# A Review of the Literature Pertaining to KAFOs and HKAFOs for Ambulation

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## ABSTRACT

*The purpose of this review is to evaluate the scientific literature regarding the clinical use of knee-ankle-foot orthoses (KAFOs) and hip-knee-ankle-foot orthoses (HKAFOs) for ambulation to establish what is known and what requires further research to optimize the application of these orthoses. A search of the literature was carried out using a number of computerized databases. Based on their abstracts, publications were included and ranked when they were written in English and evaluated some aspect of ambulation with [H]KAFOs (KAFO and HKAFO). A total of 240 articles were identified that met the inclusion and exclusion criteria; however, there were only two systematic reviews and two randomized control trials located. A selection of recent cross-sectional studies and non-systematic reviews were also considered. The results of this review indicate that, while a reasonable amount of literature has been written regarding [H]KAFOs, the level of evidence regarding the use of [H]KAFOs for ambulation is generally low. There was some evidence (grade C recommendation) 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. There was also some evidence that regardless of orthotic device used walking speed is slow and energy cost high in people with paraplegia. The main limitation of most studies of [H]KAFOs for ambulation was small sample size and inadequate study design.*

This review evaluates the scientific literature regarding the clinical use of knee-ankle-foot orthoses (KAFOs) and hip-knee-ankle-foot orthoses (HKAFOs) for ambulation to establish what is known and what requires further research to optimize the application of these orthoses. This review includes unilateral and bilateral KAFOs, as well as those that are incorporated into more proximal lower limb orthoses such as HKAFOs and the various reciprocating gait orthoses (RGOs). The focus is on custom-made devices intended for long-term use and not prefabricated items that are worn for less than 1 year. Orthoses whose primary function is not to enhance ambulation, such as fracture braces and post-operative immobilization devices, are excluded from this review.

## BACKGROUND

KAFOs are used when mechanical control of the knee joint is required in weight-bearing due to weak or absent muscle function or joint deformity. As the name implies, KAFOs physically encompass the foot, ankle, and knee, providing direct control of each of those joints. KAFOs can be worn unilaterally or bilaterally as required. Hip stability is not provided by the orthosis but can be augmented when necessary by shifting the trunk center of mass posteriorly so that the ground reaction force is oriented posterior to the hip joints, creating tension in the anterior Y ligament of the hip joint and internally stabilizing the hip joints. This posture allows for stable standing in adults but is not recommended for children as the Y ligament is not yet mature.

There are many variations of KAFO design, usually a result of the varying location and combination of horizontal bands. [1] Lehmann et al. [1] showed that most of the band variations on KAFOs, including the posterior low thigh, posterior calf, and suprapatellar band, are often unnecessary. This led to the development of the Scott-Craig Orthosis [2] that incorporated only a rigid posterior thigh band and a rigid anterior tibial band, thus decreasing the weight of the orthosis, an important design consideration when dealing with extensive lower limb muscle weakness or paralysis. Extending the shoe plate beyond the metatarsal heads and reinforcing the lateral supports from stirrup to sole plate also provided a more stable base of support. Off-set knee joints with bale locks and a solid ankle set in 5 to 10 degrees of dorsiflexion were also used. Nene et al. [3] noted that this was the most commonly prescribed orthosis for paraplegic patients.

For many years, the available technology meant that the mechanical knee joint was either entirely locked or entirely unlocked. Eccentric or off-set knee joints that remain unlocked rely on alignment of the knee, hip, and trunk to orient the ground reaction force anterior to the knee, creating an external extensor moment and therefore maintaining knee stability. Ambulation with a locked knee results in energy expensive compensatory gait maneuvers, because the knee is unable to contribute to the shortening of the leg needed during swing phase for ground clearance by the foot. More recently, stance-control orthotic knee joints have been developed that automatically stabilize the knee during stance phase and release during swing phase. [4–12]

Weak or absent lower limb muscles compromise the ability to stand and walk independently. Many physiological and psychological benefits have been proposed for standing and walking providing incentive in the pursuit of technologies to facilitate both. Standing frames are rigid devices that allow for standing only, while the Parapodium and ORLAU Swivel Walker allow both stable standing and limited walking on level surfaces by combining a standing frame with rotating foot-plates. [3]

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. Hip guidance orthoses (HGOs) and reciprocating gait orthoses (RGOs) are examples of HKAFOs. HGOs, such as the ParaWalker, consist of bilateral KAFOs linked via specially designed low friction hip joints with flexion/extension stops and a release mechanism that allows for sitting. [3] Used in conjunction with crutches, HGOs allow reciprocal ambulation. The Walkabout (PolyMedic Australia, Ashmore, Queensland) orthosis [13] provides reciprocal guidance of the hips during gait via a medial hinge linking bilateral KAFOs; however, it does not need to cross the hip joints and, as defined above, is not considered an HKAFO.

RGOs link the hip joints together so as to provide hip stability as well as reciprocal motion. [14] Examples of RGOs include the original Louisiana State University reciprocating gait orthosis (LSU-RGO), which linked the hips using two Bowden cables; the RGO Generation II, in which ratchet knee joints and hip joints with two locking positions were added; the modified advanced reciprocating gait orthosis (ARGO) that used only a single Bowden cable in addition to gas assisted knee extension; and the isocentric reciprocating gait orthosis (IRGO), which replaced the single ARGO cable with a solid rocker bar.

The advent of functional electrical stimulation (FES), a method of stimulating muscles deprived of nervous control to provide muscular contraction and produce functionally useful movement, led to the development of hybrid orthoses that incorporate mechanical stability from an orthosis with FES to assist propulsion. Although FES can be used by itself, extensive stimulation must be provided to both stabilize the lower limb joints and create a stepping motion. Examining FES technology in any depth is beyond the scope of this review, but, where it is used in conjunction with orthoses, it is acknowledged.

Ambulation with any of these devices by individuals with extensive paresis or paralysis of the lower limbs usually requires additional walking aids such as crutches or walking frames. The types of gait patterns used include swingthrough, swing-to, and reciprocal. Reciprocating gait is thought to avoid the large vertical shifts in body center of mass that occur with swing-through and swing-to gaits. [3] Depending on the degree of lower limb muscle weakness or paralysis, these gaits typically require substantial support and strength from the upper limbs.

# METHODS

## SELECTION OF THE LITERATURE

A search of the literature was carried out using a number of computerized databases (PubMed 1950s-January 2006, Ovid MEDLINE 1966-January 2006, CINAHL 1982-January 2006, RECAL Information Services, Cochrane Database of Systematic Reviews 1991-January 2006) and the search terms "knee-ankle-foot orthosis," "reciprocating gait orthosis," "hip-knee-ankle-foot orthosis," "orthotic devices," and their acronyms and synonyms. Additionally, references in relevant publications and non-indexed journals were examined. Publications without abstracts were not considered. Publications were included when they were written in English and evaluated some aspect of ambulation with [H]KAFOs (KAFO and HKAFO) and hybrid orthoses. Abstracts from conference proceedings were not considered, and those papers focused solely on standing with [H]KAFOs were excluded.

## RANKING OF THE LITERATURE

Based on the information available in the abstracts, study design was ranked using the following categories: (1) systematic review or meta-analyses, (2) randomized control trials, (3) cohort studies, (4) case-controlled studies, (5) cross-sectional studies, (6) case studies, (7) expert opinion, and (8) anecdotal ( Table 1 ). [15] To facilitate further review, category 7 was subdivided. Studies categorized as expert opinion were subdivided into (7a) technical note such as the description of new orthotic devices, modeling/simulation studies of orthotic devices, or mechanical testing of orthotic devices and (7b) non-systematic reviews of the literature.

| Rank | Methodology | Description |
|---|---|---|
| 1 | Systematic reviews and meta-analyses | Systematic review: review of a body of data that uses explicit methods to locate primary studies and explicit criteria to assess their quality.<br>Meta-analysis: A statistical analysis that combines or integrates the results of several independent clinical trials considered by the analyst to be "combinable" usually to the level of re-analyzing the original data, also sometimes called pooling, quantitative synthesis.<br>Both are sometimes called "overviews." |
| 2 | Randomized controlled trials (finer distinctions may be drawn within this group based on statistical parameters such as the confidence intervals) | Individuals are randomly allocated to a control group and a group who receive a specific intervention. Otherwise the two groups are identical for any significant variables. They are followed up for specific endpoints. |
| 3 | Cohort studies | Groups of people are selected on the basis of their exposure to a particular agent and followed up for specific outcomes. |
| 4 | Case-control studies | "Cases" with the condition are matched with "controls" without, and a retrospective analysis is used to look for differences between the two groups. |
| 5 | Cross-sectional surveys | Survey or interview of a sample of the population of interest at one point in time. |
| 6 | Case reports | A report based on a single patient or subject; sometimes collected together into a short series. |
| 7 | Expert opinion | A consensus of experience. |

Table 1. System used to rank the evidence contained in each article [15]

## EVALUATION AND REVIEW OF THE SELECTED LITERATURE

Studies identified as systematic analyses, meta-analyses, or randomized control trials were evaluated to answer the question: "What do we know about [H]KAFOs for ambulation that has been validated by controlled studies, meta-analyses or systematic reviews?" A journalistic review [16] of recent cross-sectional studies and non-systematic reviews was used to attempt to answer the question: "What do reports without controls suggest about [H]KAFOs for ambulation?"

A selection of recent cross-sectional studies (1995 to 2006) was evaluated using a modified version of the criteria de-scribed by Ijzerman et al. [17] All selected studies were summarized regarding five different aspects: study sample (including diagnosis, gender, age, and walking experience before study), types of orthotic devices being compared (and whether they were adequately described), study design (including noting whether the measurement was assessed on the same or separate occasions and the sequence of measurements), types of main outcome measures, and whether statistical analysis was undertaken.

# RESULTS

## DEMOGRAPHICS OF SELECTED LITERATURE

An initial search of all databases using the selected keywords resulted in the identification of 498 citations. When the inclusion and exclusion criteria were applied, the total number was reduced to 240 citations (see Appendix 1 - PDF). Figure 1 depicts the number of articles ranked in each category after inclusion and exclusion criteria were applied. Of these, 47.9% (115 articles) were ranked as cross-sectional, 23.8% (57 articles) as case studies (category 6), and 26.7% (64 articles) as expert opinion (category 7). There were only two articles ranked as systematic reviews [17,18] and two ranked as randomized control trials. [19,20] Clinical trials, as defined by Morris [21] were ranked as cross-sectional studies for want of a better categorical descriptor.

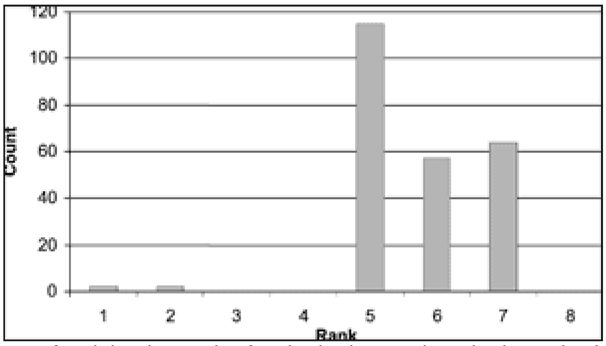


Figure 1. Number of articles by rank after inclusion and exclusion criteria were applied.

Figure 2 depicts the distribution of articles by decade of publication and Figure 3 depicts the journals that published more than one article identified by this review. Most of the articles were published in the 1990s (47.9% or 115 articles) and mostly in *Archives of Physical Medicine and Rehabilitation* (12.5% or 30 articles), *Prosthetics and Orthotics International* (10.8% or 26 articles), *Paraplegia* (10.4% or 25 articles), and *Spinal Cord* (6.25% or 15 articles). The majority of these articles included subjects with spinal cord injury (37.9% or 91 articles) or unspecified paraplegia (22.5% or 54 articles) ( Figure 4 ). Other populations included myelomeningocele (10.8% or 26 articles), Duchenne muscular dystrophy (7.5% or 18 articles), polio or post-polio (2.9% or 7 articles), and hemiplegia/stroke (2.1% or 5 articles).

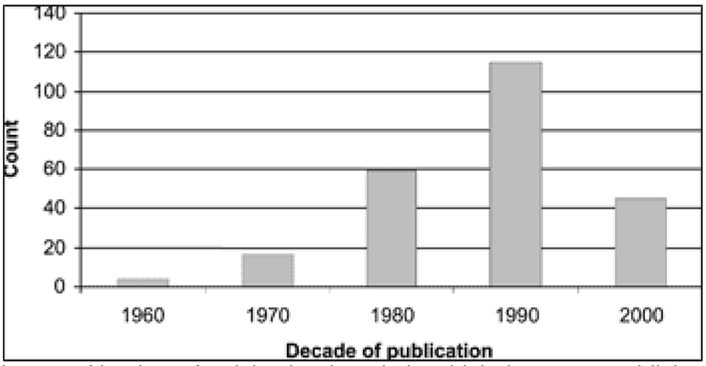


Figure 2. Number of articles by decade in which they were published.

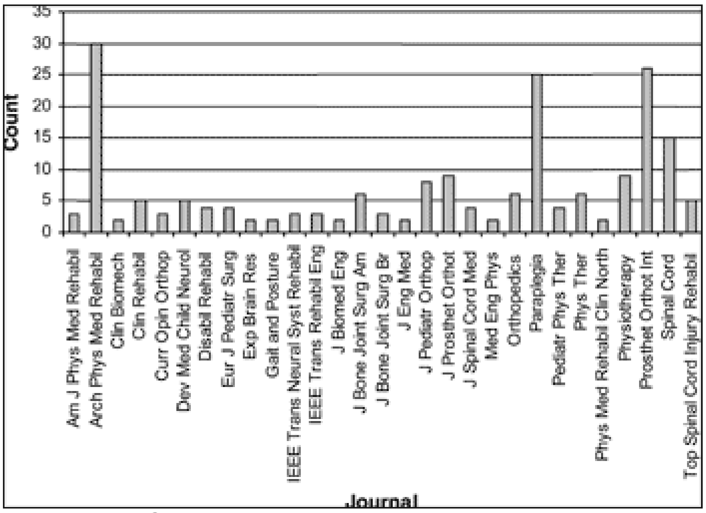


Figure 3. Number of articles by journal. Only those journals with more than one publication were included in this figure.

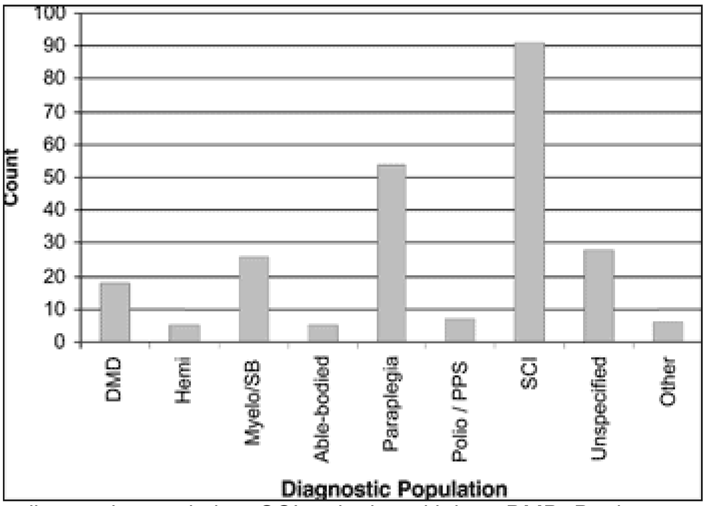


Figure 4. Number of articles by diagnostic population. SCI, spinal cord injury; DMD, Duchenne muscular dystrophy; Myelo/SB, myelomeningocele and spina bifida; PPS, post-polio syndrome; Hemi, hemiplegia after stroke.

Table 2 summarizes the articles by type of device evaluated or reviewed. Thirty-three articles did not specify in their abstract what device was evaluated or reviewed and 48 articles included more than one device. Only two articles included more than two devices. [22,23] The majority of articles included RGOs (32.9%), KAFOs (29.2%), and FES (21.7%). RGOs and FES were most often included in the same article (12.5%).

| % | KAFO | HKAFO | HGO | RGO | FES | Swivel Walker | Para Walker |
|---|---|---|---|---|---|---|---|
| KAFO | 29.17 | | | | | | |
| HKAFO | 0.00 | 5.00 | | | | | |
| HGO | 0.00 | 0.00 | 5.42 | | | | |
| RGO | 1.25 | 2.08 | 2.50 | 32.92 | | | |
| FES | 4.17 | 1.25 | 1.67 | 12.50 | 21.67 | | |
| Swivel Walker | 0.42 | 0.00 | 0.42 | 0.00 | 0.00 | 4.58 | |
| ParaWalker | 0.42 | 0.00 | 0.42 | 1.25 | 1.67 | 0.00 | 7.50 |

Bold numbers indicate percentage of articles that included that particular device and regular type indicates articles that included both devices.

Table 2. Percentage of articles by type of orthosis studied

## REVIEW OF SYSTEMATIC ANALYSES AND RANDOMIZED CONTROL TRIALS

Only two articles were ranked as systematic reviews [17,18] and two were ranked as randomized control trials. [19,20] A metaanalysis was attempted in only one of the two systematic reviews. [18] Table 3 provides a summary of these publications.

| Reference | Rank | Inclusion/ Exclusion Criteria | Outcome Measures | Results and Conclusions |
|---|---|---|---|---|
| Ijzerman et al. (1999)[17] | 1 | Reviewed 12 comparative trials of HKAFOs with and without FES for adults with complete thoracic lesions. | Study sample (size, gender, age, level of lesion, previous walking experience with orthosis), type of walking system (training period), study design (design type, measurement day, and sequence), outcome measure, statistical analysis. | All studies reviewed were internally invalid due to design type (simple within-subject comparison without randomization of order) and lacked statistical power due to small sample sizes and heterogeneity of study population. Recommended an interrupted time series design to obtain greater statistical power. |
| Bakker et al. (2000)[18] | 1 | Reviewed 9 controlled and uncontrolled clinical trials and case studies regarding intervention with KAFOs for children with Duchenne muscular dystrophy (DMD). | Meta-analysis calculated mean percentage of success after 1, 2, and 3 years. | Scientific strength of studies reviewed was poor. Concluded that use of KAFO in the management of DMD can prolong assisted walking and standing but uncertain whether it can prolong functional walking (most studies were vague on what constituted functional walking). Recommended a quasi-experimental study to clarify effectiveness of KAFOs. |
| Robb et al. (1999)[19] | 2 | Randomized control trial of HGO and RGO use in 22 children with paraplegia above L3-L4. | Recorded at 6 weeks (baseline) and 12 months: Number of orthotic alterations, frequency of use and time spent in orthoses, graded ability to don/doff orthosis, recorded maximum walking distance and type of negotiable surfaces, walking aids used, Hoffer mobility grade, complications and difficulties, other abilities in orthosis, parent and child rating, post-discharge walking training. Recorded at 5 and 10 years: whether orthosis was being used. | Entry to study necessitated surgical correction of deformity in 15 patients. Initial improvement in Hoffer grade: 60% of children used wheelchair before enrollment but at 12 months none used wheelchairs for primary mobility; 30% of HGO and 50% of RGO users were able to walk outside over a variety of surfaces. Statistically significant results at 12 months: RGO users more able to walk over gravel surfaces than HGO users; HGO users improved more in ability to rise from sitting to standing than RGO users; and more alterations were required for HGO than RGO. At 5 years: 44% of users gave up orthotic use. At 10 years: 23% of patients still using their orthoses. There was no difference in orthosis use at 5 and 10 years. Sample size inadequate to distinguish effects of the two orthoses. |
| van Hedel et al. (2004)[20] | 2 | Randomized control trial of obstacle avoidance with AFO, KO, and KAFO in 21 young, healthy adults. | Orthosis worn on trailing leg. Recorded EMG, kinematics, swing phase duration, clearance between foot, and obstacle. Three runs each of 50 steps, twice without and then once with orthosis. Evaluated changes within runs (adaptation) and between runs (transfer). | Significantly less adaptation during second run with less muscle activity and more stable movement pattern, indicating more efficient performance of task. Rate of adaptation was similar in the 3 orthotic conditions. Transfer values between runs 2 and 3 were significantly lower with KO and KAFO and there was significantly lower transfer values (worse performance) in KAFO compared with AFO group. Concluded constraint of knee joint affects performance more than ankle alone. |

Table 3. Summary of systematic reviews and randomized control trials

These four studies examined different orthotic devices (two studies each of KAFOs and HKAFOs) in different populations (adults with spinal cord injury, boys with Duchenne muscular dystrophy, children with paraplegia mostly due to myelomeningocele, and able-bodied adults), so the results and conclusions cannot be combined. However, of the three studies conducted in clinical populations, none were able to provide evidence regarding functional ambulation with [H]KAFOs in their respective study populations. The lack of evidence was predominantly due to the low scientific strength of the studies (small sample sizes, inadequate and inappropriate study designs, patient selection, and measurement bias) included in the reviews.

The randomized control trial conducted by Robb et al. [19] compared the use of the HGO and RGO in 22 children with paraplegia above L3–L4. They evaluated function with the orthoses at 6 weeks (baseline) and 12 months and conducted telephone interviews at 5 and 10 years to ascertain whether the orthosis was still being used. The study comprised heterogenous subjects with respect to lesion level and type of lesion, age at first use of orthosis, and degree of scoliosis. Although the authors reported that neurological level and scoliosis did not significantly affect their assessment of time spent standing with the orthosis at baseline and 6 weeks, they did not report whether other measures were affected by these variables, including age at first use of orthosis, all of which could be substantial confounders. Overall, the authors acknowledged that sample size was inadequate to distinguish the effects of the two orthoses tested. Despite a 10-year follow-up, quantitative data were available only over the first 12 months. The evaluations at 5 and 10 years were conducted primarily by telephone interviews and were therefore limited in scope.

The randomized control trial conducted by van Hedel et al. [20] compared performance of an obstacle avoidance task in 21 able-bodied subjects, examining adaptation to the task and transfer of learning of the task between multiple repetitions of the task performed with and without orthoses. This study was well designed to illustrate the effect on the performance of obstacle crossing due to constraint of the ankle and knee of the trailing leg. The authors concluded that in able-bodied subjects, constraint of the knee joint affects performance of an obstacle avoidance task more than constraint of the ankle alone. Because this study was conducted in able-bodied subjects, there can be no firm conclusions drawn with regard to how people with pathology would perform given the same conditions. Further study is required to confirm whether similar results would occur in individuals with pathology requiring orthotic treatment.

## EVALUATION AND REVIEW OF RECENT CROSS-SECTIONAL STUDIES

Evaluation of cross-sectional studies, including clinical trials, was restricted to publications that were electronically available through the author's institution. This meant that only the more recent publications were reviewed (1995 to 2004). Twenty-seven (23.5%) of the 115 articles ranked as cross-sectional studies were reviewed, of which 10 were clinical trials and the rest prospective studies of varied design [12] or retrospective reviews. [5] Clinical trials were defined as experiments where an intervention is compared with another or no treatment but there is no attempt to randomly allocate subjects to different groups. [21] They can be identified as controlled clinical trials if they include a control group and uncontrolled clinical trials if they do not. All except one of the clinical trials were uncontrolled. [24]Table 4 (PDF) summarizes the data from the reviewed cross-sectional studies.

The reviewed cross-sectional studies predominantly involved adults with spinal cord injury (15 articles), children with myelomeningocele (6 articles), or both (1 article), although overall there was an even number of studies on adults and children. Males were subjects more often than females, especially in studies of those with spinal cord injury. One study included able-bodied subjects only. [25] There were five studies with substantial sample sizes ranging from 70 to 144, three of which were retrospective reviews [26–28] and two prospective studies. [29,30] Of the remaining studies, 14 had 10 or fewer subjects and eight had between 14 and 28 subjects.

Although there were four articles that used a randomized crossover design, three of them described the same study, [13,31,32] comparing ambulation of 10 spinal cord–injured adults (lesion level T9 to T12) walking with the Walkabout Orthosis (WO) and the IRGO by measuring energy expenditure, 32 functional tasks, [13] and patient perception. [31] These outcome measures reflect the most common outcome measures encountered in the reviewed cross-sectional studies ( Figure 5 ). Despite a well-designed study that included standardization of previous experience with HKAFOs (none), training received by each subject with each orthosis (2 to 3 times over 6 to 8 weeks), the "washout period" between orthoses (2 months), the walking devices used (elbow crutches only), and personnel involved (a single physical therapist and orthotist provided all training and orthoses), loss of subjects from various aspects of the study reduced their sample size and affected their ability to detect a difference in certain measures (e.g., walking over different surfaces). Dietary-induced thermogenesis and day-to-day variability in energy expenditure measurements were not addressed. Overall, comparing the WO with the IRGO, significantly less assistance was required when using the WO for the sit-to-stand and stand-to-sit task, and more assistance when walking on inclines; less time was required to don and doff the WO; walking was significantly faster with the IRGO over flat surfaces and on ramps; physiological cost index (PCI) and oxygen cost were significantly greater with the WO; and, at commencement of the study, significantly more subjects preferred the WO, but there was a significant change in subject preference over the course of the study so that neither orthosis was preferred at the end of the study. Differences in function and energy expenditure were attributed to the greater mechanical rigidity, support, and hip flexion assist of the IRGO. Due to these mixed results, the authors concluded that neither orthosis provided for functional ambulation after 8 weeks of training, where functional ambulation was considered to include the ability to transfer independently from sit to stand as well as traverse different surfaces and inclines without assistance. These conclusions were supported by the infrequent use of these orthoses by the subjects who reportedly did not find them useful for performing home duties or pursuing vocational goals.

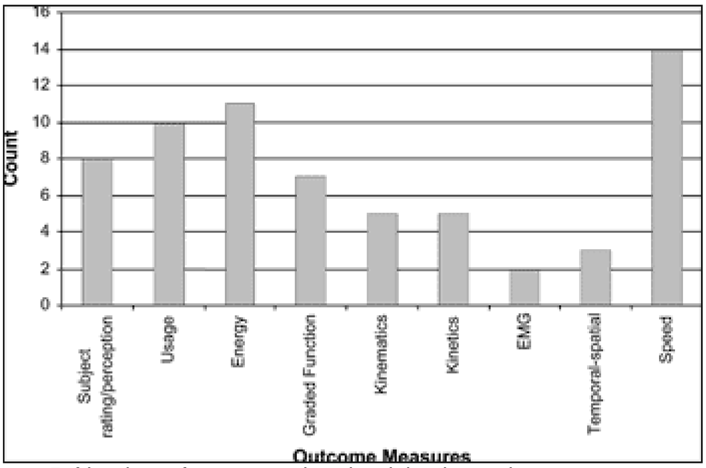

Figure 5. Number of cross-sectional articles by main outcome measure.

The study by Gerber et al. [33] was unusual in that it was the only study located by this review that involved patients with osteogenesis imperfecta (OI). They assessed the risks and benefits of withdrawal of HKAFOs from 10 children with OI who were prescribed orthoses. Unfortunately, despite a randomized crossover design and matching of patients in each group, the sample size (5 in each group, braced and unbraced) was too small to detect a difference between braced and unbraced periods despite twice as many fractures occurring during the unbraced period (17 compared with 8 in the unbraced and braced groups, respectively).

Of the remaining cross-sectional studies evaluated, the clinical trials were focused more on measures of function, in particular metabolic energy expenditure and walking speed. None of the clinical studies using a "within-subjects" design randomized the order of presentation of the conditions tested, meaning that they did not attempt to account for carryover or period effects. The retrospective studies were mostly concerned with patient perception and usage of orthoses and parameters that might predict who will continue using orthoses after prescription and training, for how long and for what activities. Three of the studies were concerned with methodological issues of measurement and relationships between variables. [30,34,35]

The two studies by Ijzerman et al. [34,35] used the gait of spinal cord injured subjects ambulating in the ARGO to illustrate certain methodological issues. The 1998 study [34] explored the relationship between self-selected walking speed and the crutch force time integral so as to show that walking speed can confound and/or bias measurement and interpretation of oxygen cost comparisons between orthotic systems. Their results indicated that, for *within*-subject measurements, if self-selected walking speed is different between orthoses being studied and if there is a strong relationship between walking speed and the outcome measure of interest, e.g., oxygen cost, then any difference between orthoses in the outcome measure can be biased.

The 1999 study [35] then investigated the speed dependence of oxygen cost and crutch force and whether heart rate and crutch force measurements can be used to detect differences in energy expenditure between and within groups. Their results indicated that none of the outcome measures tested (crutch force time integral, crutch peak force, or heart rate) were cross-sectionally valid, i.e., able to discriminate *between* subjects. They concluded that since heart rate cannot be used to compare oxygen uptake during walking *between* subjects, PCI should not be either. Although heart rate, and therefore PCI, was found to be valid for predicting *within*-subject differences in oxygen uptake, the authors were doubtful that paraplegic ambulation constitutes a submaximal work load, which is the assumption upon which the linear relationship between heart rate and oxygen uptake is based. [36] Evaluation of reproducibility indicated that a difference in oxygen uptake and cost of 35% (40% for PCI) should be measured before it can be considered a true difference. Oxygen uptake and cost were therefore considered to be more responsive than PCI, requiring smaller sample size to detect a difference. Thus, the authors concluded that PCI should not be used as the main outcome measure because of the limited number of patients generally available for comparative trials and recommended that walking speed be used as an outcome measure in comparative trials because of better reproducibility.

Only two studies included able-bodied control subjects. [24,30] Like the Ijzerman et al. [34,35] studies, the study by Bernardi et al. [30] was also focused on measurement issues: evaluating the importance and necessity of metabolic measurements to quantify locomotor impairment in a clinical context. As such, they had a very mixed diagnostic population, with only 11 of the 96 subjects being RGO users with a spinal cord injury. Despite inclusion of RGO users, it was not the intention of this study to provide evidence of efficacy of ambulation with the RGO beyond establishing that ambulation in this group is significantly slower and more metabolically expensive than that of normal subjects.

As well as including control subjects, the Bartonek et al. [24] study was one of three clinical studies that compared the use of different orthotic devices in children with myelomeningocele (MMC). [37,38] Using a mixed design, Bartonek et al. [24] quantitatively evaluated the three-dimensional shoulder and pelvic kinematics of eight children with lumbo-sacral MMC, comparing between two subgroups with different muscle strengths (between subjects design), between the subjects with MMC and controls (between subjects design), and between subjects with MMC wearing first a Ferrari KAFO and then a Ferrari Ankle Foot Orthosis (AFO) (within-subjects design without randomization of order). With regard to the orthotic comparison, the authors reported that there was no significant difference in peak-to-peak displacement of the shoulders and pelvis in all planes. However, the authors did not provide $p$ values for any of their results, aside from setting significance at $p < 0.05$, leaving the reader unable to interpret the results for themselves. The authors did not discuss the effect of the small sample size (which was smaller for the Ferrari AFO group due to loss of data from two subjects) on their ability to detect a difference between orthoses. Further confounding the results is the difference in experience of the subjects with each orthosis: They had previously worn Ferrari KAFOs but were provided with only 2 weeks of alternating use with both orthoses prior to testing to accommodate to Ferrari AFOs.

Thomas et al. [38] also used a mixed design in their prospective longitudinal evaluation of oxygen cost and walking speed in 23 children with MMC between T12 and L3-4, comparing independent groups from two centers using RGOs (14 subjects) and HKAFOs (9 subjects). Subjects were assessed once a year for 3 years. Although they attempted to match groups and reported that there were no significant differences between groups in age, intelligence and muscle strength at the start of the study, they did not assess whether the ambulation status between groups differed despite this information being recorded. Ambulation status at the onset of the study appeared to be better overall in the HKAFO group with all nine subjects classed as community ambulators compared with only half of the 14 RGO subjects being community ambulators and half household ambulators. Perhaps, given the ambulation status of the HKAFO group, it was not surprising that walking speed was significantly faster in HKAFO users compared with RGO users in all 3 years. This may also reflect a difference in the training received at each center, although this was not reported by the authors, and raises questions as to the validity of the between-group comparisons. Withingroup comparisons indicated that the only significant change over time was a reduction in oxygen consumption and walking speed between years 2 and 3 for the HKAFO users. Although the effects of dietary induced thermogenesis were accounted for by the fasting protocol, the effects of maturation and day-to-day variability in metabolic energy expenditure were not considered.

Katz et al. [37] compared the energy expenditure of ambulation with a HKAFO and an IRGO in a group of 8 children with thoracic or high lumbar paraparesis (7 due to MMC and 1 with spinal cord injury), using a within-subjects design. Despite a small sample size, they also separated their subjects into two subgroups based on functional level: thoracic and thoracolumbar (group A) and upper lumbar (group B). The authors attempted to standardize the fit and weight of the orthotic devices by using the same KAFOs for both and changing the superstructure to either a HKAFO or IRGO. They also attempted to standardize the degree of training received for each device, but did not allow the same amount of "familiarization" at home (average 7 weeks for RGO and 26 months for HKAFO), although the variability in this period was large for both groups. A potentially significant confounder was gait pattern in the HKAFO group with mixed use of both swing-through and swivel gaits as compared with the RGO group who all walked with a reciprocating gait. Overall, they reported that subjects in group A walked significantly faster and with a significantly lower oxygen cost in the IRGO compared to the HKAFO, but despite faster walking speeds with the IRGO in group B compared with group A, there was not a difference in oxygen cost between orthoses for group B. Unfortunately, it is unclear if group A would have walked faster with the HKAFO had all subjects been using the same gait pattern or if the HKAFOs had been tested after the RGOs. Although the subjects acted as their own controls (within subjects design), there was no attempt to account for carryover effects (measurement sequence was not randomized). The effects of dietary-induced thermogenesis, maturation, and day-to-day variability in metabolic energy expenditure were not considered.

Four other studies included children with MMC, all of them retrospective reviews examining the use of orthoses following provision and training. [26,28,39,40] Two of the studies were conducted at facilities in the United Kingdom [26,40] and one each in Australia [39] and Israel. [28] All the studies reviewed the use of RGOs, with one study also including HGOs [39] and another specifying the ParaWalker RGO. [40] Overall, the reviews spanned between 7 and 16 years and included children with lesions between T6 and L4 who had used orthoses between 2.5 and 9 years at time of follow-up. Sykes et al. [26] also included subjects with spinal cord injury but did not specify the level of lesion of any of their subjects.

Two of the studies [39,40] evaluated self-reported usage parameters: Phillips et al. [39] reported that over an average 2.5- year follow-up period, the children in their review used orthoses on average 3.5 hours per day and were independent when ambulating with either crutches or a Rollator in the community (n = 13) or home (n = 8). They noted that on average there were 1.5 adjustments required and 0.54 breakdowns of the orthoses per year. Roussos et al. [40] reported that over an average 9.7-year follow-up period, the children in their review used orthoses on average 5 days per week at home or at school predominantly with crutches (86%). They reported that all children could walk over a flat level surface and many did well on carpet (96%) and pavement (75%) even when the pavement was sloped (75%); fewer subjects reported being able to walk on grass (18%) or negotiate a single step (25%). Neither of these two studies provided statistical analyses of their results.

Katz-Leurer et al. [28] evaluated the success of an RGO prescription program whereby a trial RGO was provided initially to determine patient suitability. They reported that based on this evaluation program, 70% of children go on to receive their own RGO. Those who received an RGO following the program had significantly better parental cooperation and lower lesion level than those who did not. Of the 49 who received an RGO during the reviewed period, 30 (61%) stopped using their RGO after a mean of 4 years, whereas the remainder still used the RGO at last follow-up (7 years). Access to the treatment center was the primary factor identified by the authors to distinguish between those who continued using the RGOs and those who did not. Despite a mean use of 8 hours per day predominantly at school, the authors did not consider the children to have achieved a satisfactory level of independent daily function due to difficulties with donning, stand-to-sit transfers, ascending and descending stairs, and negotiating sloped surfaces.

Sykes et al. [26] determined that of a total of 85 patients who received RGOs over a 7-year period, 71% had stopped using them. The responses of 35 subjects who subsequently answered a questionnaire were grouped by age (±18 years) and current use of the RGO. Those under age 18 used their orthoses on average 27 months with 13 of 22 (59%) subjects no longer using their orthoses. Those over age 18 used their orthoses on average 24 months, with 7 of 13 (54%) subjects no longer using their orthoses. The authors noted that daily usage was greater by the younger subjects mainly due to use at school, whereas adults tended to use the RGO mostly at home for exercise. Those who stopped using the RGO differed significantly from those who continued using the RGO with regard to degree of independence with the RGO, perception of the RGO as a functional tool, and a feeling of well-being as a result of the RGO.

Two of the cross-sectional studies included in this review investigated the use of orthoses by subjects with Duchenne muscular dystrophy (DMD): one was a within-subjects, repeatedmeasures pilot study [41] and the other a retrospective review. [27] The study by Taktak and Bowker [41] primarily described the design and development of a specific type of orthosis. Although this was the main focus of the article, they attempted a pilot study to evaluate the modular KAFO system that they developed, comparing it with a traditional KAFO by evaluating time to supply, weight, PCI, walking speed, time taken to don and doff, and patient perception. Overall, design and execution of this study was weak. Of the seven subjects with DMD included in the study, only 5 had traditional KAFOs available for comparison and of those, 2 were withdrawn from the study before evaluation of PCI and walking speed, and another subject's data was eliminated from the final results. Standardization of some of the tests was lacking: Supply of the KAFOs was determined by each individual occasion, varying greatly and with little indication given of the manner in which the traditional KAFOs were originally supplied. Donning and doffing were evaluated regardless of whether the patient, parent, or physical therapist was performing the task. Statistical analyses were not attempted.

Vignos et al. [27] retrospectively evaluated the long-term value of operative and orthotic treatment in controlling contractures and prolonging walking in boys with DMD, based on 40 years of experience at one institution. Subjects (n = 144) were divided into three groups, based on whether KAFOs alone, KAFOs and surgery, or neither were provided at the time that the ability to walk independently was lost. Because KAFOs were provided at the time that the ability to walk was lost, it was implied that the subjects who did not receive an intervention, did not continue to walk. The authors reported that for the first 2 years, both interventions controlled heel cord contractures, but that in the longer term, 5 to 7 years, KAFOs in conjunction with surgery controlled heel cord contractures significantly better than KAFOs alone. Regardless, there was no significant difference between intervention groups regarding duration of walking or standing after orthoses were provided.

Both the Taktak and Bowker [41] and Vignos et al. [27] studies were considered in the systematic review by Bakker et al. [18] described earlier, but only one study met their inclusion criteria. [27] The study by Taktak and Bowker [41] was excluded from the systematic review as it primarily described the design and development of a specific type of orthosis. Bakker et al. [18] pointed out that although Vignos et al. [27] provided some evidence that KAFOs prolong assisted walking and standing and indicated that 2 to 3 hours of standing and walking in orthoses was prescribed, they did not indicate whether this goal was attained nor whether this was considered functional ambulation.

Of the remaining cross-sectional studies in this review, all but one included subjects with spinal cord injuries: Two clinical trials compared function with different orthotic systems, [22,23] whereas one study simply described energy expenditure when walking with a particular orthosis. [42] Using a within-groups design, Bonaroti et al. [22] compared bilateral KAFOs to FES with AFOs in 5 children with spinal cord injury between T1 and T8. Although FES with AFOs allowed for faster performance of sit to stand and stand and reach actions, there was no significant difference among systems in any of the mobility activities such as 6-meter walk, stair ascent, or descent. Before the study, subjects were therapeutic users of KAFOs. Once enrolled in the study, subjects were implanted with percutaneous electrodes and provided with 4 weeks of conditioning exercises before training in upright mobility with both systems. It is unclear what effect conditioning exercises had on use of the KAFOs. This is a drawback of not randomizing the subjects into separate groups, nor randomizing the presentation of conditions. Given the small sample size, it is also uncertain that the study had sufficient statistical power to detect a difference in performance between the two systems.

Merati et al. [23] studied the energy cost of ambulation in 14 adults with spinal cord injury between C7 and T10 divided into independent groups, using three different orthoses: HGO (n = 4), RGO (n = 6), and RGO with FES (n = 4). A wheelchair ergometer was used by all subjects for comparison to orthotic ambulation as the authors wanted to attempt to account for the effects of blood redistribution (inadequate venous return during exercise) that occurs in paraplegics during upright motion. Subjects were tested over 2 days: first, at three self-selected walking speeds using the orthosis, and second, at their maximum speed in the orthosis and in the wheelchair ergometer at incremental speeds until muscular exhaustion occurred. Regardless of orthosis used, maximum walking speed was significantly slower in the orthosis than the wheelchair, reaching only about 10% of wheelchair velocities. The relationship between heart rate and oxygen consumption for the HGO and RGO was significantly different to the wheelchair, but not for the RGO with FES and wheelchair, leading the authors to suggest that at nearmaximal work loads measures of oxygen consumption underestimate cardiac strain that can accelerate fatigue, but that the addition of FES can improve venous return and stroke volume. At very low speeds, oxygen cost was significantly higher using the RGO with FES compared with all other conditions, indicating that despite improved cardiovascular efficiency, the overall energy demand of orthotic ambulation was high regardless of the device used, an observation supported by the results of a questionnaire that showed only 3 of 12 (25%) subjects still using orthoses 4 years after the study. Although Merati et al. [23] attempted to standardize training (2 hours/day for 4 weeks), accommodation time (2 months), and room temperature and used blood lactate measures to ensure that subjects were not working anaerobically, there was no analysis or discussion of whether there was a statistically significant difference between groups at the outset, nor was there information as to how they were assigned orthoses, and dietary induced thermogenesis and day-to-day variability in metabolic energy expenditure was not considered.

Massucci et al. [42] evaluated energy expenditure of 6 adults with spinal cord injury between T3 and T12 walking with the ARGO. The authors attempted to ensure all subjects had the same training with the orthosis prior to testing and accounted for the weight of the portable spirometer and the effects of dietary induced thermogenesis in their protocol. However, they did not standardize the use of walking aids and the authors stated that this appeared to contribute to the high variability of results. In the discussion, the authors compared their results with that of able-bodied subjects walking at freely selected speeds but did not provide a reference for this data. Overall, they concluded that walking with the ARGO is slow, energy expensive, and places considerable strain on the heart.

Giannantoni et al. [43] used a within-subjects, repeated-measures design to investigate the effect of ambulating with RGOs on urodynamics in 5 adults with spinal cord injury between T1 and T12 diagnosed with detrusor hyperreflexia and detrusor-sphincter dyssynergia. Training with the orthosis was standardized before assessment of urodynamics, compared at baseline while sitting in a wheelchair to walking with the RGO 7 days later. Although the authors concluded that there were undesirable changes in urodynamic values in all subjects when walking in an RGO, they also comment in the results and the discussion that there were no significant urodynamic differences in patients with lesions below T9 and above T5, which would include three of the subjects in their study. Given these apparently contradictory remarks, the results of this paper were difficult to interpret.

Two studies prospectively evaluated the effect of orthotic gait training in subjects with spinal cord injury. [44,45] Using a pre- and post-test design, Felici et al. [44] evaluated the effect of 2 months treadmill training with an ARGO on energy expenditure and speed of over ground walking with an ARGO in 6 adults with spinal cord injury between T5 and L1. Nakazawa et al.45 prospectively evaluated the effect of gait training using a "long brace reciprocating gait orthosis" on the electromyography (EMG) activity of the soleus and tibialis anterior in 3 adults with spinal cord injury between T8 and T12. Both studies standardized training, but only Felici et al. [44] commented on the similar prior orthotic experience of their subjects. They did not describe how the energy expenditure data was sampled or averaged, nor whether subjects fasted before testing to account for dietary induced thermogenesis, and day-to-day variability was not considered. In the Nakazawa et al. [45] study there was no baseline pre-treatment evaluation and although statistical tests were described in the methods, no results of statistical analyses were presented.

Both studies reported beneficial effects of treadmill training: Despite the small sample size and lack of statistical analysis, Nakazawa et al. [45] observed that their results demonstrated that orthotic gait training for 12 weeks induced modulation of the EMG activity in the soleus muscle that was not due solely to the spinal stretch reflex. Felici et al. [44] noted that treadmill walking was significantly less energy expensive than walking over ground and reported that after treadmill training (for 2 months), efficiency of walking with the ARGO significantly improved both on the treadmill and off and increased significantly from baseline for over ground walking.

The remaining cross-sectional studies involving adults with spinal cord injury evaluated ongoing use of orthoses. [29,46] All were prospective studies with varying sample sizes, orthoses, and degree of follow-up. Franceschini et al. [29] evaluated use, function, walking speed, and speed of donning and doffing in 74 patients with lesions between T1 to T12 at discharge and after 6 months, using an RGO, ARGO, or HGO. Training before discharge was standardized. They reported that those who did not abandon the orthosis at 6 months (67.6%) had the ability to climb stairs, rapidly don and doff the orthosis, and scored highly on the Garrett score (grading walking ability) at discharge; furthermore, in subjects who did not abandon the orthosis, speed significantly increased at follow-up. However, the authors noted that the orthosis was still not used for functional walking.

Middleton et al. [46] used a questionnaire to evaluate the use of the Walkabout orthosis in 25 adults with lesions between C5 and T12, 7 to 12 months and 24 months after completion of gait training. They found no statistically significant differences between patients with complete and incomplete lesions with regard to frequency, duration, and intensity of orthotic usage. However, there was a significant difference in preference for walking aids: patients with incomplete lesions ambulated outdoors using crutches or a walking frame, whereas those with complete lesions preferred to remain at home in the parallel bars. Five patients discontinued using the Walkabout between 7 and 20 months. The authors also reported that the orthoses were used mainly for therapeutic rather than functional purposes.

Scivoletto et al. [47] evaluated use of the RGO at the end of training and at 1-year follow-up in 24 adults with lesions between T1 and T12. They reported a 46% abandonment rate at 1-year follow-up, but found no statistically significant difference between users and non-users regarding sex, time from injury, level of injury, degree of training, marital status, or employment. They did note, however, that users tended to be less heavy than non-users and used the device to work. The users also had a significantly higher functional capacity at the end of training than the non-users. Evaluation of anxiety and depression was non-significant between users and non-users; however, non-users had a higher frequency of E-score (extroversion) on the personality questionnaire.

Using a standardized questionnaire, Jaspers et al. [48] interviewed 14 adults who had used an ARGO for at least 1 year. The authors reported that at the time of interview, 12 (85%) used the ARGO on a regular basis and only two subjects commented that they were disappointed in their expectations. The ARGO was used on average three times a week for 1 to 2 hours but mainly indoors for therapeutic purposes. Half of the regular users said they could use the orthosis independently.

The final study included in the cross-sectional category evaluated the effects of RGO joint motion constraints on the PCI, gait, and EMG of three able-bodied adults trained to use a four-point gait.25 An assessment RGO with 24 possible combinations of hip, knee, and ankle configurations was used, although only 12 configurations were evaluated. The authors attempted to relate their findings to what might be accomplished with hybrid FES orthoses, although they acknowledged that the results from able-bodied subjects walking in an orthosis are not directly applicable to paraplegics walking in an orthosis. The authors concluded that efficiency of walking (measured with PCI) improved when the flexionextension coupling ratio was 1:1, the knee flexed, and the ankle plantarflexed and that a similar FES strategy might be used to improve paraplegic ambulation with orthoses. However, further confirmation of these results in a paraplegic population is required.

## OVERVIEW OF NON-SYSTEMATIC REVIEWS

From among the articles ranked as non-systematic reviews (7b), five (28%) were available for further review. The review by Merritt and Yoshida[49] included 55 references spanning 1955 to 1999; the review by Nene et al. [3] included 106 references spanning 1931 to 1993; the review by Waters and Mulroy[50] covered many different pathologic gaits, including that of spinal cord–injured and myelomeningocele subjects, for which 29 references were cited spanning 1963 to 1997; the review by Jaeger [51] covered issues regarding the application of FES, with only a small section on the use of FES in conjunction with orthoses which cited 16 references spanning 1974 to 1991; the final review by Dall and Granat [14] included 33 references spanning 1971 to 1999.

Merritt and Yoshida[49] indicated that most of the subjects in the studies they reviewed had complete paraplegia at the thoracic level, were older than 20 years, and had been paraplegic for a minimum of 2 years, an observation supported by this review, although data regarding time since lesion was incurred and whether the lesion was complete or incomplete were provided less often than age and lesion level, despite being equally important descriptors of the sample population. Nene et al. [3] observed that studies of paraplegic ambulation were somewhat limited, and most were for patients with myelomeningocele. Our review would suggest that while this may have been the case initially, since HGOs and RGOs were originally designed for children, more recent literature has focused increasingly on adult paraplegic ambulation.

Both Nene et al. [3] and Merritt and Yoshida [49] provided an overview of the indications and applications of [H]KAFOs and hybrid orthoses for paraplegic ambulation. Merritt and Yoshida [49] described each orthosis and used the available literature to attempt to answer three questions: Which patients can achieve the best energy expenditure using FES coupled with KAFOs and can a combination of FES and KAFO conserve energy compared to FES alone? Should paraplegics ambulate, and how much effort should we expend to meet the goal of walking again? Are there physical and medical reasons for ambulation in paraplegia?

Nene et al. [3] described FES as the electrical stimulation of muscles deprived of nervous control so as to provide muscular contraction and produce functionally useful movement. In combination with orthoses, FES was intended to augment propulsion reducing the stress placed on upper limbs, while the orthosis would provide support of joints and improve safety compared with ambulation with FES alone. After reviewing the different systems, Nene et al. [3] concluded that problems encountered, both technological (selectivity and effective control of stimulation) and physiological (muscle fatigue), remain unresolved. They concluded that FES continues to be largely experimental, a conclusion that Jaeger [51] in his review of FES agreed with, noting that the problem of restoration of mobility in spinal cord injury is compounded by individual variation in residual muscle function necessitating different protocols for restoring mobility. Waters and Mulroy [50] and Merritt and Yoshida [49] stated that the use of FES in conjunction with orthoses appears to have only minimal impact on walking speed and oxygen consumption. Jaeger [51] cited some case studies that suggested that the addition of FES to orthoses increased walking speed and reduced crutch forces, but Merrit and Yoshida [49] believed that the few studies available were inconclusive regarding improved energy conservation. Ijzerman et al. [17] drew similar conclusions after their systematic review, indicating that the 12 studies comparing orthoses with and without FES that they reviewed were internally invalid and lacked statistical power.

The question of whether paraplegic ambulation should be pursued was difficult to answer. Nene et al. [3] commented that the paraplegic person experiences immense social pressure to attain an upright posture and walk again. From a practical and financial standpoint, Merritt and Yoshida[49] observed that time spent fitting and training patients and modifying, customizing, and repairing devices can be considerable, especially when wheelchair ambulation is energy efficient, readily available, proven, and relatively inexpensive. Nene et al. [3] summarized the factors to be considered for walking as motivation to walk, upper body strength, nature of lesion (partial/ complete), level of lesion, advancing age, physical reserve, weight, degree of spasticity, decubitus ulcers, inherent agility and coordination, and intelligence. Nene et al. [3] noted that two groups of patients were most frequently considered suitable candidates for locomotion with bilateral KAFOs, namely patients with injury at the thoraco-lumbar level and patients with an incomplete injury, but that with the introduction of HKAFOs paraplegic people with thoracic level lesions could also ambulate. Merritt and Yoshida [49] thought that the time spent donning and doffing orthoses and the energy expenditure required to use them could change the mind of even a highly motivated individual. These comments were echoed in the retrospective reviews examining usage and patient perception described earlier. Nene et al. [3] thought that energy cost of ambulation, independence, cosmesis, system reliability, and finances were all pertinent in considering the functionality of orthoses.

Although there have been many physiological benefits proposed for paraplegic standing and ambulation, studies that provide evidence that these benefits exist are limited, especially regarding whether ambulation provides any greater benefit than standing alone. Osteoporosis prevention, contracture prevention, spasticity reduction, decubitus ulcer prevention, improved venous and lymphatic drainage, cardiovascular fitness, reduced muscular atrophy (with FES), and overcoming architectural barriers have all been proposed as possible benefits of paraplegic ambulation. [3,49] Merritt and Yoshida [49] suggested that while FES may positively affect certain physiological properties such as increasing muscle cross-sectional area and blood flow, there were few studies of the impact of orthoses alone. Nene et al. [3] recommended that long-term studies are needed to determine the physiological benefits of orthotic ambulation for paraplegics.

Both Nene et al. [3] and Merritt and Ysohida[49] stated that functional ambulation is defined as the ability to walk 75 m in 1 minute and cover a distance of one city block or 250 m without undue stress, although they acknowledged that few paraplegics could accomplish these tasks. Merritt and Yoshida [49] suggested that a better definition of functional ambulation would be the use of orthoses for most daily activities with wheelchair use for long distance travel only (>100 m). However, the studies reviewed earlier would suggest that even with this definition, paraplegics still would not achieve functional ambulation as they do not use their orthoses for daily activities. Nene et al. [3] and Waters and Mulroy [50] also concluded that with time, fewer paraplegics use their orthoses for functional activities and that ambulation remains mainly therapeutic.

Nene et al. [3] reviewed studies of paraplegic ambulation and found that there was some suggestion that walking speed decreased and energy cost increased with increasing level of lesion. This was supported by Waters and Mulroy, [50] who reported that lower extremity muscle strength is the primary determinant of walking ability in spinal cord injury, because with increasing loss of lower limb muscles, paraplegics rely on upper limb weight-bearing, which has a high energy demand. They suggested that adults with spinal cord injury are the opposite of children with myelomeningocele, who have a higher ratio of upper arm strength to gross body weight due to atrophy of the lower limbs. Both Nene et al. [3] and Waters and Mulroy [50] reported that there was also some suggestion that regular use of orthoses lowers energy cost and increases walking speed, probably by providing cardiovascular conditioning. When comparing ambulation in different orthoses, the results are mixed. Some authors found differences and others did not, and very often differences were not statistically significant. However, regardless of method of ambulation and type of orthosis, there is general acknowledgment that the energy cost of paraplegic walking is intrinsically high. [3,50] Furthermore, Waters and Mulroy [50] indicated that individuals with spinal cord injury have a reduced VO2 max because of decreased active muscle mass and activity. Ambulation therefore occurs at near maximal capacity, near the threshold of sustainable exercise intensity.

Although most of the non-systematic reviews were concerned with the physiological impact of paraplegic ambulation with orthoses, Dall and Granat [14] were concerned with the mechanical function of orthoses. They reviewed the qualitative and quantitative evidence for mechanical function of the reciprocal link in HKAFOs used for paraplegic ambulation. The authors stated that qualitative descriptions of linkage function were often sketchy and at times contradictory. They indicated that most articles agreed that the basic function of the linkage was to constrain the hips to reciprocal flexion and extension, with fewer articles mentioning that the link also acts to stabilize the hip joints during weight-bearing. Timing of the action of the linkage was said to be during double support in some articles and during swing in others. Dall and Granat [14] indicated that only four articles considered whether the cables in two cable systems had different functions and that while there was consensus that the posterior cable prevents bilateral hip flexion and the anterior cable prevents bilateral hip extension during double support, there was no consensus on the function of the cables during swing phase.

Although Dall and Granat [14] state that there were seven articles that provided quantitative data on the action of the reciprocal link during walking, only six were actually cited: three that directly measured cable forces during walking, two that inferred linkage function from comparisons of energy expenditure when walking with and without the linkage engaged, and one that modeled the swing phase of gait with an ARGO. They concluded that the quantitative studies provided evidence that the reciprocal link does prevent bilateral hip flexion in stance but that it did not appear to be used to drive hip flexion during swing and that some evidence suggested that the reciprocal link may actually restrict efficiency during the swing phase.

## STANCE CONTROL KAFOs

Stance control KAFOs are a relatively new technological development intended to improve ambulation and have been the subject of limited research to date. Of the eight articles identified in this review regarding stance control KAFOs, six were case studies [4–6,9–11] and two were cross-sectional studies for which the articles were not available at the time of review. [12,52] These orthoses are indicated for isolated quadriceps paralysis and/or unilateral paralysis as most often occurs in poliomyelitis and post-polio syndrome. The aim of these orthoses is to improve ambulation by automatically stabilizing the knee in stance and automatically releasing in swing, thus attempting to address the drawbacks encountered by locked knee KAFOs. Knee flexion in swing serves to functionally shorten the leg for ground clearance; it also serves to convert the swing limb to a compound pendulum, enabling the leg to swing forward with less effort. [53] The leg's moment of inertia is reduced as the knee is flexed and the foot and shank masses are brought closer to the hip joint's axis of rotation. This reduces the natural period of the leg, enabling the leg to swing forward in shorter time than if the leg were fully extended. Additionally, the smaller moment of inertia reduces the effort, and thus the energy, required to swing the leg forward. Walking with a locked knee leads to energyexpensive gait compensations to achieve ground clearance of the swing leg, further increasing the effort required to advance the leg.

## KAFOs FOR OTHER DIAGNOSTIC POPULATIONS

This review identified only a small number of articles regarding KAFOs for other diagnostic populations. There were seven articles involving patients with polio or post-polio syndrome of which only three were ranked as cross-sectional studies [54–56] and the remaining were case studies. [6,11,57,58] The three studies were of different designs: Agboatwalla et al.[56] prospectively followed the rehabilitation treatment, including orthoses, of 38 Pakistani children with acute polio; Luna-Reyes et al. [55] used a mixed between- and within-subjects design to evaluate the energy expenditure of Filipino children with (n = 16) and without (n = 41) poliomyelitis; Waring et al. [54] conducted a retrospective study of lower-extremity orthotic management for ambulation in 104 subjects with poliomyelitis. Five articles discussed hemiplegic patients. Only one was ranked as a cross-sectional study, [59] and the remainder were case studies [60–62] and expert opinion. [63] The study by Ofir and Sell [59] was a retrospective review of 843 patients with hemiplegia spanning 9 years and evaluating functional ambulatory status on hospital admission and discharge, type of orthotic devices used, time lapsed from onset to admission for rehabilitation, and length of stay at the rehabilitation facility.

# DISCUSSION

This review was undertaken over a single month from January to February 2006. Therefore methodological decisions were made based on the time available to accomplish the task. The author based the ranking and demographic analysis on information available in abstract form, limited the literature to be reviewed to that which was electronically available through the author's institution, and chose to build on existing work wherever possible. Such practical considerations therefore limit the scope and nature of this review and may have reduced the strength and objectivity of the findings. Furthermore, because only one person ranked all the articles, reliability and repeatability of the rankings were not ensured. It should also be noted that, unlike the other databases used for this literature review, the abstracts provided by RECAL are generally descriptions written by the operators of the database and tend to provide less information than abstracts contained in the other databases accessed for this review. This may also have affected the accuracy of the ranking process. The discussion here pertains predominantly to paraplegic ambulation with orthoses, because very few articles were identified regarding stance control KAFOs and use of KAFOs by patients with poliomyelitis or hemiplegia.

The results of this review indicate that, while a reasonable amount of literature has been written about [H]KAFOs, more so about HKAFOs than KAFOs, the level of evidence regarding the use of [H]KAFOs for ambulation is generally low. There were two systematic reviews [17,18] and two randomized control trials identified. [19,20] Unfortunately, none of these studies were able to provide evidence regarding functional ambulation with [H]KAFOs in the respective study populations. There were two uncontrolled clinical trials (one of which was described in three articles) that used a randomized crossover design. [13,31–33] However, both had sample sizes that were ultimately too small to detect an effect. The remaining cross-sectional studies often had confounding variables due to inadequate study design. There was some evidence from longitudinal studies and retrospective reviews that use of HKAFOs diminishes with time in both adults and children with paraplegia (constitutes a grade C recommendation) ( Table 5 ). Discontinuation of HKAFO use ranged from 29% to 39% for children with myelomeningocele followed for over 7 years[26,28] and ranged from 54% to 85% in adults with spinal cord injury followed for up to 24 months.[29,46–48] When orthoses are used, they are used mostly for therapeutic purposes (grade C recommendation).[29,46,48] There is some evidence that regardless of orthotic device used, walking speed is slow and energy cost high in people with paraplegia (grade C recommendation). Results from multiple studies [32,34,35,49,65–71] suggest that oxygen cost is approximately five times higher and walking speed approximately five times less in adults with spinal cord injury compared with ablebodied adults. For children with myelomeningocele, oxygen cost is approximately three times higher and walking speed approximately five times slower than in able-bodied children. [37,38,72,73] There was some evidence from one cross-sectional study that treadmill training with an ARGO may improve function during over-ground walking with an ARGO. [44]

| Grade of recommendation | Description |
|---|---|
| A | Directly based on Category 1 or 2 evidence (systematic reviews and/or randomized controlled trials with definitive results that do not overlap the threshold clinically significant effect), at least one meta analysis. |
| B | Directly based on Category 2, 3, or 4 evidence (randomized controlled trials with non-definitive results, i.e., a point estimated that suggests a clinically effective effect with confidence intervals that overlap the threshold clinically significant effect, cohort studies or case control studies) or extrapolated from Category 1, 2, 3, or 4. |
| C | Directly based on Category 5 or 6 evidence (cross-sectional survey or case studies) or extrapolated from Category 1, 2, 3, or 4. |

Table 5. Grades of recommendation described by Shekelle et al. [64]

A number of pertinent studies published predominantly in the 1980s concerning ambulation with HGOs and RGOs were not evaluated in this review but should be considered. [74–84] HGOs and RGOs were originally designed for ambulation by children with paraplegia, but the RGO in particular has been evaluated more often in adults with paraplegia. It has been suggested that the HGO is more mechanically efficient than the RGO because of greater rigidity, especially during single limb support. [74] Jefferson and Whittle [75] demonstrated that the lower limbs remain parallel in the coronal plane when ambulating in an HGO, providing better ground clearance of the limb in swing. In a cross-over study of ambulation with the HGO and LSU RGO in 22 children with paraplegia, Jefferson and Whittle [75] commented that inter-subject differences were much greater than inter-orthosis differences despite differences in pattern of movement with the two orthoses. Although reciprocal gait can be achieved with both the HGO and RGO and probably is more efficient in the HGO, patient preference has reportedly favored the RGO due to better cosmesis. [74]

It was found in this review that the main limitation of most studies of [H]KAFOs for ambulation was small sample size and flaws in study design. Studies with the largest sample size are generally retrospective reviews. Unfortunately, retrospective reviews tend to be uncontrolled and facility specific because the outcomes are determined by the overall treatment and context within which treatment occurs, including the facility setting and the time spanned by the review. Differences in the period of follow-up between studies make it difficult to generalize findings. With regard to clinical trials, even if a study with small sample size has sufficient statistical power at the outset, it is extremely vulnerable to subject dropout or withdrawal, which occurred in a number of the cross-sectional studies included in this review. [13,24,41]

Small sample size also limits the ability to divide subjects into subgroups or analyze subsets of data where it may be appropriate to do so. This is especially relevant given the variation in residual muscle function that can be present in the diagnostic populations prescribed these orthotic devices.

Designing adequate research methodology to investigate the effect of [H]KAFOs is challenging due to the large variance in populations who use these devices, the significant impact of heterogeneity within each population, and the resultant small number of potential subjects available to participate in research that would meet strict inclusion and exclusion criteria required to minimize this heterogeneity. While it is highly unlikely that we will have large numbers of strong randomized controlled trials investigating rehabilitation with [H]KAFOs in the foreseeable future, scientific research regarding [H]KAFOs could be strengthened by maximizing sample size. Given the difficulties of conducting randomized controlled trials in rehabilitation, greater numbers of randomized crossover interrupted time series trials as recommended by Ijzerman et al. [17] would remove the dilemma of withholding intervention, as all subjects would eventually receive an orthosis, and allow direct comparison of various orthotic designs. Sample size might also be addressed by conducting multi-center trials, creating centralized databases for collection of data, and/or establishing standardized reporting and outcome measures that would allow for subsequent pooling of results among studies within metaanalyses.

The application of orthoses is deficit specific, so what might be pertinent to one population ambulating with [H]KAFOs might not be to another. Hence, the population being evaluated must be adequately described for the data to be interpreted and the information generalized or compared among studies. Most authors report number of subjects, age, sex, diagnosis, and level of lesion. Less frequently reported is time since injury, whether the lesion is complete and incomplete, and prior experience with orthoses, all factors that affect study results. Regarding study protocols, most authors describe training provided and type of orthotic device used, although many articles do not provide adequate descriptions of the orthotic device used. Standardization of aspects such as residual muscle function, prior experience with orthoses, training provided, personnel involved, and type of gait used are all important to the interpretation of results, because all of these variables are potential confounders.

In comparative studies without randomization of orthotic condition, carryover and period effects cannot be accounted for and can be particularly troubling given that the amount of ambulation practice and the conditioning effects of ambulation may influence the results. In the absence of randomized control trials, which can be difficult to execute in rehabilitation research, randomization of orthotic conditions is required to improve the level of evidence available. Function of any orthosis is also predicated on the intimate and comfortable fit of the device. Only one study attempted to account for this variable in its study design by standardizing the orthosis used between conditions. [37] This aspect of orthotic research should be kept in mind when conducting comparative studies of different orthoses.

[H]KAFOs for paraplegic ambulation have received a lot of attention regarding development of technology. However, evaluation of function with this technology could be improved. Although the goal may be to restore functional ambulation, few paraplegics are able to meet current definitions of functional ambulation and most studies are vague as to their definition and measurement of functional ambulation. 18 If functional ambulation is to be the primary goal of providing [H]KAFOs, then it should be clearly defined and described. This may help to improve patient satisfaction and use by redefining expectations and help develop a realistic role for [H]KAFOs within rehabilitation.

Although the ability to ambulate functionally using these devices is still a topic of debate, it is generally agreed that, in the paraplegic population, walking is slow and laborious. [3,23,30,32,42,49,50] This has led to much interest in and investigation of the energy cost of paraplegic ambulation. However, we appear to lack understanding as to the impact that spinal cord injury has on metabolic function, and it is possible that our ability to appropriately measure and interpret the impact of function and orthotic devices on energy expenditure is hampered by this lack of understanding about the underlying physiology. Recent studies, in particular by Ijzerman et al., [34,35] have raised broader concerns regarding our interpretation of energy expenditure results. Perhaps our ability to evaluate the efficacy of orthotic ambulation will improve once we better understand the impact spinal cord injury has on metabolic function.

Regarding energy expenditure, there are a number of other methodological issues that should be considered. Dietary-induced thermogenesis is the effect of food on metabolic energy expenditure due to the energy required by the process of digestion and absorption of nutrients. The effects of this reach a maximum 1 hour after a meal, [85] therefore testing a minimum of 2 hours after eating has been proposed. Some of the studies reviewed that included measurement of metabolic energy expenditure mentioned fasting before testing as part of their protocol. [38,42] However, day-to-day variability and the effect of maturation were not considered by any of the studies reviewed, with the exception of Ijzerman et al. [35] When measuring metabolic energy expenditure within subjects on different occasions, variability is present due to individual biological fluctuations that occur from day to day. Ijzerman et al. [35] indicated that there was a difference of 35% in oxygen uptake and cost (40% for PCI) on repeated measurements in spinal cord–injured adults ambulating with the ARGO. Using the Cosmed K4 (Cosmed, Rome, Italy) and a 10 minute, over-ground walking test, within-subject variability for oxygen cost was 13% in able-bodied children. [86] This means that differences in excess of that which occurs due to day-to-day variability must be measured for changes in metabolic energy expenditure to be attributed to the treatment or intervention being investigated. This issue did not appear to be accounted for in the repeated measures or longitudinal studies reviewed here.

The issue of maturation is pertinent only to longitudinal measurements of metabolic energy expenditure in children. It is well accepted that body size and composition affect the amount of oxygen consumed during physical activity. Higher oxygen consumption by children compared with adults has been attributed to the higher proportion of lean muscle mass in children. Oxygen consumption then decreases with age as the proportion of bone and fat increase. [87] Although the effects of body size may be accounted for somewhat by dividing the volume of oxygen by body weight, this approach does not account for variations in body composition (ratio of lean muscle and skeletal tissue mass to fat mass) resulting from maturation. Maturation refers to the rate with which a mature biological state is attained.[88] During maturation, males generally put on relatively more muscle tissue and females gain relatively more fat tissue, [89] resulting in differences in metabolic energy expenditure between the sexes and over time in the same individual. Therefore, if time lapses between measurements, the contribution of changes in body size and composition must be controlled or accounted for to attribute changes in energy expenditure to an intervention. The most common measure of body composition is estimating the relative amount of body fat (% fat) using skin fold thickness or body mass index. Otherwise, an indirect method based on the relationship between energy expenditure and age might be used to account for the effects of maturation, as it is generally accepted that oxygen cost decreases with increasing age. The issue of maturation was not considered in the longitudinal studies of pediatric energy expenditure reviewed here.

Appropriateness of PCI as a measure of energy expenditure in the paraplegic populations remains debatable. Ijzerman et al. [35] expressed doubt that paraplegic ambulation constitutes a sub-maximal work load, which is the assumption on which the linear relationship between heart rate and oxygen uptake is based. [36] However, it should be noted that Bar-On and Nene90 studied the relationship between oxygen uptake and heart rate in 44 subjects with paraplegia (lesion level T3 to T10) during an incremental arm cranking exercise and reported an almost linear relationship.

Another methodological issue to be considered is the placement of markers for motion analysis studies. In motion analysis, the assumption is that external markers located over palpable, skeletal landmarks may be used to reconstruct the position and orientation of reference frames embedded within the bones. Therefore, where markers are placed determines what is being measured. Because the orthosis often obscures the anatomical landmarks required by the biomechanical models used in motion analysis, markers are often placed on the orthosis instead. When markers are placed entirely on the anatomical limb, then motion of the anatomical limb is measured. When markers are placed entirely on the orthosis, then motion of the orthosis is measured. When markers are placed on both the anatomical limb and orthosis, it is difficult to establish where motion is coming from. As there is no standard regarding marker placement for the evaluation of motion with an orthosis, marker placement must be carefully considered and clearly described by the investigators for the results to be interpreted appropriately.

One final point regarding the proposed physiological benefits of ambulation: This review excluded studies that pertained only to walking, so a thorough review of the literature pertaining to the physiological benefits of being upright was not explored fully. It is likely that the physiological benefits of standing and ambulation will differ for children and adults with paraplegia because children are still developing and maturing and adults are not. From the studies reviewed here, it would appear that there has been some attempt made to evaluate the physiologic benefits of FES, [23,49] and there was one cross-sectional study regarding the effect of RGO ambulation on urodynamics. [43] Other studies reported in the literature but not evaluated in this review indicate that there are benefits of walking, especially for children.[91] For example, Mazur et al. [91] compared the cases of 36 patients with highlevel spina bifida who had participated in a walking program with those of 36 matched patients for whom a wheelchair had been prescribed early in life. They reported that the patients who walked early had fewer fractures and pressure sores, were more independent, and were better able to transfer than were the patients who had used a wheelchair from early in life. However, during childhood and early adolescence, the patients who had always used a wheelchair had spent fewer days in the hospital than did those who had participated in the walking program. There were no major differences reported between the two groups with regard to skills of daily living, function of the hands, and frequency and severity of obesity. Overall, the non-systematic reviews evaluated suggest that despite a perception that orthoses can be used for therapeutic purposes, further research is required to evaluate many of the proposed physiological benefits of paraplegic ambulation. [3,49]

## CONCLUSION

The results of this review indicate that while a reasonable amount of literature has been written about [H]KAFOs, more so about HKAFOs than KAFOs, the level of evidence regarding the use of [H]KAFOs for ambulation is generally low. 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. There is also some evidence that regardless of orthotic device used, walking speed is slow and energy cost high in people with paraplegia. The main limitation of most studies of the use of [H]KAFOs for ambulation was small sample size and inadequate study design. Designing adequate research methodology to investigate the effect [H]KAFOs is challenging due to the large variance in populations that use these devices, the significant impact of heterogeneity within each population, and the resultant small number of potential subjects available to participate in research that would meet strict inclusion and exclusion criteria required to minimize this heterogeneity. Given the difficulties of conducting randomized controlled trials in rehabilitation, greater numbers of randomized crossover interrupted time series trials is recommended to improve the level of evidence available regarding [H]KAFOs for ambulation.

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