E-MAG Active,

a newer Stance Control Knee Ankle Foot Orthosis (SCKAFO)

in the context of workers' compensation

By

WorkSafeBC Evidence-Based Practice Group

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December 2010

Clinical Services – Worker and Employer Services

About this report

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The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

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Cite as

WorkSafeBC Evidence-Based Practice Group, Edeer D, Martin CW. E-MAG Active, a newer Stance Control Knee Ankle Foot Orthosis (SCKAFO) in the context of workers' compensation. Richmond, BC: WorksafeBC Evidence-Based Practice Group; December 2010. Available at: http:/worksafebc.com/health_care_providers/Assets/PDF/E-MAG-SCKAFO.pdf

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List of acronyms

CDC	US Centers for Disease Control and Prevention
CVA	Cerebrovascular Accident
DKBS	Dynamic Knee Brace System
DME	Durable Medical Equipment
IEEE	Institute of Electrical & Electronics Engineers
ISPO	International Society of Prosthetics and Orthotics
JRRD	Journal of Research & Development
KAFO	Knee Ankle Foot Orthosis
O&P	Orthotics and Prosthetics
ORIF	Open Reduction Internal Fixation
PALS	Participation and Activity Limitation Survey
PCI	Psychological Cost Index
RGO	Reciprocating Gait Orthosis
ROM	Range of Motion
SCKAFO	Stance Control Knee Ankle Foot Orthosis
SCI	Spinal Cord Injury
SCO	Stance Control Orthosis
SCOKJ	Stance Control Orthotic Knee Joint
SPL	Swing Phase Lock
TBI	Traumatic Brain Injury
WAC	Washington Administrative Code
WCB	Workers' Compensation Board

Background

Orthoses are devices designed to support or correct the function of an impaired limb. Stance Control Knee Ankle Foot Orthoses (SCKAFOs), also known as Stance Control Orthoses (SCOs), are a relatively new generation of lower limb orthoses. SCKAFOs may utilize various mechanisms, but in general are designed for locking the knee joint during the stance phase of gait and unlocking it (allowing the knee to bend) during the swing phase. They are specifically useful in paralysis or paresis subsequent to a multitude of nervous system disorders (e.g. CVA, craniocerebral trauma), spinal cord diseases (e.g. progressive spinal muscular atrophy, post-polio syndrome, after spinal cord injury, incomplete paraplegia), myopathies (e.g. progressive muscular dystrophy, aftermath of polymyositis) and diseases affecting the peripheral nervous system (e.g. radicular syndromes such as intervertebral disk hernia, peripheral nerve lesions, polyneuropathy).[1]

Epidemiological data on disability variables, specifically on individuals with paralysis, is limited. From May to August 2008, a study funded by the Reeve Foundation and the US Centers for Disease Control and Prevention (CDC) undertook a survey of 33,000 randomly sampled US households.[2] Approximately 1.9% (~5.5 million) of Americans had some type of paralysis, and 0.4% (~1,275,000) reported spinal cord injury, which was five times higher than previously estimated. The largest portion (28%) of the spinal cord injuries reported was related to workplace accidents.[2] According to another study (1993), over 18% of the disabled US adult population had a spinal cord injury.[3] One other US study (1997) found that approximately 989,000 people were using various types of knee braces.[4] The 1993 study stated that 58% of lower extremity braces were abandoned by their users for a multitude of reasons.[3]

In Canada, Participation and Activity Limitation Surveys (PALS) were undertaken by Statistics Canada in 2001 and again in 2006. Based on a definition of mobility disability being "difficulty walking half a kilometre or up and down a flight of stairs, about 12 steps without resting, moving from one room to another, carrying an object of 5kg (10 pounds) for 10m (30 feet) or standing for long periods," 2,923,000 adults felt they had a mobility disability. Almost 90% of these adults reported some level of disturbance in their participation in everyday activities. About 180,000 individuals reported that their perceived needs for assistive technology were not met. The survey reported that there were 135,770 Canadian adults using or in need of some type of brace or supportive device. The majority of these people with disabilities were paying for their own assistive devices – 70.26% in Canada, and 79.59% in BC (the highest percentage amongst all provinces/territories). Adults with disabilities reported that the major reason for their unmet assistive device needs was the 'cost'.[5]

Although the PALS surveys did not provide us with specific information about the use of SCKAFOs, it does help us understand the overall rates of mobility-related disability issues and use of assistive technologies in Canada.

Stance Control Knee Ankle Foot Orthoses (SCKAFOs) or Stance Control Orthoses (SCOs)

Traditional KAFOs are generally one of two types: Locked Knee Joint KAFOs, which provide stance phase stability, but prevent knee motion during the swing phase (a stiff leg with difficulty in ambulation); and Eccentric Knee Joint KAFOs, which allow knee motion during the swing phase, but provide limited stability during stance (increasing risk of buckling and falling).[6] One major shortcoming of a locked knee joint KAFO is reported by various authors to be the patient's adaptation of compensatory gait patterns, such as increased upper-body lateral sway, ankle plantar flexion of the contralateral foot (vaulting), hip elevation during swing phase (hip hike), or leg circumduction.[7] These abnormal gait patterns can initiate soft tissue and joint dysfunctions in the hip and lower back leading to pain and motion loss[8] and increased muscular effort with possible higher energy expenditure.[9]

Stance Control KAFOs (SCKAFOs) were developed over the last few decades and only recently have become clinically available. Stance control knee ankle foot orthoses differ from more traditional orthoses by virtue of a 'free swinging' joint. They keep the knee rigid and locked during stance and allow it to flex or extend freely during the swing phase.[10] With the stance control feature, flexion of the knee is blocked during stance, the weight-bearing phase of the gait. According to Yakimovich et al.,[7] the ideal SCKAFO should:

- resist knee flexion at any angle during stance and should allow free knee motion during swing
- allow knee extension any time in stance phase (to climb or to recover from a stumble)
- quickly switch between swing and stance phases of the gait (reaction time < 6 ms)
- be able to be used at least 1 full day before recharging (if electromechanical) is required
- be relatively noise free
- be lightweight (< 5 lb, which is the weight of a regular KAFO)
- be of minimal bulk
- be relatively inexpensive and cost effective

Other authors have reported on experiments with hybrid orthotic systems using both stance control and functional electrical stimulation (FES).[11] Stein et al. suggested that a SCKAFO with FES may provide a better physiological cost index (PCI), reasonable speed, and a more normal-looking gait preferable to the user.[12]

Mechanical SCKAFOs are usually activated by a particular movement during the gait, such as ankle range of motion (ROM) or limb inclination. The UTX (1989), SCOKJ (2000), SPL, FullStride and SafetyStride are among the first generation SCKAFOs manufactured. In 2003, microprocessor-controlled SCKAFOs including the Becker E-Knee and Otto Bock Sensor Walk were introduced. An interview article from the O&P EDGE (an orthotics and prosthetics industry publication) displays a matrix (Table 1) by Kelly Clark, which lists different properties of various SCKAFOs.[11] In his review of engineering designs of SCKAFOs (2009), Yakimovich points out that reliance on specific joint angles to switch between stance and swing phases is the major functional limitation of some of these SCKAFOs presently on the market.[7]

As also mentioned in the O&P EDGE article, SCKAFOs are not widely used.[6, 11] In the same article, a quote by G. Bedard points out that out of 500 attendees of the 2007 Annual Meeting and Scientific Symposium of the American Academy of Orthotists and Prosthetists, only "30 percent had any experience in providing SCOs; only 15 percent had fitted as many as five; and only two people had fitted ten or more." The issue of reimbursement was also mentioned. Based on Medicare usage figures they had estimated that only 1200 to 1600 SCKAFOs per year were utilized. Bedard presents a retrospective analysis of UTX SCKAFO Systems delivered in the US from November 2002 to August 2007. Percentages of orthoses delivered, broken down by medical condition they were utilized for, were: 24% for polio-related sequelae, 14% for 'weak quadriceps', 7.7% for spinal cord injury, 7.1% for femoral mononeuropathy, 4.6% for multiple sclerosis, 3.3% for genu recurvatum, 2.9% for muscular dystrophy, 2.7% for cerebrovascular accident, 2.5% for inclusion body myositis, and 2.1 % for total knee arthroplasty (TKA). Another expert, J. Michael, suggests that SCKAFOs should not be prescribed based on the diagnosis, but rather based on the biomechanical dysfunction of the limb. Using an example, he illustrates that not all spinal cord injury patients have quadriceps weakness, and this lack of weakness makes them inappropriate candidates for using SCKAFOs. Other various experts interviewed for the O&P EDGE article frequently think of 'diagnosis' as only the starting point for SCKAFO patient selection. In his 2005 paper, Yakimovich points out that there were 4 SCKAFO knee joints available in Canada with prices ranging from $2200 to 4000 CAD. With the added cost of materials and labour, these prices were likely to be unaffordable for many potential users.[13]

When prescribing SCKAFOs and selecting the most appropriate one for the patient, the following factors should be taken into account, according to the manufacturer:[14, 15]

- age and cognitive state of the patient
- diagnosis and prognosis
- biomechanics of the muscles and joints, such as muscle strength and range of motion
- contraindications
- properties of the candidate SCKAFOs (cost, size, weight, noise)
- reimbursement
- desired vocational and leisure activities
- expertise availability (to fit and to follow up)
- initially being a KAFO or SCKAFO user

Some general contraindications for SCKAFOs as noted by the manufacturer include:[14, 15]

- impaired cognition (cannot learn/benefit from gait training)
- knee-flexion contracture >10º (up to 15º with E-MAG Active)
- moderate to severe spasticity of the hamstrings
- lack of hip abductors in bilateral patients

- inability to advance limb in swing phase (weak hip flexors)
- uncorrectable genu varum/valgum >10° (up to 15º with E-MAG Active, as long as the patient generates extension moment in terminal stance)
- lack of motivation or inappropriate expectations
- body weight >300 lb (>187 lb with E-MAG Active)

E-MAG Active

The Evidence-Based Practice Group at WorkSafeBC recently received a review request from the Medical Technology Assessment Committee (MTAC) regarding E-MAG Active orthotic system, which presently costs approximately $15000 CAD. It was brought to the attention of MTAC in relation to a claim by a 64-year-old heavy equipment operator who was injured in September 2008. The worker had his right leg driven over by a truck, resulting in an open right distal femur fracture with ORIF, followed by numerous complications (fat embolism syndrome with cognitive impairment, post traumatic OA of the right knee, varus deformity of the right knee with extensor weakness, and pain and instability despite reaching plateau with rehabilitation). The patient walks with crutches and has respiratory and cardiac issues, which are not factors affecting his ambulation.

E-MAG Active has recently been introduced by Otto Bock as a SCKAFO that utilizes an electromagnetic technique (hence, the name E-MAG which refers to this Electronic Magnet). It became available in the market in North America in December 2008.[Balkowski J. Market Manager – Technical Orthopedics, Otto Bock Healthcare, Burlington, Ontario. Email Mar 25, 2010.]

Although appearance and comfort are important, functionality is seen by most users as the key element for any specific orthotic device. E-MAG Active retains two basic functions: locking the knee joint in the stance phase and unlocking it for the swing-through phase. This enables a dynamic gait and secure standing.[16] The intelligent sensors of E-MAG Active are placed to measure the position of the leg and to control the orthotic joint system accordingly.[17] Input from both a gyroscope and accelerometer, located within the thigh section of the orthosis, determines the user's position within the gait cycle. The locking mechanism of the E-MAG Active is a friction wedge lock and requires all flexion load be removed from the joint to unlock for the swing phase. The E-MAG Active will remain locked if the patient ambulates on varying terrains and elevations. [Balkowski J. Market Manager – Technical Orthopedics, Otto Bock Healthcare, Burlington, Ontario. Email Mar 25, 2010.] One major feature of E-MAG Active is its independence from the ankle joint and foot sole operations when switching between stance and swing phases. Even if the patient has no ankle function, they can still use E-MAG Active and achieve appropriate stance control. The self-adjusting software of E-MAG Active enables different flexion angles (5°, 7.5° or 10°).[18] Locking and unlocking is calibrated based on body position, and can be recalibrated as the user's gait changes over time. The gait may improve or worsen depending on the progression of the patient's disease or the response to treatment. [Balkowski J. Market Manager – Technical Orthopedics, Otto Bock Healthcare, Burlington, Ontario. Email Mar 25, 2010.]

To use E-MAG Active the patient is required to have both functional extensors and flexors of the hip with a strength of 3 to 5 (based on the Kendall and Kendall scale).[19] The patient must also have the capacity for full extension of the knee, both prior to the initial contact and at the terminal stance (to lock and unlock the knee).[Balkowski J. Market Manager – Technical Orthopedics, Otto Bock Healthcare, Burlington, Ontario. Email Mar 25, 2010.]

Table 1 presents the specific indications and contraindications for E-MAG Active as determined by the manufacturer.

Indications	Contraindications
Paresis and paralysis of muscles and muscle groups of lower extremities (quadriceps weakness is primary indication)	Cognitive impairment preventing understanding of the mechanism of the device and gait training
Pronounced deviations in the frontal and sagittal plane (knee and ankle)	Insufficient residual muscles (lack of knee joint hyperextension)
A severely atrophic, bony leg with little soft tissue coverage	Severe spasms (leading to inconsistent functionality)
A severely shortened leg (> 5 cm)	Knee flexion contracture greater than 15°
Requirement of a dorsal stop in the ankle in order to reach knee joint extension	Hip flexors and extensors strength < 3/5
Ankle stiffness	Genu varum/valgum >15°
Requirement of a pronounced dorsiflexion function	Need for ambulation on changing terrain and elevation (when using the SCKAFO)
Weight up to 187 lb / 85 kg	

Table 1. Indications and contraindications for E-MAG Active. [Balkowski J. Market Manager – Technical Orthopedics, Otto Bock Healthcare, Burlington, Ontario. Email Mar 25, 2010.],[15, 16, 20, 21]

Otto Bock manufactures three types of SCKAFOs (Sensor Walk, E-MAG Active, and FreeWalk), each with different features.

- E-MAG Active requires the lowest patient weight (up to 187 lb); FreeWalk has a limit of 265 lb and Sensor Walk has a recommended limit of 300 lb.
- Both the E-MAG Active and Sensor Walk joints can accommodate a knee flexion contracture up to 15° (although clinical assessment of E-MAG suitability is strongly recommended for cases with contracture >10°); FreeWalk can accommodate a knee flexion contracture up to 10°.
- E-MAG and FreeWalk both need a full knee extension moment during the initial and end phases of the gait cycle in order to trigger/release the locking mechanism; Sensor Walk does not have this requirement. Limiting dorsiflexion at the ankle (via a dorsal stop) may aid in creating this extension moment at the knee (for E-MAG Active, not possible for Free Walk) and may be an appropriate adjustment. Success of this action ultimately depends on the individual and their physiological abilities and limitations. [Brash T. Clinical Product Specialist – Orthotics & Specialty Rehab, Otto Bock Healthcare, Burlington, Ontario. Email June 23, 2010.]

- At the ankle joint, E-MAG Active accommodates full ROM with no minimum patient requirements (similar to Sensor Walk). FreeWalk requires patients to have a minimum of 10° passive ROM at the tibiotalar joint.
- Similar to FreeWalk, E-MAG Active requires a minimum hip muscle strength of 3/5 for both flexors and extensors (based on the Kendall and Kendall scale); whereas for Sensor Walk, a minimum score of 3/5 is required for hip flexor strength, with no requirement for hip extensor muscle strength.
- As long as the patient generates extension moment in the terminal stance phase, E-MAG Active can accommodate up to 15° valgum/varum at the knee joint. This limit is only 10° for the FreeWalk and Sensor Walk products.

In summary, Otto Bock recommends E-MAG Active for “patients that present with flaccid paralysis/paresis of the knee extensors coupled with limited ankle ROM.”[21]

Literature review

We performed a systematic literature search using the terms 'stance control orthosis', 'stance control knee ankle foot orthosis', and 'stance control KAFO' through the OvidSP interface (Cochrane Database of Systematic Reviews, ACP Journal Club, the York University (UK) Database of Abstracts of Reviews of Effects, Cochrane Controlled Trial Registry, York University (UK) Health Technology Assessment database, York University (UK) NHS Economic Evaluation database, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE and Ovid MEDLINE Daily Update). We also searched the RECAL Legacy database (UK) (for prosthetics and orthotics), the IEEE Xplore Digital Library, the Journal of Rehabilitation Research & Development (JRRD) of the US Department of Veterans Affairs, and the Journal of Prosthetics & Orthotics of the American Academy of Orthotists & Prosthetists. We selected articles published until July 30, 2010 with at least an abstract in English. We discarded any articles focusing solely on ankle-foot orthoses, hip joints, or on Functional Electrical Stimulation (FES) products. Pediatric device study papers were also excluded. In addition, we reviewed the various conference papers presented during the 12th International Society of Prosthetics and Orthotics (ISPO) Conference held in Vancouver, BC, in August 2007 and publications from 'Capabilities' and 'Orthopädie-Technik'. Nineteen articles were included in this review. A flow chart of the article selection process is included in Appendix 1. No formal critical appraisal of the articles was undertaken.

One review article by Michael (2006) points out the lack of high-level scientific evidence on the use of KAFOs for ambulation.[22] However, he also acknowledges the possibility that the newly introduced SCKAFOs might change this and lists them under the section 'major research priorities' in his paper. A narrative review by Hurley focuses on KAFO use by traumatic brain injury (TBI), spinal cord injury (SCI), and cerebrovascular accident (CVA) patients. She states that with the introduction of stance-control technology, KAFO use in these patient groups needs to be reevaluated. She proposes that SCKAFOs allowing active knee extension in CVA patients may lead to faster recovery with less physical therapy time with the potential for early discharge from formal rehabilitation programs. While she underlines how important it is for SCI patients to stand and ambulate (maintaining joint ROM and bone density, and decreasing spasticity and associated bowel/bladder complications), she acknowledges that SCKAFOs can only be used for select SCI patients who have residual hip flexors and extensor function. Because of significant spasticity and possible cognitive impairment, SCKAFOs may not be the best choice for some TBI patients. Hurley outlines an important gap in the literature and calls for more research with SCKAFOs with standardization of outcome measures to allow for comparability of study results.[23]According to a systematic review by Fatone (2006), the number of studies on various lower limb orthoses substantially increased in the 1990s.[24] Kaufman published a paper in 1996 which prompted more research in SCKAFOs in particular. This was a case report on a post polio subject who was tested using a standard lock-knee KAFO and a free-knee (unlocked) configuration. The orthosis with the free-knee configuration lowered the energy required for walking in that particular patient.[9] In 1998, Suga et al. published a study of a newly designed KAFO, with a knee joint utilizing a microcomputer, called Intelligent Orthosis.[25] In 1999, Irby's paper summarizing the design, construction, and testing of a new Dynamic Knee-brace System (DKBS) with an optimized wrap-spring clutch followed. This optimized design provided 38° of flexion during swing; however, safety improvements were needed.[26] In another 1999 paper, Irby highlighted the energy efficient gait with DKBS.[27] In their 2001 paper, Harrison et al. proposed and discussed 3 different SCKAFO designs. Each design had its own pros and cons: roller-clutch bearing design (unlocking force too high), lever-lock design (joint sliding action not smooth, expensive) and wedge-joint design (easy to manufacture, but requires small extension moment and is wider in the sagittal plane).[28] Papers by McMillan (2004), Yakimovich (2005), Irby (2005), Stein (2005) and Hebert (2005), which evaluated gait patterns with various SCKAFOs, followed.[8, 12, 13, 29, 30] McMillan et al. compared a Horton SCKAFO (SCOKJ) with a conventional KAFO in 3 male subjects. They found that spatiotemporal parameters (speed, cadence, stride, step length) were improved, gait was more symmetric, and extraneous trunk and pelvic movements were decreased when walking with SCOKJ. In 2005, Irby et al. from the Mayo Clinic (Rochester, MN, USA) studied a newly developed DKBS, a SCKAFO with an electromechanical wrap spring clutch and sensors at the knee and footplate. They studied 21 patients with mild to moderate muscle strength loss. Findings from the novice DKBS user group were compared to the experienced KAFO user group. The novice group was rated higher in the majority of the outcome measures utilized. This led the investigators to speculate that the already compensated gait patterns of the experienced group were interfering with the immediate adaptation to the new SCKAFO.[29] In 2006, Bernhardt undertook a survey – as part of a larger field study – to gather opinions of DKBS users. Twenty subjects, of whom 14 were prior KAFO users, participated. DKBS scored well in areas of effectiveness, operability, and dependability. However, scores on weight, cosmesis, and donning and doffing of DKBS reflected the need for further improvement.[10]

A new SCKAFO knee joint, which provides knee support at any knee angle, knee extension in stance, and unlimited knee motion in swing, was developed by Canadian researchers in 2005. This slimmer and lighter electromechanical SCKAFO, employing a friction-based belt-clamping mechanism, was tested in 3 able-bodied subjects and 3 KAFO users.[13] In their 2006 paper, the authors presented a functional evaluation of this SCKAFO when used by a 58-year-old able-bodied male subject.[31] Later, Yakimovich et al. presented their findings when 3 prior KAFO users with moderate knee extensor weakness evaluated the same SCKAFO.[32] They found that while the new SCKAFO design led to improved gait kinematics for prior KAFO users and permitted a natural knee loading response, the performance, safety, lifetime, and cosmesis of the device required further improvement. Hence, in 2007, during the 12th ISPO World Congress, they presented a refined design, called Ottawalk, with reduced size, weight, and cost; while at the same time it was reported to have increased performance and safety. The major change within this product was elimination of the electromagnetic solenoid and its replacement by a pushrod-based mechanical control system.[33] In 2007, Irby et al. studied gait changes over time in 14 DKBS users. They concluded that in general, this new SCKAFO led to significant temporodistance changes in velocity, cadence, stride length, and knee flexion over a 3-month period. Previous KAFO use had an observed impact on the outcome. They also observed that significant changes in joint kinematics required a longer period of

SCKAFO use, i.e. 6 months.[34] Zissimopoulos et al. studied the Horton Stance-Control Orthotic Knee Joint (SCOKJ) on 9 non-impaired subjects. They compared gait kinematics when the subjects used the SCOKJ in three different modes: 'locked', 'unlocked' and 'auto' (stance-control). Walking kinematics and stability during stance was better when using the 'auto' mode.[35] A paper by Rasmussen (2007) explains the combination of a bilateral SCKAFO and a reciprocating gait orthosis (RGO). With SCKAFO addition, the gait pattern of a high level spinal cord injury patient became more efficient.[36] Researchers from South Korea developed a SCKAFO for level walking, which uses electro mechanical control with a wrap spring clutch knee joint coupled with a foot switch system. They compared the controlled and locked knee gait in 4 post-poliomyelitis patients using this new SCKAFO. Maximum knee flexion during swing phase was increased and energy consumption was decreased.[37]

Three articles on SCKAFOs were published in 2009-2010. A 2010 article by Davis et al. reported on a study of ten subjects using an orthosis that incorporates the Horton Stance Control knee joint.[38] They compared energy expenditure and walking velocity of these subjects when using two different modes of the orthosis: stance control active and knee joint locked. They found that walking velocity was improved significantly when using the stance control mode ($p<0.001$). However, contrary to the authors' expectations, energy expenditure did not change when the stance control was activated. The 2009 paper by Lemaire reviews a new hydraulic knee-flexion control SCKAFO which uses an angular-velocity-based approach. With this new SCKAFO, Ottawalk-Speed, a threshold angular velocity can be set to activate knee-flexion resistance in case of stumbling and falling.[39] The other 2009 paper, a narrative review by Yakimovich, examines and discusses the properties of various SCKAFOs (Otto Bock FreeWalk/Becker UTX, Horton Stance Control Orthosis, Fillauer Swing Phase Lock, Becker Orthopedic 9001 E-Knee, Dynamic Knee Brace System, Ottawalk Belt-Clamping Knee Joint, and Dual Stiffness Knee Joint). Although the Otto Bock Sensor Walk, which is a dynamic knee brace system, is listed in the 'summary of characteristics of commercial SCKAFO designs' table, E-MAG Active is not included.[7] Currently, there are no review articles, or any other study papers (case reports, comparative studies, or cost effectiveness studies) specifically about E-MAG Active.

During the 12th ISPO World Congress, held in Vancouver, BC, in August 2007, summary papers on some new, experimental orthotic devices were presented. One study presented had explored the usage and appreciation for SCKAFOs in 8 former polio patients. The rejection rate was 38% and the non-user group scored lower in physical functioning.[40] Another summary paper detailed a microprocessor-controlled hydraulic KAFO, which allowed flexion of the knee during swing phase, sitting down, stair descension stance phase, and 'stance yielding', instead of locking the knee during the stance phase.[41]

In 2006 the journal Prosthetics and Orthotics published a supplement with proceedings from the Academy's Seventh State-of-the-Science Conference on Knee-Ankle-Foot Orthoses for Ambulation. A series of papers on ambulatory KAFOs reflecting views of different professional groups, such as biomechanical engineers, orthotists, physiotherapists, and physiatrists were included. Some of these papers have sections referring to SCKAFOs.[6, 42-44] One other narrative paper from this supplement, by Taylor, was on KAFOs for patients with neuromuscular deficiencies. He points out that patients in need of orthotic care will often be interested in the newest technologies, with the hope for a better quality of life; “However, many will remain best served by less sophisticated orthoses” and although promising, the role of stance control for this patient group is still not clear.[45]

A summary table of the 19 studies reviewed can be found in Appendix 2.

Coverage policies

There is no specific coverage policy regarding E-MAG Active at WorkSafeBC. In WorkSafeBC's Rehabilitation Services & Claims Manual, 'orthotic supplies' are mentioned under 77.23 Artificial Limbs.[46]

The policy manual of the US Department of Veterans Affairs contains a section on 'orthotics' but does not include a specific policy regarding E-MAG Active or SCKAFOs in general. In summary, orthotic devices are covered if a VA-authorized provider prescribes it as 'medically necessary'. Under this policy item, 'lower limb orthotics' are defined as: "…used to substitute for absent motor power, to assist weak segments, to support segments that require immobilization, to provide traction or for the attachment of devices. These are usually prescribed for the hip, knee, ankle, lumbar, sacral or any combination."[47]

We also searched the website of the Washington State Department of Labor & Industries for information on stance control orthotics.[48] "The insurer will only pay for custom fabricated prosthetic and orthotic devices that are manufactured by providers specifically licensed to produce them. These providers include licensed prosthetists, orthotists, occupational therapists, certified hand specialists and podiatrists."

"Providers are not required to obtain prior authorization for orthotics or DME [durable medical equipment] when:

- The provider verifies that the claim is open/allowed on the date of service, and
- The orthotic/DME is prescribed by the attending provider (or the surgeon) for an accepted condition on the correct side of the body, and
- The fee schedule prior authorization indicator field is blank.

Prior authorization is required for:

- Prosthetics, surgical appliances and other special equipment described in WAC [Washington Administration Code] 296-20-03001,Treatment requiring authorization.
- Replacement of specific items on closed claims per WAC 296-20-124, Rejected and closed claims.

If DME or orthotics requires prior authorization and it is not obtained, then bills may be denied."[48]

The Workers' Compensation Board of Alberta states that: "When prescribed by a physician, the WCB will provide or pay for orthotic devices such as crutches, canes, supports, braces and any other device(s) considered necessary to alleviate the results of a work injury. The orthotic devices are provided on a permanent or temporary basis, as needed. The WCB may also supply prosthetic or orthotic devices as a rehabilitation measure."[49] Also, their WCB Prosthetics and Orthotics Fee Guide October 2008 includes a note re: stance control. "NOTE: Stance control orthoses can be utilized on a one-off basis as needed following the Unlisted Device process of the contract."[50]

According to Otto Bock Canada, the total number of E-MAG Actives sold in North America, in 2009, was 73. [Balkowski J. Market Manager – Technical Orthopedics, Otto Bock Healthcare, Burlington, Ontario. Email Apr 7, 2010.] We did not come across any specific coverage policy on E-MAG Active from any of the searched workers' compensation organizations or health insurance companies. However, the E-MAG has become the most expensive SCKAFO available in the market, surpassing the Sensor Walk which was $US 8,500.[7]

Conclusion

KAFOs are recorded as being abandoned by their users with rates of 58% to 79%, or 60% to 100%, depending on the study.[9, 10] How these acceptance rates will change with the newly introduced SCKAFOs depends on improvements in their performance, safety, weight, bulkiness, and noise properties, as well as on the functional and cosmetic expectations of the patients using them.

The literature on KAFOs is limited (there have been only a few randomized controlled trials on KAFO use for ambulation)[22] and available studies generally have small sample sizes and inadequate study designs.[24] Amongst KAFOs, SCKAFOs are a fairly new group; hence the literature available on SCKAFOs is even more limited, and typically consists of case reports and cross-sectional comparison studies with small sample sizes. Most of the information on SCKAFOs is from the manufacturer companies, from expert views or anecdotal clinical success stories. There is only one narrative review article, by Yakimovich, which explains the features of various SCKAFO designs. He points out that there have been improvements in mobility and walking with SCKAFOs, compared to fixed-knee KAFOs. However, controlling knee flexion during stance, knee extension assistance, and switching between the stance and swing phases with SCKAFOs still requires technical improvements.[7] The low quality scientific evidence on SCKAFOs can only be overcome by more studies, preferably with more crossover designs and interrupted time-series trials using larger study samples and longer study durations.

We have not come across any studies – even case reports – specifically on E-MAG Active. Therefore, we suggest that any decision on utilizing E-MAG Active for an injured worker needs a thorough, individual-based assessment. E-MAG Active's pros and cons need to be evaluated based on the individual patient's characteristics.

E-MAG Active pros:

- free swing phase and controlled stance phase
- decreased gait anomalies (such as vaulting, hip hiking, or circumduction during swing phase)
- more natural esthetic and smoother gait pattern
- suggested reduced pulmonary/cardiac stress, avoidance of compensatory movements and new contractures and joint damage resulting from immobilization, promotion of muscle development of the existing muscles, relieved contralateral side
- possible usage during leg length reductions
- no requirement of ankle functionality (accommodates full ROM with no minimum patient requirements at the ankle joint)
- ability to accommodate up to 15° of valgum/varum at the knee joint if patient generates extension moment in terminal stance
- ability to accommodate up to 15° knee flexion contracture in conjunction with a dorsal stop at the ankle

E-MAG Active cons:

- high cost
- need for appropriate cognitive skills
- need for a muscle strength of 3 to 5 (Kendall and Kendall scale) for both hip extensors and flexors
- ability to achieve knee joint hyperextension
- lower body weight limit of up to 187 lb
- not preferred for ambulation on uneven terrain or ascending/descending stairs

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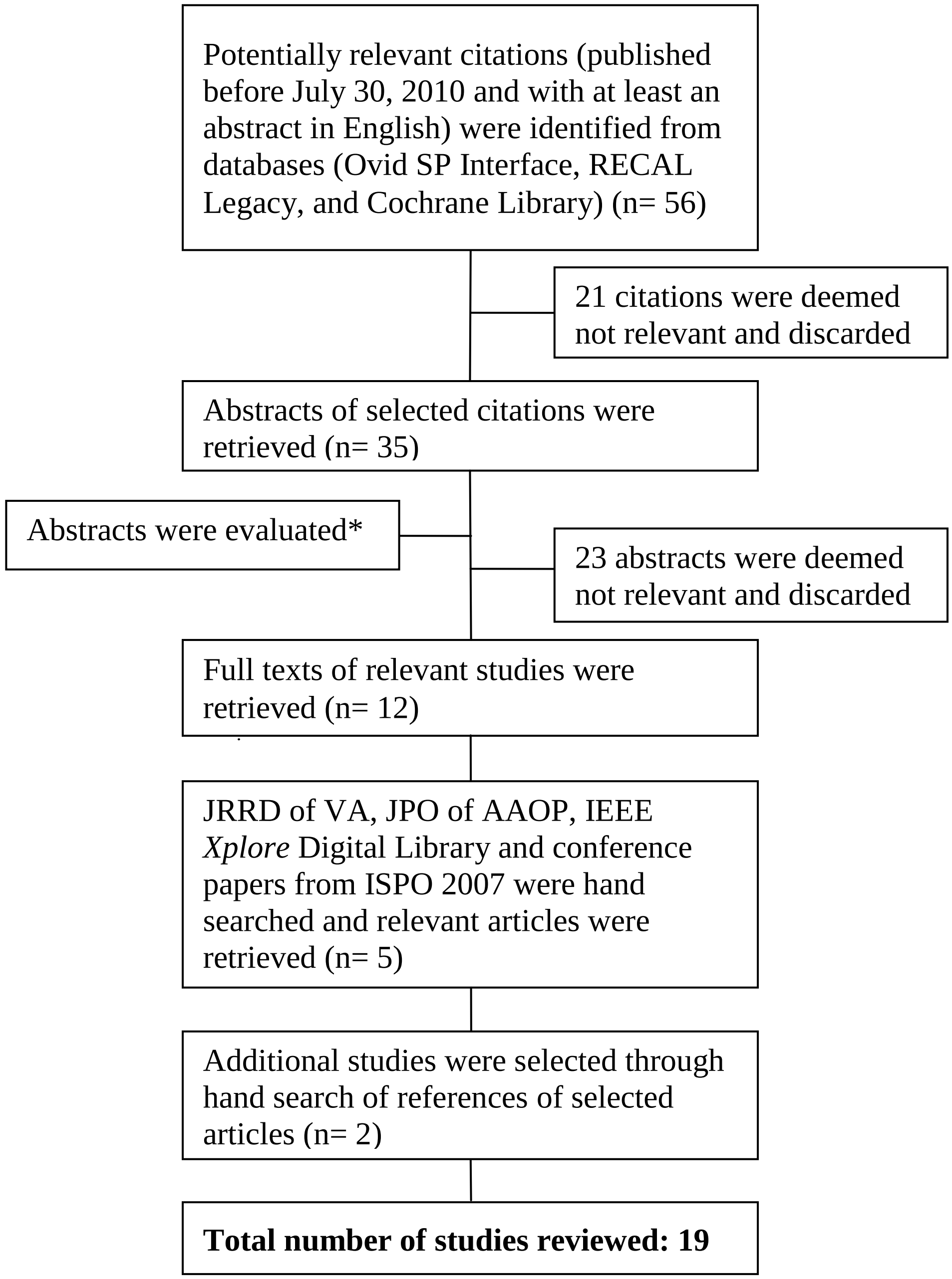
Appendix 1

Flow diagram (Study selection)



* Exclusion criteria applied during abstract reading

- Clinical studies focusing solely on
  - ankle-foot orthoses,
  - hip joints, or
  - Functional Electrical Stimulation (FES) were excluded
- Studies solely on pediatric orthotic devices were excluded

Appendix 2 Summary Table - Stance Control Knee Ankle Foot Orthoses (SCKAFOs)

Study	Study design	Study setting/ population	Study subjects	Age	% Male	Diagnosis	Orthoses	Prior use of KAFO	Time to adapt SCKAFO	Training on orthotic use	Analysis	Reported Variables														Conclusion	Comments	(EBPG Level of evidence)
												1	2	3	4	5	6	7	8	9	10	11	12	13	14			
Davis PC 2010 [38]	Case series (comparing Horton SCO with locked & stance-control modes)	Australia	10 able-bodied subjects & 3 KAFO users	Mean age: 35.3 years (able-bodied), 56.3 years (KAFO users)	40% male	- 9 had polio - 1 had motor neuron disease	Horton Stance-Control Orthotic Knee Joint (SCOKJ) 3 modes: - Locked - Stance control (joint locks during stance & disengages prior to swing) - Free knee	Regular SCO users (average: 6.2 months)			- Gait measurements (temporospatial characteristics) - Energy consumption measurements (oxygen cost & physiological cost index) - SPSS for the stat analysis (paired t-tests and Wilcoxon's signed rank test as appropriate)			B													Walking velocity was improved with the stance control mode of the orthosis (p<0.001). However, contrary to the authors' expectations, energy expenditure did not change.	4
Lemaire ED 2009 [39]	Design (angular-velocity control approach)	Ottawa Hospital Rehabilitation Centre, Canada	1 able-bodied subject	29 years	Male	Able-bodied subject	Hydraulic knee-flexion control SCKAFO (Ottawalk-Speed)								L						M					Provides free knee motion during walk, engages upon knee collapse, supports body-weight when the end-user recovers	A threshold angular velocity can be set to activate knee-flexion resistance in case of stumbling & falling	4
Yakimovich T 2009 [7]	Narrative review	Ottawa Hospital Rehabilitation Centre, Canada	Various SCKAFO designs				Otto Bock FreeWalk, Becker UTX, Horton Stance Control Orthosis, Fillauer Swing Phase Lock, Becker Orthopedic 9001 E-Knee, Dynamic Knee Brace System, Ottawalk Belt-Clamping Knee Joint, and Dual Stiffness Knee Joint				Narrative comparisons (mostly with regular KAFOs)	B	L			M			L	B				M		- Improvements in mobility & walking with SCKAFOs compared to fixed-knee KAFOs - Controlling knee flexion, knee extension assistance, & switching between stance & swing phases with SCKAFOs requires more technical improvements		5
Hwang S 2008 [37]	Design (compared locked SCKAFO to controlled SCKAFO)	Institute of Medical Engineering, Wonju, South Korea	4 subjects	37 years	0% male	Post-poliomyelitis patients	Electromechanically controlled KAFO with wrap spring clutch knee joint (has a foot switch system) - For level walking			Accommodation period: 4-6 weeks	- Gait analysis - Energy consumption analysis	B	L			L			L							All subjects had higher max knee flexion during swing & less energy consumption with the controlled KAFO		4
Irby SE 2007 [34]	Prospective clinical field trial (open label) (comparisons within & between groups) Measurements at 0, 3, 6 months	Mayo Clinic, Rochester, Minnesota, USA	14 subjects (Inclusion: can walk 100 m, use a locked KAFO, sufficient hip flexor strength; Exclusion: cognitively impaired, poor balance, painful back or limbs, contractures of hip >15°, of knee >10°, >5° dorsiflexion at ankle)	Mean age: 51 years	79% male	- 9 post-polio - neuropathies - incomplete SCI - spina bifida - MS - Muscular dystrophy	DKBS (SCKAFO with an electromechanical wrap spring clutch & sensors at the knee & footplate)	-Experienced: 7 (using locked KAFO) -Novice: 7 (not using locked KAFO)	-significant gains in temporo-distance measures, in 6-month period		Gait measurements via computerized video motion analysis Two-way ANOVA with repeated measures (0, 3, 6 months) was conducted for analyzing differences between experienced & novice users; & aggregate groups	B		H												- With SCKAFO use, in 3-month period, significant temporodistance changes were observed (in velocity, cadence, stride length, and knee flexion) - Previous KAFO use had an impact on outcome - Significant changes in joint kinematics required a longer period of SCKAFO use (at 6-months)	- Increased peak hip flexion in both periods (0-3 months & 3-6 months) for all subjects (p=0.02) - For all study subjects (aggregated) velocity, cadence & stride increased significantly from month 0 to month 6	4

Reported variables
1: Natural gait/posture, 2: Energy and/or O_2 consumption, 3: Speed, 4: Falls, 5: Weight/bulkiness, 6: Noise, 7: Appearance/comfort, 8: Compensative posture/movements, 9: Effectiveness/functionality, 10: Stability/dependability, 11: Usage, 12: Donning/doffing, 13: Cost, 14: Rejection rate
Abbreviations
M: more/high, L: less/low, B: better, W: worse, SCI: Spinal cord injury, MS: Multiple sclerosis, DKBS: Dynamic Knee Brace System, SPL: Swing Phase Lock, ROM: Range of motion, PCI: Psychological Cost Index
EBPG Rating/Evaluation of Studies – Please see Appendix 3: EBPG levels of evidence

Study	Study design	Study setting/ population	Study subjects	Age	% Male	Diagnosis	Orthoses	Prior use of KAFO	Time to adapt SCKAFO	Training on orthotic use	Analysis	Reported Variables														Conclusion	Comments	(EBPG Level of evidence)
												1	2	3	4	5	6	7	8	9	10	11	12	13	14			
Rasmussen AA 2007 [36]	Case report	Missouri, USA	1 subject (Isocentric RGO user)	30 years	Male	T-10 spinal cord injury	SCKAFO (SCOKJ, Horton) Isocentric RGO	Reciprocating Gait Orthosis (RGO) user	1 month	Training during physical therapy (twice a week, 1 month)	3-D Gait analysis	B		H												More efficient gait pattern with SCKAFO addition	- Asymmetry in step lengths disappeared - with similar amount of hip flexion the gain in forward progression was greater with the SCKAFO	4
Sabelis LWE 2007 [40]	Prospective clinical trial (comparisons between groups)	Department of Rehab, University of Amsterdam, Netherlands	8 subjects	Mean age: 63 years	88% male	- 8 had polio	- SPL (5) - E-knee (2) - FreeWalk (1)			- Training on the use of SCKAFOs															38%	Non-users scored lower in physical functioning (based on SF36)	Rejection rate of 38% was high	4
Zissimopoulus A 2007 [35]	Field study	Department of Veterans Affairs Motion Analysis Lab, Chicago, USA	9 non-disabled adults	Mean age: 25 years	44.6% male	Non-disabled	Horton Stance-Control Orthotic Knee Joint (SCOKJ) 3 positions - Locked - Unlocked - Auto (knee stability during stance & flexion during swing)	NA	On average 7 days to become comfortable in operating the device	Training with SCOKJ for about 10 days	SPSS was used - repeated-measures ANOVA, Wilcoxon signed rank test, paired t-test was applied accordingly	B	H								B					'Locked' mode had the highest effect on gait & compensation was also high in 'locked' mode	In general, kinematics for the auto and unlocked modes were similar Oxygen cost during 'auto' mode was not low	4
Bernhardt KA 2006 [10]	Field trial (Comparing DKBS with the previously used KAFO) Surveys and lab tests at the beginning & after 3 months	Mayo Clinic, Rochester, Minesota, USA	20 subjects	Mean age: 53 years	70% male	- 12 had polio - 8 had trauma and other neuromuscular disorders	DKBS	14 used other KAFOs before (either free or locked KAFOs)	Opinions on DKBS did not change significantly after 3 months of use		Lab. measures: ROM, 6-min walk test, KAFO user survey One-sample Student's t-test OR non-parametric Sign test Also a stratified analysis	B				M		W			B		W			Stability, operation were areas found to be important in previous 'opinion' studies & DKBS scored well at these; but improvements are needed in weight and size	Overall opinions on DKBS were positive SCKAFO use can be a positive experience for an orthosis user	4
Yakimovich T 2006 [31]	Case report (Design evaluation)	Canada	1 subject (for functional evaluation)	58 years	Male	Able-bodied subject	Electromechanical SCKAFO, with a knee joint employing a friction-based belt-clamping mechanism, providing resisted stance knee flexion				- Mechanical testing - Functional evaluation					L										- Subject maintained full ROM of knee throughout the gait cycle - New SCKAFO was slimmer & lighter compared to other SCKAFOs in the market	New SCKAFO prevented knee flexion while allowing knee extension in stance and provided free knee motion in swing	4
Yakimovich T 2006 [32]	Non-randomized before-after trial (comparing new SCKAFO & currently used KAFO)	Canada	3 prior KAFO users	Mean age: 56.3 years	All male	Knee extensor weakness	SCKAFO	Prior KAFO users		20 min training with the new SCKAFO, before the tests	- Kinematic gait analysis - Questionnaire about both orthoses - Mean increase in knee flexion angle was 21.1° - Mean ROM increased 23.2°	B		L		L			L							New SCKAFO design - improved selected gait kinematics for prior KAFO users - permitted a natural knee loading response	With new SCKAFO - Increased knee flexion during swing - Increased total knee ROM - Less compensative postural abnormalities	4
Irby SE 2005 [29]	Clinical study (comparing new SCKAFO & currently used KAFO; comparing experienced and novice user groups)	Mayo Clinic, Rochester, Minnesota, USA	21 subjects	- Novice group mean age: 61 years; -Experienced group mean age: 48 years	71.4% male	- patients with mild to moderate strength loss - 12 polio patients - 9 others (pathologies or trauma inc. neuropathies, incomplete SCI, spina bifida, MS, Muscular dystrophy)	DKBS (a SCKAFO with an electromechanical wrap spring clutch & sensors at the knee & footplate)	13 experienced KAFO users 8 novice KAFO users		Varying time of training (10 min minimum)	ROM & manual strength testing SAS was used - Wilcoxon test: physical data - Paired t-test: locked vs. SCO - ANOVA: experienced & novice groups			H (novice)		M			L							Novice KAFO users did better than the experienced ones in improving their gait patterns when using SCKAFO, compared to using KAFO		4

Reported variables
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EBPG Rating/Evaluation of Studies – Please see Appendix 3: EBPG levels of evidence

Study	Study design	Study setting/ population	Study subjects	Age	% Male	Diagnosis	Orthoses	Prior use of KAFO	Time to adapt SCKAFO	Training on orthotic use	Analysis	Reported Variables														Conclusion	Comments	(EBPG Level of evidence)
												1	2	3	4	5	6	7	8	9	10	11	12	13	14			
Hebert JS 2005 [30]	Case report Single subject cross-over design (comparing PCI with locked & stance-control modes)	Glenrose Rehabilitation Hospital, Edmonton, Alberta	1 subject	61 years	Male	Post-poliomyelitis	Horton SCOKJ Can operate in 3 modes: - free swing - locked knee - automatic stance control	55 years usage of a locked-knee KAFO -experienced community ambulator	6 months (before testing with SCKAFO)		-Instrumented gait analysis - Measuring physiological cost index with KAFO & SCKAFO - PCI: with locked: 0.554 beats/m; with stance-control: 0.447 beats/m	B	L	L					L							SCKAFO use improves gait biomechanics & energy efficiency compared to locked knee orthosis	Stance-control mode reduced pelvic retraction, rotational excursion, improved hip power at braced limb side; eliminated vaulting, reduced abnormal ankle and hip power generation at non-braced limb	4
Stein RB 2005 [12]	Case study	Centre for Neuroscience, U Alberta, Edmonton, Canada	1 SCI patient	25 years	Male	Spinal Cord Injury (SCI)	- wheel chair - wheel chair/FES - KAFO - SCKAFO/FES	- wheel chair - wheel chair/FES - KAFO			Analyzed - PCI - O_2 consumption - Speed with 4 different ambulation means	B		L									B			Wheel chair/FES system was a more efficient locomotion system; but SCKAFO/FES was preferred as an acceptable walking system	With SCKAFO/FES, heart rate is increased & speed is slower, but patient uses it because it provides a natural gait	4
Yakimovich T 2005 [13]	Case series (Design evaluation)	Canada	3 able-bodied subjects & 3 KAFO users	Mean age: 35.3 years (able-bodied), 56.3 years (KAFO users)		- 3 able-bodied subjects - 3 KAFO users (diagnosis N/A)	SCKAFO	Prior KAFO users				B							L					L	L		The SCKAFO had minimal effect on able-bodied subjects' walk It increased the knee ROM and decreased compensatory posture in prior KAFO users	4
McMillan AG 2004 [8]	Pilot study	Arkansas, US	3 subjects (convenience sample)	- 56 years - 59 years - 30 years	All male	All with significant weakness at right lower extremity - 2 postpolio - 1 nerve root injury (L4 level)	Horton SCOKJ, providing 3 different modes (locked, unlocked, auto) which could be selected by moving a small lever		Before the study, subjects were using SCOKJ KAFO for - 2 years - 6 months - 8 months		-Gait analysis -Obstacle course -Treadmill walking trials	B	L	H				B	L		B	B				- All 3 had improved spatiotemporal measures, more symmetric gait, less compensatory moves, were more satisfied with SCOKJ - 2 were faster at the obstacle course - 2 had lower heart rate with SCOKJ	Speed, cadence, stride, step length were improved, gait symmetry was better, & extraneous trunk/pelvic movements were less with SCOKJ	4
Irby SE 1999 [26]	Case report (Design evaluation)		1 able-bodied subject	30 years	Male	Able-bodied	DKBS with optimized wrap-spring clutch	NA			Kinematic analysis	B														A new DKBS was designed with an optimized wrap-spring clutch, which controls knee flexion and was able to provide 38° flexion during swing	The factor of safety of this new DKBS was 1.7 and needed to be improved	4
Irby SE 1999 [27]	Case report (Design evaluation)		1 able-bodied subject	30 years	Male	Able-bodied	DKBS with wrap-spring clutch				Single sample, one-tailed Student's t-test		L													O_2 consumption as a function of treadmill speed was greater for locked KAFO mode than for DKBS mode		4
Kaufman RA 1996 [9]	Case report Repeated measures design (O_2 consumption, energy cost, gait efficiency)	VICON VX System Laboratory Oxford, UK	1 subject	40 years	Male	Post-poliomyelitis (lower left extremity)	- Newly designed SCKAFO, called free-knee - Standard locked-KAFO	Orthosis used in professional life		Brief orientation	- Linear regression (O_2 cons. rate vs. walking speed) - Paired t-test (statistically significant difference in gait efficiency)	B	L													- New KAFO provides a more energy-efficient gait		4

Reported variables
1: Natural gait/posture, 2: Energy and/or O_2 consumption, 3: Speed, 4: Falls, 5: Weight/bulkiness, 6: Noise, 7: Appearance/comfort, 8: Compensative posture/movements, 9: Effectiveness/functionality, 10: Stability/dependability, 11: Usage, 12: Donning/doffing, 13: Cost, 14: Rejection rate
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EBPG Rating/Evaluation of Studies – Please see Appendix 3: EBPG levels of evidence

Appendix 3

WorkSafeBC Evidence-Based Practice Group levels of evidence adapted from 1,2,3,4

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

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