Sensor Walk White Paper

QUALITY FOR LIFE

Executive Summary

Sensor Walk, a microprocessor- controlled stance control orthosis (SCO), provides the clinical benefits of a more natural gait. Developed by Otto Bock HealthCare in conjunction with Mayo Clinic, this knee-ankle-foot orthosis (KAFO) is designed to improve quality of life for patients by making it easier and more secure to walk when the patient exhibits knee instability during weight bearing. Through state-of-the-art technology, Sensor Walk enhances stability during stance phase and provides stumble recovery by anticipating the need for stance stability even before the foot is in contact with the ground amid the swing phase of gait.

In research involving the functional prototype for Sensor Walk, Mayo Clinic concluded that the microprocessor SCO:

- Immediately provided significant improvements in kinetic and kinematic measures vs. a locked KAFO for new users.
- Provided significant gains in kinetic and kinematic measures vs. a locked KAFO within three to six months for experienced KAFO users.
- Allowed a normal knee-flexion pattern during the swing phase.
- Overcame the typical pattern of KAFO rejection by providing patients with enhanced outcomes.
- Made walking more energy-efficient vs. a locked KAFO by allowing the knee to flex freely during the swing phase.
- Accommodated patients who could not use other SCOs because of their weight, flexion contracture, or poor genu varum-valgum alignment.

Why Stance Control?

A traditional KAFO can lock the knee in full extension, which provides stability but also causes patients to ambulate with a gait deviation that can lead to overuse injuries. This in turn requires more energy to get from point A to point B.

A stance control orthosis (SCO) allows the knee to bend during the swing phase of the gait cycle and blocks knee flexion for stability during the stance phase. By allowing the knee to bend during swing phase, SCOs allow a more normal gait, which may reduce secondary complications from gait compensations, and allow the patient to walk with less effort.

SCOs are available in three types of mechanisms:

1. **Weight-activated.** This mechanical SCO locks with knee extension and SCO contact with the ground. It releases with knee extension movement in Terminal Stance/Preswing.
2. **Gait-activated.** This mechanical SCO locks with knee extension. It releases with knee extension and dorsiflexion in Terminal Stance/Preswing.
3. **Microprocessor-controlled.** An electronic control system locks and unlocks the SCO, based on sensor inputs. Input from both knee and foot contribute to engaging and disengaging of flexion blocking mechanism.

Introduction

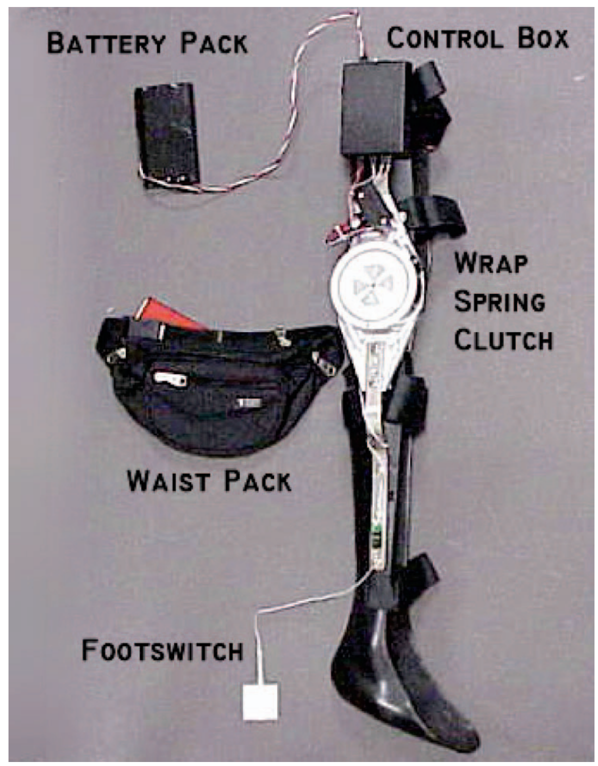
An estimated 989,000 Americans wear a KAFO, according to a 1997 study. This includes people diagnosed with polio, stroke, neuropathies, spinal cord injuries, neurovascular trauma, spina bifida, multiple sclerosis, muscular dystrophy and other neurological or development defects.

The introduction of stance control orthoses is the first significant advance in KAFOs since braces switched from metal and leather to thermoplastics in the 1970s.

Orthotists choose the appropriate SCO by matching the device's function to how the patient presents clinically as it pertains to muscle strength, range of motion assessment, and cognitive abilities. Similar to a prosthesis, use of a stance control orthosis requires in-depth assessment of the patient's presentation, attention to detail for fitting the device, and regular follow-up to ensure the SCO engages and releases at the correct periods in the gait cycle.

Dr. David Sutherland, a pediatric orthopedist with Children's Hospital in San Diego and the University of California, San Diego, led the initial development of a KAFO with a wrap spring clutch design at the knee joint. Physicians in Mayo Clinic's Division of Orthopedic Research in Rochester, Minnesota, later built on Sutherland's work. Mayo Clinic eventually designed six iterations of an electromechanical stance control orthosis, which provided stability in the stance phase of the gait cycle and allowed unhampered knee motion in the swing phase.

Mayo Clinic
Sensor Walk Prototype



Funding

Funding from the National Center for Medical Rehabilitation Research in the National Institute for Child Health and Human Development supported Mayo's design efforts and clinical testing.

The Mayo device included a standard polypropylene shell KAFO; two sensors–at the knee to measure knee angle and at the footplate to measure load between the foot and floor; a wrap spring clutch replacing the lateral knee joint to provide braking capability to support the anatomic knee joint; a microprocessor- controlled release for the clutch; electronic circuitry; and a battery pack carried in a waist pack.

Sensor Walk

Introducing Sensor Walk

Mayo Clinic licensed the patents on its functional prototype to Otto Bock HealthCare in 2004. Otto Bock, in conjunction with Mayo Clinic, refined the SCO to improve function and aesthetics. For example, Otto Bock engineers eliminated the waist pack by incorporating a lithium ion battery and all circuitry into the knee joint assembly. They also upgraded from one foot switch to four load cells (the technology used to deploy automobile airbags on impact) to allow customized fitting.

In September 2007, Otto Bock introduced the Sensor Walk Electronic KAFO, featuring:

- Microprocessor control for precise programming customized to the patient's gait.
- Sensors in the footplate that disengage the wrap spring clutch and allow the knee to bend in late stance phase–when weight has been transferred to the contralateral side and is ready for single limb support.
- A knee sensor that senses extension of the knee after heel rise and sends a signal to the microprocessor, which in turn stops the actuator, which puts the wrap spring clutch in its passive/flexion blocking state. The Sensor Walk is then ready to block flexion of the knee at any angle. Sensor Walk ensures stability before the foot contacts the ground and throughout the stance phase.
- Three modes–SCO, free swing and locked–to accommodate changes in the patient's ability and special circumstances.
- Manual release that is not inhibited when flexion load is acting on the knee joint. Therefore, it is easier to lock and unlock the joint from stand to sit.
- Automatic lock. When Sensor Walk is turned off, it will block flexion and act as a locked KAFO.

Sensor Walk is the only SCO with all of the following:

- Stance control release as the foot unloads, allowing a more natural gait because knee extension is not required to unlock the joint.
- Initiation of stance control in mid-swing–before contact with the ground–to make walking more secure and to provide stumble recovery.
- Heavy-duty design for a weight limit up to 300 pounds (136 kg).
- Capability to manage knee flexion up to 15°.

Sensor Walk has been prescribed for a variety of conditions, including stroke, polio, bilateral disability and traumatic injuries (to U.S. military personnel). Many patients have converted from a locked KAFO. Using Sensor Walk, many have escaped their wheelchairs, shed their canes, and regained their ability and confidence to climb stairs or walk on uneven terrain.

Sensor Walk

Patient Indications.
Sensor Walk is intended for patients who:

- Exhibit weak or absent quadriceps or knee instability in the sagittal plane while bearing weight during the stance phase of the gait cycle.
- Are able to exhibit a reciprocating gait.
- Have hip flexor strength of at least Grade 3.
- Have a step length over level ground exceeding the length of the opposite foot.
- Have the muscle strength in their torso or pelvis required to swing the Sensor Walk forward while walking in the absence of Grade 3 hip flexors.
- For bilateral users, patient must exhibit Grade 3 hip abductors.

		Joint Range of Motion			Muscle Strength*			Joint Deviations**	
	Weight	Hip	Knee	Ankle	Hip	Knee	Ankle	Knee Valgum/Varum	Ankle Valgus/Varus
Sensor Walk	Up to 300 lbs (136 kg)	Accommodates full R.O.M.	Up to 15° knee flexion contracture	Accommodates full R.O.M. No minimum patient requirements	Flex 3-5 Ext 0-5	Flex 0-5 Ext 0-5	Flex 0-5 Ext 0-5	Accommodates up to 10° valgum/varum	No minimum patient requirements

*Based on Kendall and Kendall scale presented in "Muscle Testing and Function," Williams and Wilkins Co., ©1971. Five-point grading system: 5 = Motion against gravity, with full resistance; 4 = Motion against gravity, with some resistance; 3 = Motion against gravity, with no resistance; 2 = Motion, with gravity omitted; 1 = Some muscle contractility with no joint motion; 0 = No muscle contractility.
**Indicates whether the device accommodates the degree of corrected joint deviation, from anatomical neutral position.

Research Highlights Advantages in Sensor Walk

To test the Sensor Walk prototype, Mayo Clinic's Motion Analysis Laboratory conducted several studies, all but one involving actual KAFO users. Five articles based on Mayo Clinic research document the device's performance and the real-life advantages it offers to patients who need a KAFO.

Instant Improvement for New KAFO Users

In the first quantitative analysis of an SCO, Mayo Clinic used automated 3-D motion analysis to compare the Sensor Walk prototype to a locked KAFO. Kinematic measures focused on three primary compensations for stiff-knee gait: hip hike (pelvic obliquity), circumduction (hip abduction) and vault (contralateral ankle plantarflexion in stance). Kinetic measures looked at velocity, cadence and stride length.

The authors concluded that novice KAFO users "demonstrated significant improvements" with the Sensor Walk prototype compared to a locked KAFO.

"Novice users showed significant changes between the locked KAFO and SCO conditions for three of the four [kinetic] measures"–velocity, cadence and stride length, the authors said. Single- limb support time also increased with the prototype.

Kinematic data indicated that the prototype significantly reduced gait compensations. "Both novice and experienced users demonstrated increased peak knee flexion in swing, with a concomitant reduction in compensatory motions such as vaulting and dynamic pelvic obliquity," the authors wrote. They made the following conclusions about the Sensor Walk prototype:

- "Maximum pelvic obliquity for the novice group was significantly reduced …"
- "Hip flexion was significantly increased for the novice group …"
- "Dynamic knee range of motion was significantly increased" for novice and experienced groups.
- Maximum contralateral ankle plantarflexion was "significantly reduced" for both experienced and novice users.

The authors noted that limited time to adjust to the prototype affected results for experienced KAFO users. Having developed "ingrained compensatory movement patterns" from walking with a locked KAFO for as much as decades, many experienced users "tended to adopt a more cautious walking pattern" with the prototype, the authors wrote.

Solutions in Stance Control

In striving to provide the most favorable outcome for patients, Otto Bock has developed three models of stance control orthosis (SCO):

Sensor Walk. A microprocessor-controlled SCO for patients with flaccid paralysis/paresis of the knee extensor(s) and hip extensor(s) plus intermittent lack of full knee extension. Sensor Walk provides exceptional stability by blocking flexion with the knee in any position–a feature that provides stumble recovery and security while walking on uneven terrain or ramps in stance control mode. Users don't need knee extension to unlock the knee joint.

E-MAG Active. An electronic SCO for patients with flaccid paralysis/paresis of the knee extensors and limited ankle range of motion. Patients must have hip extensors and flexors of muscle grade 3 to 5. The E-MAG Active controller is calibrated to capture the user's unique gait pattern. A gyroscope monitors the position of the user's leg and signals the knee joint to unlock for swing.

FreeWalk. A mechanical, gait-activated SCO for patients with flaccid paralysis/paresis of the knee extensor. This lightweight SCO automatically locks with knee extension and unlocks for swing phase after ankle dorsiflexion of 10°.

Significant Gait Benefits Over Time

A clinical field trial at Mayo Clinic concluded that the Sensor Walk prototype provided "significant gains" in walking velocity, cadence, stride length and knee flexion within three to six months for experienced and novice KAFO users.

"All users benefited from SCO use, demonstrating significant improvements in temporodistance factors at 3 months," the authors wrote. In addition, "all subjects significantly increased peak knee flexion … They also tended to increase hip flexion …"

Given an adjustment period, experienced KAFO users "demonstrated a significant increase in peak knee flexion" and "tended to increase velocity … This was combined with a significant increase in cadence."

The authors concluded that, since some experienced users achieved significant change in kinematic variables with the prototype at the six-month mark, a minimum of three months may be required "to realize objective kinematic benefits of SCO technology."

Participant Demographics

ID#	Gender	Age (yrs)	Height (m)	BMI	Diagnosis	KAFO experience (Yrs)	KAFO Ankle
1	M	60	1.79	29.9	Polio	No recent use	Free
2	M	70	1.71	24.7	Polio/MS	No recent use	Rigid
3	F	51	1.59	29.9	Polio	No recent use	Free
4	M	68	1.72	34.0	Polio	No recent use	Rigid
5	M	56	1.72	20.6	Polio	No recent use	Free
6	M	76	1.68	27.1	Polio	No recent use	Free
7	M	11	1.68	26.0	Polio	6	Rigid
8	M	46	1.85	31.8	Industrial accident/ peripheral neuropathy	10	Free
9	M	39	1.63	19.2	Polio	37	Free
10	F	55	1.65	22.8	Polio	18	Rigid
11	M	33	1.70	25.2	Incomplete SCI	14	Free
12	M	54	1.80	29.7	Polio	50	Free
13	F	47	1.61	38.4	MS	No recent use, wears sport orthosis	Free
14	M	63	1.83	38.0	Limb girdle disease (muscular dystrophy)	No recent use	Free

Allowing Normal Knee Flexion

The same study noted that, unlike other SCOs, the Sensor Walk prototype was able to disengage under load to allow normal knee flexion late in the stance phase:

"Furthermore, this study documents the knee joint moment at the instant of foot-off … This net moment would tend to collapse the knee and cause binding of most locking mechanisms. … During gait the position of the limb just before foot-off (pre-swing) creates an extrinsic knee flexion moment as confirmed by this laboratory data. The wrap spring clutch is able to disengage under this load allowing a normal knee flexion pattern. Other self-engaging mechanisms cannot provide this functionality."

Achieving Patient Satisfaction

A standardized survey of patients using the Sensor Walk prototype, administered by Mayo Clinic as part of a larger field trial study, indicated that "the subject population was happy with the operation and stability …"

The authors cited past studies documenting the historically high rejection rate for KAFOs. Between 58 percent and 79 percent of KAFO users stop using their orthosis, and over 40 percent of users state they are dissatisfied with their orthosis. Frequency of use mirrors satisfaction levels, with effectiveness, operability and dependability the most important criteria for meeting the user's expectations.

In the Mayo survey of patients using the Sensor Walk prototype:

- The prototype "scored well in areas of effectiveness, operability, and dependability…"
- The prototype "scored well on its own and in comparison to the alternatives of a locked KAFO, free knee orthosis, or none at all."
- The prototype "did not feel as heavy compared to a locked orthosis when the stance control mechanism was activated," according to a number of participants.

Having shown that using an SCO can be a positive experience, the authors added one observation: "Carefully matching a patient's physical capabilities to an appropriate knee joint mechanism can only further improve the experience."

Participant Demographics

Gender	Age (yrs)	BMI	Diagnosis	Current orthosis
M	60	29.9	Polio	None
M	70	24.7	Polio/Multiple sclerosis	None
F	51	34.0	Polio	None
M	68	20.6	Polio	Free
M	56	27.1	Polio	None
M	41	23.2	Spina bifida	Locked
M	76	26.1	Polio	None
F	53	40.1	Incomplete spinal cord injury	Locked
M	11	36.1	Polio	Locked
M	46	31.8	Industrial accident/peripheral neuropathy	Locked
F	65	26.2	Unknown weakness/neuropathy	Free
M	39	19.2	Polio	Locked
F	52	23.9	Polio	Locked
M	68	31.8	Inclusive body myositis	Free
F	55	22.8	Polio	Free
M	33	25.2	Incomplete spinal cord injury	Locked
M	54	29.7	Polio	Locked
F	47	38.4	Multiple sclerosis	Free
M	55	26.1	Polio	Locked
M	63	38.0	Limb girdle muscular dystrophy	None
Average	53	28.7		
St Dev	15	6.1		
Min	11	19.2		
Max	76	40.1		

Walking Requires Less Energy

Evaluation of a post-polio patient at Mayo Clinic indicated that walking with the Sensor Walk prototype "reduced metabolic energy requirements," compared to a locked KAFO.

"[A] KAFO design that allows free-knee motion during swing is effective in lowering the energy required for walking," the authors wrote. The oxygen consumption and energy cost were "significantly lower during free-knee gait," whether on a flat surface or an incline.

The results prompted the authors to advocate a freely moving leg during the swing phase: "The principle presented in this study should be applied to all future KAFO designs. The results of this study are applicable to any patient who suffers from partial or complete paralysis of the lower extremity and requires a KAFO for ambulation."

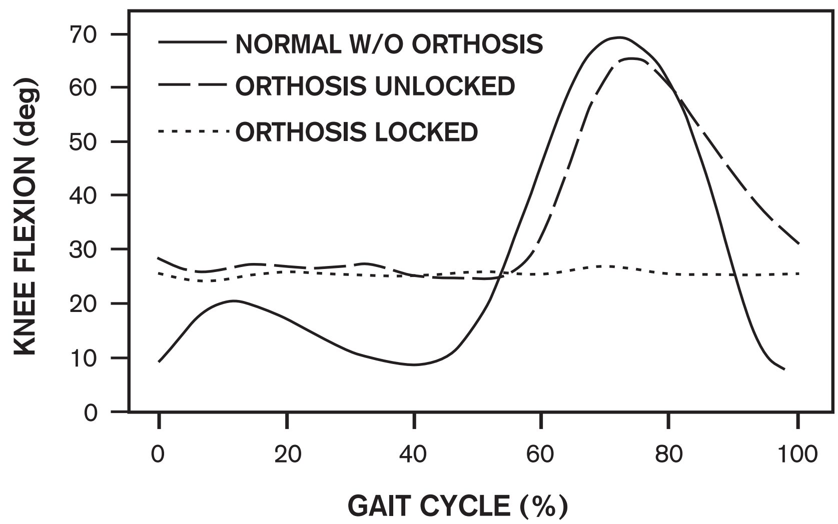
The authors also concluded that the energy cost of locked-knee gait is higher and the gait efficiency lower than previously reported because other studies used healthy adults who could use muscle substitutions to compensate for the immobilized knee or allowed the ankle complete freedom.

Previous studies also indicated that KAFOs are abandoned in favor of wheelchairs because patients found that, even with the aid of an orthosis, walking still required too much energy. Walking with KAFOs is much less energy efficient than normal walking, whereas values for wheelchair propulsion approximate values for normal walking.

Providing Natural Knee Motion

Mayo Clinic's evaluation of a post-polio patient also attributed more normal knee motion to the Sensor Walk prototype.

"Dynamic gait analysis clearly has shown improvements in the knee-motion pattern" while using the prototype, the authors wrote. "The knee swing-phase motion pattern approached the motion of an able-bodied individual when the free-knee algorithm was used to control the knee function of the orthosis."



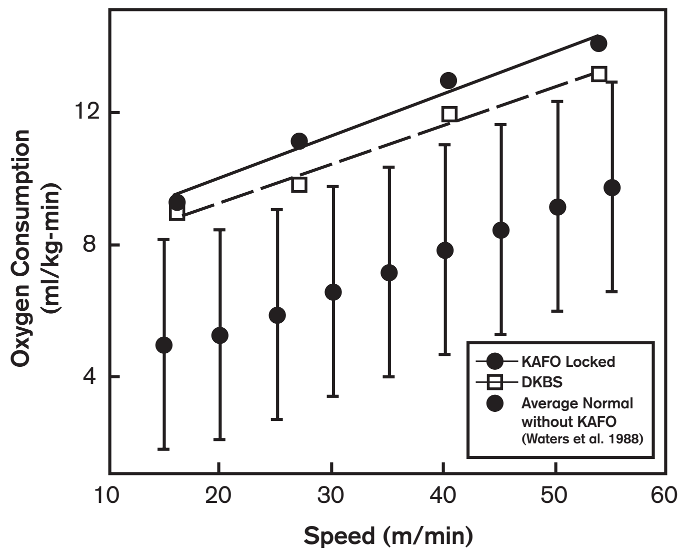
Knee motion when walking with stiff-knee gait (locked) and free-knee gait (unlocked). Both conditions provided a locked, stable knee during stance. The locked condition did not allow knee motion during swing whereas the unlocked condiguration allowed normal knee motion in swing phase.

A More Energy-Efficient Gait

In cardiovascular testing of a healthy, 30-year-old male, Mayo Clinic found that using the Sensor Walk prototype "allowed a more energy efficient gait," compared to a locked KAFO. A locked knee requires gait compensations resulting in increased muscular effort and increased vertical displacement of the body's center of mass.

"Physiological energy studies indicate that significant improvements may be realized by individuals requiring KAFO's for ambulation," the authors said of the prototype.

Oxygen consumption with the locked KAFO was greater than that for the SCO prototype at every treadmill speed above a very slow pace, prompting the authors to comment: "This measure is the most important indicator of [the prototype's] impact on the intended user population because it is an indicator of the intensity of effort required," the authors wrote.



Oxygen consumption rate versus treadmill speed. Linear regression lines indicate trends of the KAFO locked and DKBS data. The oxygen consumption as a function of treadmill speed for the KAFO locked condition was greater than that for DKBS condition (p < 0/05). Average normal values (including 90% confidence intervals) are shown for comparison. Reductions in the oxygen consumption rate, relative to average normal data, ranged from 6% at 16.1 m/min to 22% at 53.6 m/min during DKBS use.

Accommodating More Patients

Multiple studies noted that the Sensor Walk prototype could be the only option for many SCO candidates. Based on the patient selection criteria for commercially available SCOs, "nearly half of the participants in this study would not qualify for at least one of these models because of their weight, the presence of a flexion contracture, or poor varus-valgus alignment," the authors wrote.

Conclusion

Mayo Clinic research indicates that the prototype for Sensor Walk provided numerous advantages over a locked KAFO. By allowing a more natural gait with more normal motions, the prototype made it possible for patients to achieve more energy-efficient ambulation. In addition, allowing the knee to bend during swing phase may prevent the long-term effects of gait compensations associated with a locked KAFO. In addition, Sensor Walk provides the security of enhanced stability and stumble recovery. All of these benefits represent improved quality of life for patients.

Mayo Clinic research also indicates that the Sensor Walk prototype instilled increased patient satisfaction through performance on KAFO users' three most important criteria: effectiveness, operability and reliability. The results suggest that Sensor Walk is a remedy for the historically high rejection rate for KAFOs. Since patients benefit only when using the device, higher satisfaction is likely to result in higher usage. And that will do much to ensure more effective use of healthcare dollars.

Trends and differential use of assistive technology devices: United States, 1994. Russell JN, Hendershot GE, LeClere F, Howie L J. 1997. Advanced data from vital and health statistics; No. 292.

Gait of stance control orthosis users: The Dynamic Knee Brace System. Steven E. Irby, Kathie A. Bernhardt & Kenton R. Kaufman. Prosthetics and Orthotics International, December 2005; 31(4): 269 – 282.

Gait changes over time in stance control orthosis users. Steven E. Irby, Kathie A. Bernhardt & Kenton R. Kaufman. Prosthetics and Orthotics International, December 2007; 31(4): 353 – 361.

Consumer opinions of a stance control knee orthosis. Kathie A. Bernhardt, Steven E. Irby & Kenton R. Kaufman. Prosthetics and Orthotics International, December 2006; 30(3): 246 – 256.

Energy Efficient Knee Ankle Foot Orthosis. Kenton R. Kaufman, S.E. Irby, J.W. Mathewson, R.W. Wirta, D.H. Sutherland. J Prosthetics Orthotics 8(3):79-85, 1996.

Automatic Control Design for a Dynamic Knee-Brace System. Steven E. Irby, Kenton R. Kaufman, James W. Mathewson, and David H. Sutherland. IEEE Transactions on Rehabilitation Engineering, Vol. 7, No. 2, June 1999: 135-139.