Summary from the Academy's Seventh State-of-the-Science Conference on Knee-Ankle-Foot Orthoses for Ambulation

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ABSTRACT

This article summarizes the results from deliberations by an international multidisciplinary group of experts convened by the American Academy of Orthotists and Prosthetists to review the State-of-the-Science regarding use of custom-made knee-ankle-foot orthoses (KAFOs) to assist in ambulation. Based on a comprehensive review of peer-reviewed literature from the past decade, only four articles on this topic were identified as controlled trials, with only three investigating the use of KAFOs by clinical populations. The participants concluded that there is currently no substantive evidence at the highest level of scientific certainty regarding the use of KAFOs and hip-knee-ankle-foot orthoses (HKAFOs) for ambulation, but there are a number of core assumptions supported by expert opinion and peer-reviewed publications that can be considered clinical hypotheses about these orthoses. These rehabilitation beliefs can and should be tested in future research applications. Six primary research priorities and associated implications were identified. The panelists concluded that scientific research into these questions would significantly advance our understanding about the optimal application of KAFOs and HKAFOs to assist in ambulation.

This State-of-the-Science Conference was convened to examine the body of peer-reviewed evidence related to the use of knee-ankle-foot orthoses (KAFOs) to assist in ambulation. The goal was to establish what is known, what is believed to be true, and what needs to be known to optimize the application of these orthoses. Evidence reviewed was based on both unilateral and bilateral KAFOs, including those incorporated into more extensive lower limb orthoses such as hip-knee-ankle-foot orthoses (HKAFOs) and the various reciprocating gait orthoses (RGOs). Prefabricated items intended to be worn for less than one year were excluded from this review, as were orthoses not used primarily to enhance ambulation, such as fracture braces and postoperative immobilization devices.

BACKGROUND

Although KAFOs have been prescribed long-term to treat a broad range of physical disabilities for many centuries, their use has rarely been the subject of controlled studies. Retrospective reviews have suggested that the long-term use rate of KAFOs is significantly lower than that for ankle-foot orthoses (AFOs), although the reasons for this disparity are not well established and vary among different diagnostic cohorts.

Energy efficiency studies have repeatedly shown that immobilizing the knee markedly increases the energy requirements for ambulation in normal subjects, and there is some evidence that this is also true for certain individuals with physical disabilities.[1] Recent technical advances have resulted in the availability of stance control knee joints that provide stability under weight bearing while allowing knee flexion in swing, which has the potential to eliminate the historic requirements for a stiff-knee gait when walking with a KAFO.

This new biomechanical class of KAFOs (which can also be incorporated into HKAFOs) appears to be more broadly applicable than the traditional locked knee devices and might result in more frequent prescription of KAFOs in the future. Many of the conclusions in the current literature are based on the assumption that use of a KAFO implied that the knee was locked in extension throughout the entire gait cycle, including swing phase. The increasing usage of stance control technology raises questions about the validity of many longheld beliefs about these orthoses and about the applicability of the results from studies based on earlier KAFO designs.

The multidisciplinary group of experts who convened in Chicago, February 11–12, 2006, prepared individual papers on assigned topics that were presented and discussed in the course of deliberations to collectively answer four key questions:

1. *What do we know about KAFOs for ambulation that has been validated by controlled studies, meta-analyses, or systematic reviews?*
2. *What do case series, retrospective reviews, or similar reports without controls suggest about KAFOs for ambulation?*
3. *Can a generic classification method for KAFOs for ambulation be developed to guide clinical thinking and research about these orthoses?*
4. *What are the major research priorities regarding KAFOs for ambulation?*

The individual papers comprise the body of these Proceedings and are intended to provide additional information and context to assist in the interpretation of the consensus answers to these key questions. The literature ranking and review conducted by Dr. Stefania Fatone provided the foundation for the group's answers to questions one and two. The subsequent papers were instrumental in the group's deliberations on questions two through four.

Question One: What do we know about KAFOs for ambulation that has been validated by controlled studies, meta-analyses, or systematic reviews?

Based on Dr. Fatone's systematic review, as well as the collective expertise of the multidisciplinary participants, the conclusion from SSC7 was that:

At this time, there is no substantive evidence at the highest level of scientific certainty regarding the use of KAFOs and HKAFOs for ambulation.

Only four studies were identified in this category of evidence: two regarding KAFOs and two regarding HKAFOs. One was based solely on investigation of normal subjects, leaving three that dealt with clinical populations. The strength of all four studies was limited by the following factors:

- Small sample sizes restricted statistical power of the results.
- Study design weaknesses raised questions about the validity of the results.
- Controls for patient selection and for measurement bias were not very robust.

To put these results in context, it should be noted that peer-reviewed literature at these levels of evidence regarding clinical practices is lacking in many health care disciplines. For example, a recent review scoring the level of evidence in the orthopaedic literature published from January 1992 to December 2002 on surgery of the shoulder showed that only 3.1% of the studies were randomized controlled trials (RCTs), and there were no meta-analyses or systematic reviews.[2] It has also been noted that RCTs are far easier to implement when studying simple, fairly low-cost pharmacologic treatments in large study populations than when studying complex and more costly procedures such as surgery or the provision of custom-made orthoses for small heterogeneous clinical populations. Ethical dilemmas and the difficulty in recruiting large numbers of appropriate clinical subjects have also been cited as barriers to conducting RCTs in rehabilitation.

Designing appropriate research methodology to investigate the effect of KAFOs and HKAFOs is challenging due to the large variation in population groups using these devices, the significant impact of individual differences within each population group, and the small number of potential subjects that would meet strict inclusion and exclusion criteria required to minimize this heterogeneity. While the participants in SSC7 realized that it is unlikely that we will have large numbers of strong RCTs about rehabilitation with these orthoses in the immediate future, they noted that scientific research regarding [H]KAFOs could be strengthened by:

- *Maximizing sample size* . This might be addressed by conducting multicenter trials, creating centralized databases for collection of data, and/or establishing standardized reporting and outcome measures that would allow subsequent pooling of results between studies within meta-analyses.
- *Improving the design of clinical trials* . For example, randomized crossover interrupted time series trials would remove the dilemma of withholding intervention, as all subjects would eventually be fitted with an orthosis and would allow direct comparison of various orthosis designs. Random order of brace intervention should control for bias of disease/illness progression. A time period of acclimatization to different orthosis configurations should be included in the study design. Outcome should be measured by an observer blinded to the study design and intervention when possible.
- *Reporting baseline subject characteristics* . Consistent reporting of the level of impairment and muscle function when selecting and grouping subjects will result in improved interpretation and generalization of results.
- *Describing orthoses adequately* . Sufficient information on the orthoses being investigated and the biomechanical effects should be given to allow replication. Images are particularly helpful in providing information regarding the exact orthoses being investigated, and multiple views from different planes are often useful in clarifying design specifics.
- *Defining and describing ambulatory goals* . Terms such as "functional ambulation" or other outcomes should be clearly defined, as well as the method used to measure them.
- *Standardizing and validating subjective and objective outcome measures in this population* . For example, the Orthotic and Prosthetic Users Survey (OPUS)[3] could be validated in persons who use KAFOs and then adopted as a standard outcome measure in this population.

Because the evidence from RCTs, meta-analyses, and systematic reviews neither supported nor refuted the use of [H]KAFOs for ambulation, the consensus of SSC7 was that clinicians, researchers, and others should base decisions on the best available evidence in the current literature despite the lack of formal controls in most such studies.

Question Two: What do case series, retrospective reviews, or similar reports without controls suggest about KAFOs for ambulation?

Participants in SSC7 identified a number of key statements, with broad support from the literature, representing current beliefs about the use of [H]KAFOs for ambulation. Because there is, at present, no conclusive evidence in support of or in opposition to these statements, they should be considered clinical hypotheses. Future research should be undertaken to investigate these widely held beliefs.

- Experiences and conclusions drawn from a specific population do not necessarily generalize to other patient groups. For example, conclusions from pediatric experiences with KAFOs do not necessarily apply to adult use of these devices, and vice versa. Conclusions from one clinical cohort, such as people with complete spinal cord injuries (SCI), do not necessarily generalize to other cohorts, such as people who have post-polio paresis or paralysis. In addition, conclusions about KAFOs do not typically apply to the use of HKAFOs, and results with bilateral [H]KAFOs are seldom indicative of results from unilateral applications. These factors underscore the importance of interpreting results with caution.
- The prevalence of KAFO use decreases with age in adults.[4] Children typically discontinue use of ambulatory HKAFOs as they mature.[5,6] Discontinuation of locked knee [H]KAFOs in the diagnostic cohorts that have been studied ranges from 40% to 80%.[7-10] These trends have important implications for longitudinal studies, particularly when reporting on the long-term use of [H]KAFOs.
- Regardless of method of ambulation and type of [H]KAFO utilized, the energy cost of paraplegic walking is high.[11] Adults with paraplegia from SCI who continue to wear HKAFOs mainly use them for therapeutic standing and/or therapeutic ambulation.[12] Time spent donning and doffing orthoses and the energy expenditure required to use them are believed to discourage functional use.
- Restricting knee motion in normal subjects markedly increases the energy cost of ambulation.[13,14] Energy efficiency is an important factor, but not the sole determinant of whether or not an [H]KAFO is accepted by the patient.[15] The measurement of energy consumption becomes particularly important when ambulation is potentially energy cost-prohibitive.
- KAFOs are generally prescribed when the biomechanical goal is to control a weak or unstable knee in one or more planes, and less extensive orthoses will not suffice. KAFOs are commonly used when knee weakness, genu recurvatum, varus/valgus deformities, or painful instability of the knee exist along with distal ankle control problems.
- The recent introduction of stance control knee joint technology has the potential to improve the biomechanics of gait and patient acceptance, compared with locked knee KAFOs.[16]
- Thorough clinical baseline and follow-up assessments are essential in the provision of an [H]KAFO. Defining realistic goals for [H]KAFO intervention from the time of prescription, along with clear understanding of what can and cannot be accomplished by such orthoses, may improve patient acceptance of the device. Multidisciplinary assessment and management by an appropriately trained and experienced team, including gait training when appropriate, is believed to enhance the success of intervention with [H]KAFOs.
- To measure the success of [H]KAFO intervention, the goals and expected outcome should be clearly defined at the time of initial assessment.[17] Clinical and research outcomes need to be standardized and should include patient-specific goals as well as data on functional ambulation and mobility outside of a laboratory or clinic setting.

Question Three: Can a generic classification method for KAFOs for ambulation be developed to guide clinical thinking and research about these orthoses?

Participants in SSC7 were unable to identify or develop any straightforward classification method that would adequately summarize the range of KAFOs or [H]KAFOs to guide clinical thinking and research about these orthoses. A research- oriented classification scheme may differ from one intended to guide prescription decisions or other clinical considerations.

The large interindividual variations among members of the diagnostic cohorts who commonly receive [H]KAFOs, combined with the limited amount of higher level scientific information regarding the plethora of [H]KAFO designs, make it difficult to conceptualize a single classification system. The present practice of using expert opinion and experience to specify the biomechanical control provided at each joint and limb segment, as illustrated by the Technical Analysis Form,[18] currently seems to be an effective method to prescribe and to describe each individual [H]KAFO.

When future research has addressed the priorities noted in the following section of this paper, it may then be more feasible to identify or develop a concise and comprehensive classification system for [H]KAFOs.

Question Four: What are the major research priorities regarding KAFOs for ambulation?

Participants in SSC7 agreed that a long-term goal of future research will be accurate definition and determination of the societal and health care costs and benefits of [H]KAFO intervention. In view of the currently available level of evidence, it will be necessary to answer a number of preliminary questions as the basis for future research into the global cost-benefit ratio of these devices. Given the current lack of studies about KAFOs in particular, it would be prudent to give priority to studies of KAFOs rather than HKAFOs, at least in the near term.

There was consensus among the multidisciplinary experts present at SSC7 that primary research priorities regarding the use of [H]KAFOs for ambulation include:

- *Identification and/or development of standardized subjective and objective outcome measures for [H]KAFOs*
  - Determine the role of quantitative gait analysis and currently established international outcome scores and assessment instruments in assessment of the efficacy of [H]KAFOs.
  - Investigate a standardized method to quantify patient satisfaction with orthoses, taking into account factors such as comfort, cosmesis, and function, (i.e., adapting or validating a standardized questionnaire such as OPUS).
  - Define a graded level of ambulation scale that can be used to identify ambulatory goals and outcomes from [H]KAFO intervention. This must include direction on how best to categorize level of ambulation (i.e., therapeutic, household, functional, and community levels of ambulation).
  - Design and standardize a reliable method for collecting information on daily use of [H]KAFOs to allow testing of [H]KAFOs outside of the laboratory and clinic setting (i.e., quantification of ambulatory activity in the community).
- *Investigation of short- and long-term effects of [H]KAFOs on the neuromusculoskeletal system*
  - Establish whether there are physiological benefits for adults and children with paraplegia from ambulation, compared with standing alone.
  - Determine the influence of [H]KAFOs on joint contracture and other deformities (e.g., spinal deformity and degenerative knee changes).
  - Determine the role of [H]KAFOs in preventing fractures and permitting functional ambulation in persons with osteogenesis imperfecta (OI).
  - Document the effect of orthoses on biomechanical functioning of proximal body structures, as well as the contralateral and ipsilateral limbs.
  - Investigate the functional impact of orthosis alignment and design on body systems.
- *Research regarding application of stance control orthoses (SCOs)*
  - Determine clinical indications/contraindications, such as the minimum hip strength required for successful long-term use of SCOs.
  - Evaluate comparative outcomes for clinical populations that may use SCOs, including incomplete and complete SCI.
  - Investigate the value of providing a stance control KAFO in early stroke rehabilitation as a therapeutic management tool.
- *Defining the mechanical loading conditions on [H]KAFO devices to guide orthotic design and application*
  - What are the loading parameters during level walking? How are they different during functional use on stairs and inclines?
  - What is optimal loading with respect to the user and the orthosis?
  - Investigate how advanced materials and manufacturing techniques can be implemented in [H]KAFOs.
  - What are the indicators of improved design?
- *Determining the short-term and long-term effects of physical therapy intervention, including gait training, on outcome and acceptance of [H] KAFOs*
  - RCTs to answer this specific question are feasible.
  - Limited evidence is currently available regarding this clinical belief.
- *Measuring the impact of pharmacological management on successful use of [H]KAFOs, especially by persons having severe spasticity*

It should be noted that each of these research priorities was considered of primary importance, but there was no consensus that any one item from this list would have higher priority than any other.

SUMMARY

There was widespread agreement among the international multidisciplinary experts present at SSC7 that the limited number of RCTs published regarding the use of [H]KAFOs for ambulation did not provide sufficient evidence to either support or preclude their use in rehabilitation and that decisions regarding these orthoses must therefore be based on the best available evidence, which is from less rigorous studies as well as clinical expertise and experience.

SSC7 attendees could not identify a universal classification scheme that would effectively summarize the full range of [H]KAFOs and therefore endorsed the current practice of individualizing the prescription for each person, based on the patient's medical, physical, psychosocial, and biomechanical evaluations. There was universal agreement on a number of clinical hypotheses that were supported by the available peerreviewed evidence. These rehabilitation beliefs can and should be tested by future research.

Finally, the group specified six primary research priorities with associated implications. Scientific research into these questions would significantly advance our understanding about the optimal application of KAFOs and HKAFOs to assist in ambulation.

The papers that follow this overview provide the context for these decisions and present the perspective of the invited experts, based on their training and professional experiences. The scope and breadth of these contributions underscore the importance of a multidisciplinary approach to optimizing the prescription, design, and scientific evaluation of [H]KAFOs to assist in ambulation.

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