible to use dynamic stretching orthoses which can increase ROM in 2 or more planes(ultraflexsplint images)

Knee Ankle Foot Orthosis (KAFO): KAFOs cross the knee, ankle and foot, are generally custom-made, and provide knee, ankle, and foot stability. There are various mechanical joints which can be used to increase stability including locking joints and posterior offset joints. It is important consider patient compliance with KAFOs due to their bulk and relative difficulty to be donned/doffed. See Table 2 for design considerations.

Hip Knee Ankle Foot Orthosis (HKAFO): This type of lower extremity orthosis stabilizes the hip, knee, and ankle. When used bilaterally, this orthosis consists of a pair of KAFOs attached to one another by a pelvic band, or trunk orthosis. With the hip component locked a swing to/through gait pattern is used. With the hip component unlocked, the user may be able to ambulate with a reciprocal gait pattern. It is important consider patient compliance with HKAFOs due to their bulk and relative difficulty to be donned/doffed. See Table 2 for design considerations.

Reciprocating Gait Orthosis (RGO): Consists of a pair of HKAFOs that are connected to one another by a pelvic band and cable system, allowing the user to ambulate with a dynamic reciprocal gait. RGOs allow the user to ambulate with a dynamic reciprocal gait pattern by using body weight shifts. The patient must have sufficient hip extension and lordosis to benefit from an RGO. It is important consider patient compliance with RGOs due to their bulk and relative difficulty to be donned/doffed.

FES Surface Stimulation Systems: These systems provide stimulation of specific nerve/muscle groups, generally via electrodes worn on the skin. Commonly, such devices can be used to target ankle dorsiflexors to improve foot clearance. Benefits of such devices are that they don't limit ROM, there is reduced bulk, and they promote muscle hypertrophy. They require a specialist to program the device and are indicated for patients with good cognition and/or a good support system. Examples of these devices are the Walkaide and Bioness. They can be worn in conjunction with other orthoses such as a foot orthotic inside of the patient's shoe to control ankle instability.

Hybrid Systems: These systems combine traditional orthoses with functional electrical stimulation (FES) components. The FES components may provide stimulation via implanted, percutaneous or surface systems. These systems can be used for brief functional activities such as standing to cook or retrieve items or short distance walking. Of note, the use of these systems require much more training than orthoses alone.

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Stander with built in air cell filled cushions (https://easystand.com)


Solid AFO


Carbon Fiber AFO

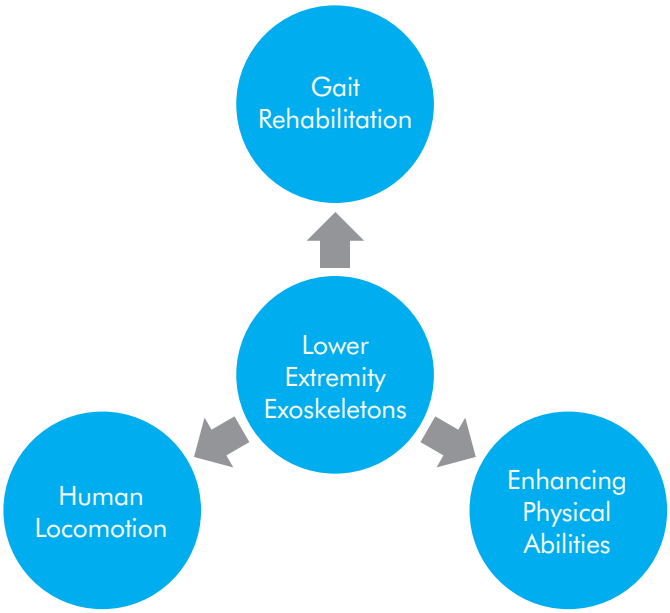

Articulated AFO


Drop Lock KAFO


Bale Lock KAFO

Stance Control KAFO

Robotics: The use of robotics in spinal cord rehabilitation has increased due to growing research interest and the advancement of robotic exoskeleton systems. Exoskeletons are wearable devices that augment, reinforce, or restore human performance. Some exoskeletons are fixed (see Lokomat below), while some are mobile devices in which clients can utilize for therapeutic and functional ambulation (see ReWalk below).[18] These devices may also be termed as motorized orthoses. Per Chen et al, exoskeletons can be classified into 3 categories:



Adapted from Bing Chen, Hao Ma, Lai-Yin Qin, Fei Gao, Kai-Ming Chan, Sheung-Wai Law, Ling Qin, Wei-Hsin. Recent developments and challenges of lower extremity exoskeletons. Journal of Orthopaedic Translation (2016)

Gait rehabilitation exoskeleton devices are utilized as training tools to improve an individual's ability to walk and improve gait mechanics while human locomotion devices provide an opportunity for clients to ambulate when they lack the strength to do so without robotic assistance. Many devices on the market can be utilized for either gait training or human locomotion, but availability, pricing, funding, and approval for home use of these devices vary across the nation/ country. There are some robotic devices that are approved for research, some that are approved by regulatory agencies for use with a skilled professional, and others that are approved for use in the home and community. Other considerations with robotic orthoses is the increased training needs for the devices. Robotics that enhance physical abilities are often utilized in military or industrial settings to increase repetition or efficiency for a particular task, and are not utilized in spinal cord injury rehabilitation. While the term exoskeleton is implied due to the application to bilateral lower extremities and the trunk, there are robotic devices being developed for a unilateral lower extremity issue or for an individual joint. Benefits of lower extremity robotic systems include: increased repetition of task-specific training, uniformity and precision of lower extremity movements, and the opportunity to ambulate for those whose impairments prohibit otherwise. Some features that are continuing to be addressed are: availability, cost, weight of the device, access to the device, and increased time for set up/ fitting. It is important to note that while there have been studies that demonstrate benefits of robotics, they have not shown them to be superior to other gait training devices.[17] Several studies have been completed to determine the safety and effectiveness of robotic devices and these studies show few adverse effects and improvement of walking patterns in clients with incomplete injuries, however, further research is warranted, especially as technology advances.[15]

Orthotic Considerations Based on Neurological Level of Injury

C1 to C6 Levels with Complete (AIS A) SCI:
Medically Beneficial Use of LE Orthotics

- Standing: Tilt table or Hydraulic standing frame[2]
- Functional Ambulation: not indicated

C7 to C8 Levels with Complete (AIS A) SCI:
Medically Beneficial for Use of LE Orthotics

- Standing: Hydraulic or standard standing frame[2]
- Functional Ambulation: not indicated[2]

SCI at the T1 to T9 levels with Complete (AIS A) SCI:
Medically Beneficial for use of LE Orthotics

- Standing: standing frame[2]
- Functional Ambulation:
  - typically not functional mobility
  - typically therapeutic/exercise ambulation[1-2],
  - significantly increased physiological demand[6-8]

SCI at the T10 to L1 Levels with Complete (AIS A) SCI:
Medically Beneficial for Use of LE Orthotics

- Standing[2]

Reciprocating Gait Orthosis (RGO)

https://www.bostonoandp.com/products/lower-limb-orthotics/reciprocating-gait-orthosis-rgo

Bioness FES Surface Stimulation Systems

https://bionessrehab.com

Fixed Exoskeleton
www.hacoma.com

Mobile Exoskeleton
www.ReWalk.com

- Functional Ambulation:
  - typically therapeutic/exercise or household ambulation, with practice and assist for independence with the use of assistive device and lower extremity orthosis[2]
  - the orthosis may also be medically necessary if it is required to substitute for lost/absent muscle function.

SCI at the L2 to S5 levels with Complete (AIS A) SCI Medically Beneficial for use of LE Orthotics:

- Standing: with orthosis[2]
- Functional Ambulation:
  - typically household to community ambulation, with practice and assist for independence with the use of assistive device and lower extremity orthosis

Possible options of LE Orthoses by SCI Motor Level:

Level of SCI	Standing	Prevent/Correct Deformity	Functional Ambulation
C1-C6	Stander	Stretching AFOS, Positional Solid AFOs, ROM Knee Orthoses	N/A
C7-C8	Stander	Stretching AFOS, Positional Solid AFOs, ROM Knee Orthoses	N/A
T1-T9	Stander	Stretching AFOS, Positional Solid AFOs, ROM Knee Orthoses	N/A
T10-L1	HKAFO/ KAFO	Stretching AFOS, Positional Solid AFOs, ROM Knee Orthoses	RGO, HKAFO, KAFO
L2-S5	HKAFO/ KAFO/ Solid AFO	Stretching AFOS, Positional Solid AFOs, ROM Knee Orthoses	KAFO, AFO

Complete SCI

*This table is assuming there is a complete SCI. A thorough evaluation of each patient must be done to determine ROM, strength and functional abilities. This table is only to be used as a rough guideline and, in addition, the specific functions of the orthoses should be determined with a trained professional such as determine solid versus semi-sold AFO or locking KAFO versus free-moving KAFO, etc.

- the orthosis may also be medically necessary if it is required to substitute for lost/absent muscle function.

Incomplete Spinal Cord Injuries (AIS C and D): When considering the use of LE orthoses for mobility and ambulation, for individuals with incomplete SCI, it is necessary to look at the strength and function of individual LE muscle groups as opposed to using the individual's Neurological Level to make recommendations.

LE Orthotic Considerations with Special Populations:

Pediatric:

- In children with SCI, orthoses are frequently used to promote normal bone alignment during growth at the hips and the spine.
- 80% to 98% of children who sustain SCI prior to skeletal maturity develop a scoliosis[9-10].
- Early bracing of the spine, using an orthosis such as a thoracic lumbar sacral orthosis (TLSO), may delay the age that surgical intervention is required, and in curves less than 20 degrees, an orthosis may reduce the possibility of a surgical fusion[11].
- Hip dislocation and subluxation is also a concern in the pediatric SCI population, as one study[12] found that 93% of patients injured prior to 11 years and 9% of children older than 11 years had at least one hip subluxed or dislocated.
- To facilitate proper femoral head and acetabular positioning while in supine an abduction pillow can be used to maintain hip abduction[13].

Bariatric:

- Weight capacity considerations

CONCLUSIONS

A thorough clinical evaluation and discussion of functional goals is essential prior to initiating orthotic use. A multidisciplinary approach incorporating the patient, caregivers, physician, physical and occupational therapists and certified prosthetist orthotist is essential for orthotic decision making.

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