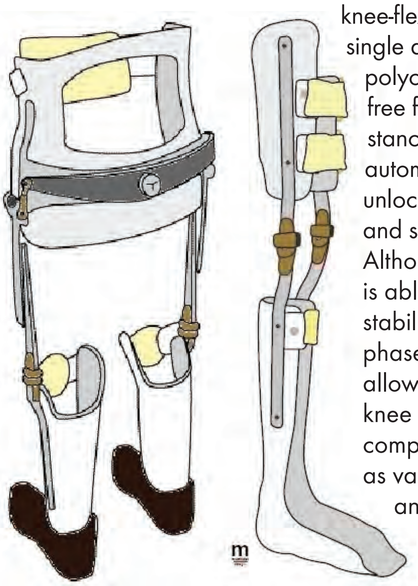
Evidence Note | The Use of KAFOs and HKAFOs for Ambulation

Key Points

- At this time, there is no substantive evidence to support or preclude the use of KAFOs and HKAFOs for ambulation.
- The main limitations of most studies of KAFOs and HKAFOs for ambulation are small sample size and inadequate study design.
- There is some evidence that use of HKAFOs diminishes with time in both adults and children with paraplegia due to high energy requirements for ambulation.
- There is some evidence that the advantages of orthotic management for SCI are primarily general health and well-being benefits related to standing and ambulating short distances in the home or indoor settings.

Health Technology Description

An orthosis is defined by the International Standards Organization (ISO) as "an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system."[1] Knee-ankle-foot orthoses (KAFOs) are orthoses that encompass the knee and ankle joint and the whole foot or part of the foot, while hip-knee-ankle-foot orthoses (HKAFOs) are essentially KAFOs that extend across the hip joint, connecting to a pelvic band or, when more trunk stability is required, lumbar or thoracic spinal support. KAFOs and HKAFOs account for 11 percent of practice by certified orthotists in the United States.[2] All knee-joint components provide coronal-plane stability with varying biomechanical control in the sagittal plane. Examples include locked joints that hold the limb in full extension until manually disengaged for sitting; locked joints with variable flexion that allow for accommodation of knee-flexion contractures; single axis, offset, and polycentric joints that allow free flexion-extension; and stance-control joints that automatically lock and unlock during the stance and swing phases of gait.[3] Although a locked KAFO is able to reliably provide stability during the stance phase of gait, it does not allow for flexion of the knee in swing, leading to compensatory actions such as vaulting, hip hiking, and circumduction that ensure clearance of the ground by the foot during swing phase.[4-7] Stance-control joints attempt to address these issues by providing reliable stance-phase control while still allowing swing-phase knee flexion. Additional stability may be provided to bilateral KAFOs by the application of a medial joint that permits motion in the sagittal plane but not in the coronal or transverse plane (e.g., the Walkabout Orthosis).[8-13]



Bilateral HKAFOs stabilize the lower limbs during stance in persons with paraplegia and allow swing-through gait when crutches are used. If the orthotic hip joints are mechanically linked, reciprocal gait may be achieved. Two fundamental mechanical designs of linked HKAFOs have been developed.[14] Both designs use lateral weight shift from one limb to the other, with the added assistance of crutches or a walker, as the basis for reciprocal gait. A hip-guidance orthosis (HGO), such as the ParaWalker, consists of bilateral KAFOs linked via specially designed low-friction hip joints with flexion/extension stops and a release mechanism that allows for sitting.[15-19] It has been suggested that the most important design characteristic of the HGO is its rigidity in single-limb support,[20] which keeps the lower limbs essentially parallel in the coronal plane,[21] providing for better ground clearance of the limb during swing. The reciprocating gait orthosis (RGO) couples motion of the two orthotic hip joints so that flexion of one hip results in extension of the other. Types of RGOs include the LSU-RGO, which utilizes two crossed-Bowden cables to couple hip motion;[22, 23] the advanced RGO (ARGO), which utilizes a single Bowden cable;[24, 25] and the isocentric RGO (IRGO) which utilizes a centrally pivoting bar and tie-rod arrangement to couple hip motion.[26-28] Although HGOs and RGOs were originally designed for use on children, more recent literature has focused on their use on adults with spinal cord injury (SCI).[29]

Scope of Review

The purpose of an Evidence Note is to provide a summary of the available evidence on a particular topic, facilitating access to knowledge. The focus of this evidence note is on custom-made orthoses intended for long-term use and not prefabricated devices, that are worn for less than a year. Orthoses whose primary function is other than to enhance ambulation, such as fracture orthoses and post-operative immobilization devices, are excluded from this Evidence Note. Given these review criteria, use of unilateral KAFOs was not well captured by this review since the literature regarding ambulation focuses primarily on persons with lower-limb paralysis who require bilateral KAFOs.

Epidemiology

The most common justification for a KAFO is the need for direct control of the knee in addition to the ankle and foot, while HKAFOs are typically used where there is bilateral lower-limb paralysis. While KAFOs can be worn unilaterally or bilaterally as required, use of unilateral HKAFOs is rare and limited to short-term application following hip arthroplasty to allow for protected walking.[3] The principal impairments addressed by KAFOs are paresis or paralysis of the muscles controlling the knee joint, upper motor-neuron lesions resulting in hypertonicity (spasticity) of the lower limb, or loss of structural integrity of the hip or knee joints. A literature review of KAFOs and HKAFOs for ambulation indicated that KAFO users include children with Duchenne muscular dystrophy (DMD) and persons with a diagnosis of polio, post-polio syndrome, or stroke; while users of HKAFOs include adults with SCI or paraplegia and children with myelomeningocele.[29]

Clinical Effectiveness

Three systematic reviews regarding the use of KAFOs and HKAFOs for ambulation were identified.[30–32]

As part of the Spinal Cord Injury Rehabilitation Evidence project, Lam et al.[32] reviewed 14 studies that reported the effects of gait training with KAFOs and HKAFOs in people with complete and incomplete SCI, and seven studies that examined the combined effect of RGOs and functional electrical stimulation (FES) on functional ambulation in people with complete SCI. They concluded that limited evidence suggests the benefits of orthotic management alone on functional ambulation are primarily for people with incomplete spinal lesions. The advantages of orthotic management are primarily the general health and well-being benefits related to standing and ambulating short distances in the home or indoor settings. There is limited evidence that a combined approach of orthoses and FES results in additional benefit to functional ambulation in paraplegic patients with complete SCI.[32]

Ijzerman et al.[30] reviewed 12 comparative trials of HKAFOs with and without FES for adults with complete thoracic lesions and reported that all the studies were internally invalid due to inadequate study design (simple within-subject comparisons without randomization of orthosis testing order) and lack of statistical power (small, heterogenous study populations).

Bakker et al.[31] reviewed nine controlled and uncontrolled clinical trials and case studies regarding intervention with KAFOs for children with DMD. They also noted that the scientific strength of the reviewed studies was poor but nevertheless concluded that use of KAFOs in the management of DMD can prolong assisted walking and standing. It remained uncertain whether KAFOs prolong "functional walking" because most studies were vague on what constitutes functional walking.

In 2006, the American Academy of Orthotists and Prosthetists (the Academy) held a state of the science conference on the use of KAFOs and HKAFOs to assist with ambulation (SSC7).[33] The literature review for this meeting identified two randomized control trials and included 27 cross-sectional studies published between 1995 and 2004.[29] The review concluded that though a reasonable amount of literature had been written regarding KAFOs and HKAFOs, the level of evidence regarding their use for ambulation was generally low.[29] There was some evidence that use of HKAFOs diminishes with time in both adults and children with paraplegia and that when orthoses are used, they are used mostly for therapeutic purposes.[11, 34–37] There was also some evidence that walking speed is slow and energy cost high in people with paraplegia regardless of orthotic device used.[12, 28, 38–46]

There are as yet no reviews regarding stance-control orthoses (SCOs).[29] To date, there have been seven cross-sectional studies,[5–7, 47–50] ten case studies,[4, 51–59] and two technical notes.[60, 61] Three have evaluated gait with the Horton's Stance Control Orthotic Knee Joint (SCOKJ),[4, 6, 55] six describe development and evaluation of the dynamic knee-brace system (DKBS),[5, 49, 50, 53, 54, 62] and two describe development and application of an electromechanical stance-control KAFO (SCKAFO).[57, 63] A single case study describes attempts to combine stance-control joints with an RGO.[58] The majority of these studies have been in able-bodied persons or persons with unilateral limb weakness resulting from conditions such as polio. Preliminary studies suggest that providing stance control may decrease compensatory maneuvers (vaulting, hip hiking) and energy expenditure compared to walking with a locked knee.[4–7, 47, 51, 53, 55, 57]

Safety

It is recommended that qualified orthotists should contribute to the assessment and prescription of orthoses and be specifically responsible for manufacture and delivery of orthotic devices.[64] An orthotist is an allied health professional who is specifically trained and educated to provide or manage the provision of a custom-designed, fabricated, modified, and fitted external orthosis to a patient.[65] Practitioners who successfully complete the education, experience, and examination requirements prescribed by an accrediting body become certified orthotists. Certification indicates that the orthotist has met established standards and has the qualifications required to render orthotic services. A certified orthotist is the best person to ensure safe provision and use of a KAFO or HKAFO.

Economic Implications

No published studies examining the cost effectiveness of KAFOs and HKAFOs were identified. A review of Medicare payment data for 2007[66] shows that the allowable base rate of a single custom-fabricated KAFO ranged from \$734–\$3,289, while the allowable cost for an RGO was approximately \$8,306 using the suggested coding for an ARGO[67] as an example.

Future Research

Designing adequate studies to investigate the effect of KAFOs and HKAFOs on ambulation is challenging due to the heterogeneous populations that use these devices and the heterogeneity within each population. It has been recommended that randomized crossover interrupted time series trials be used to improve the internal validity and statistical power of future research regarding KAFOs and HKAFOs for ambulation.[30] Furthermore, Fatone[29] indicated that the population being evaluated (diagnosis, time since injury, lesion level, whether a lesion is complete or not, residual muscle function, prior experience with orthosis, training provided, type of gait pattern used) and the orthosis being used must be adequately described in order for study data to be interpreted and the information generalized or compared between studies.

The following primary research priorities regarding use of KAFOs and HKAFOs for ambulation were identified by participants of SSC7:[33]

- Identify and/or develop standardized subjective and objective outcome measures.
- Investigate the short- and long-term effects of KAFO and HKAFO use on the neuromusculoskeletal system.
- Research application of SCOs.
- Define the mechanical loading conditions on KAFO and HKAFO devices to guide orthotic design and application.
- Determine the short- and long-term effects of physical therapy intervention, including gait training, on outcome and acceptance of KAFOs and HKAFOs.
- Measure the impact of pharmacological management on successful use of KAFOs and HKAFOs in persons with severe spasticity.

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