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# Knee-Ankle-Foot Orthosis with Controlled Swing and Stance Phase

## New options for users

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**With conventional KAFOs, the knee is locked during the stance phase. This makes it impossible to climb and descend ramps and stairs step-over-step. Ottobock has now introduced an innovative SSCO® system (Stance and Swing Phase Control Orthosis) that enables the patient to bend the knee under load as well. A microprocessor-controlled hydraulic system controls the joint in the stance as well as in the swing phase.**

People with signs of paralysis in the lower limbs often depend on a Knee-Ankle-Foot Orthosis (KAFO). Systems currently in use stabilise the user's affected leg with a conventional knee lock, allowing it to support weight. Due to the lack of functional shortening, walking with a locked orthosis is difficult. Some systems allow the knee joint to be bent in the swing phase. While such a Stance Control Orthosis (SCO) offers a gain in functionality, these SCOs, due to the nature of the system, have to be mechanically locked by means of sufficient knee extension before the beginning of the stance phase, and they are unable to respond to changing loads when the swing phase is terminated.

Something both systems have in common is that the knee is locked under load, and can only be moved or bent when unloaded. For the user this means that knee flexion under load is not possible--with the further result that walking naturally on ramps and descending stairs step-over-step is not possible.

## Mechatronics eliminate former restrictions

With the C-Brace®, Ottobock is presenting the first orthosis system that allows the flexion resistance of the knee joint to be regulated, almost continuously, by mechatronics. This means the former limitations due to locks in the knee joint are a thing of the past. The C-Brace® is presently the only orthosis system with microprocessor-controlled hydraulics that control the leg both in the stance and in the swing phase – hence the name Stance and Swing Control Orthosis (SSCO®). This provides tremendous relief for the user in everyday life. The mechatronics of the SSCO® make new movement patterns possible for the user, for example while walking on slopes or inclines, when sitting down while supporting weight on the affected leg, and when walking down stairs. Bending the knee with the SSCO® closely approximates the natural movement pattern of a sound leg. This makes all forms of walking easier. On level ground, the possibility of stance phase flexion results in a more natural and steadier gait pattern.

## Benefits are noticed immediately

The aspect of safety and self-confidence must not be underestimated. The user no longer has to focus on the impaired leg, which previously often stood in the way of a physiological movement pattern. Users are supported with intensive gait training by orthotists and therapists. Success in the training phase helps the user gain confidence in the system quickly. Here the adaptation period depends on the underlying indication and its severity as well as the preceding fitting. If the patient is still able to access a stored natural gait pattern, adaptation proceeds much more quickly when compared to users who have used other devices for many years.

## The user sets the pace

One might say that the SSCO® is based on a philosophy: it is intended to provide the user with as much support as necessary, but without interfering with the physiological movement pattern of the knee joint. Since the control characteristics are adjusted through software, the system can be adapted to the individual needs of the user.

The system is passive, which means there are no motors to drive or move the user. The orthosis moves via the body's own energy, which means that residual functions such as sufficient torso stability are required in order to enable a controlled swing-through of the leg.

## The „thinking“ orthosis system

From a technical perspective, the stance and swing phase control orthosis system represents a technology leap in orthotics. It is the first to control the entire gait cycle in a physiologically manner in real time. This is essentially made possible by the interaction of three technology elements:

The knee joint is controlled by a linear hydraulic cylinder that acts as a damper. The movement energy has to be provided by the user with residual functions of the musculature or with compensatory movements. It is merely redirected and controlled by the system (Fig. 1).

A sensor is integrated in the knee joint to measure the knee angle and angular velocity. A fibre composite spring with integrated ankle moment sensor is installed on the lower leg. It stores deformation energy during the rollover process in the stance phase, releasing it to support the initiation of the swing phase. An integrated moment sensor measures the bending moment in the area of the ankle and supplies an additional control signal for the SSCO®.

The signals that are transmitted are processed in an electronic control unit. It generates the control signals for the valves of the hydraulics, continuously adjusting the resistance in the joint to match the movement situation.

The „response time“ of the system at 20 ms is below the threshold of human perception. Thus, from the user's perspective, the SSCO® responds in real time.

## Individually adjustable

In order to obtain optimum functionality from the SSCO® for the user, the behaviour of the system is adapted to the user's individual requirements with the help of PC software and a Bluetooth connection. For example, the requirements when walking downhill are not the same as those for walking on level ground: while walking downhill, the flexion resistance is set to high in order to enable controlled bending of the knee joint. In principle the orthosis is always in „secure stance phase“ mode. When the microprocessor determines, based on the sensor signals, that the user is walking on level ground, the behaviour is adjusted immediately and the knee joint releases in real time for flexion in the swing phase.

Following the individual adaptation of the control unit, the system always behaves the same way. Fine-tuning, the need for which only becomes apparent in the course of day-to-day use, can be performed by the orthotist.

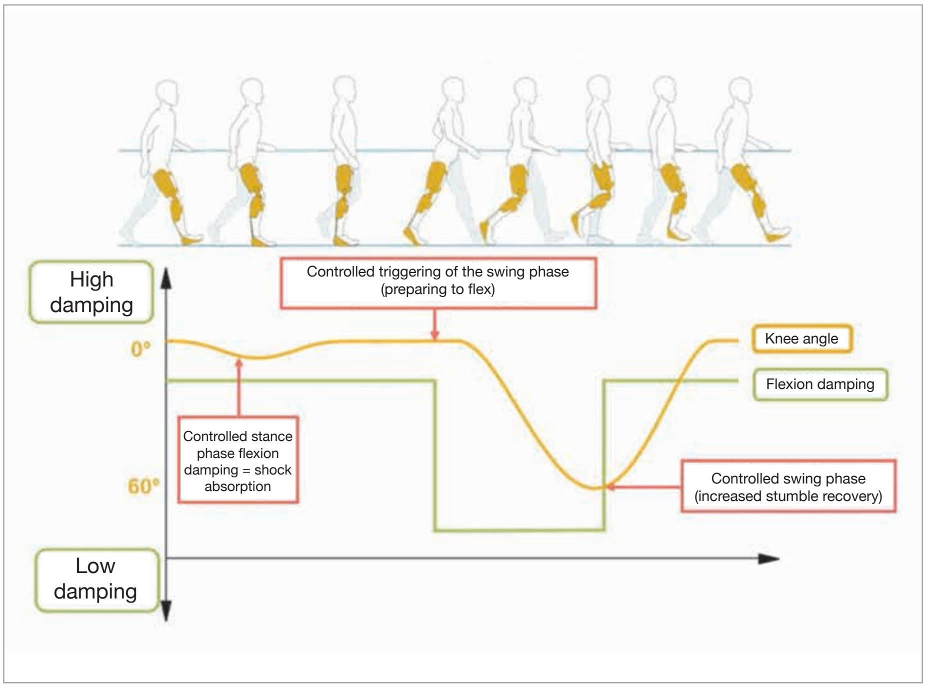


*Fig. 1: Course of the knee angle and damping behaviour.*

## Biomechanical studies and results

The functionality of the SSCO® was verified in the course of biomechanical gait laboratory testing. Six test subjects of various ages, body sizes and weights were tested. All of them used an orthosis or wheelchair due to weakened muscle groups. One test subject was previously fitted with an AFO, three with KAFOs (two of them with SCOs) and two were wheelchair users. The underlying indications were post-polio in one case, condition after spondylodesis in one case, and incomplete paraplegia in four cases. Each of the test subjects was fitted with a custom-made SSCO® (five unilateral, one bilateral) and trained in the use of the system. Walking on level ground, walking on ramps (10°) and walking down stairs both with the SSCO® and also (where possible) with the previous fitting (SCO, locking joint) were measured.

A gait analysis with the existing orthosis was performed on the first day of testing. Then the test subjects were fitted with the C-Brace® orthotronic mobility system. This was followed by gait training, where all functions were practiced with the support of a physiotherapist. The biomechanical tests with the SSCO® were performed on the second day of testing. Evaluating the data returned the following results: with the SSCO®, an improvement in the symmetry of the gait pattern compared to the original fitting was observed in all test subjects.

Five out of six test subjects utilised stance phase flexion while walking on level ground. This function allows the knee joint to flex slightly after heel strike, softening the impact before the knee joint goes back into extension in the mid-stance phase. This makes for a smoother gait.

While walking down ramps and stairs, five out of six test subjects used stance phase flexion in order to complete this task with a „normal“ step-over-step gait. Compared to conven-

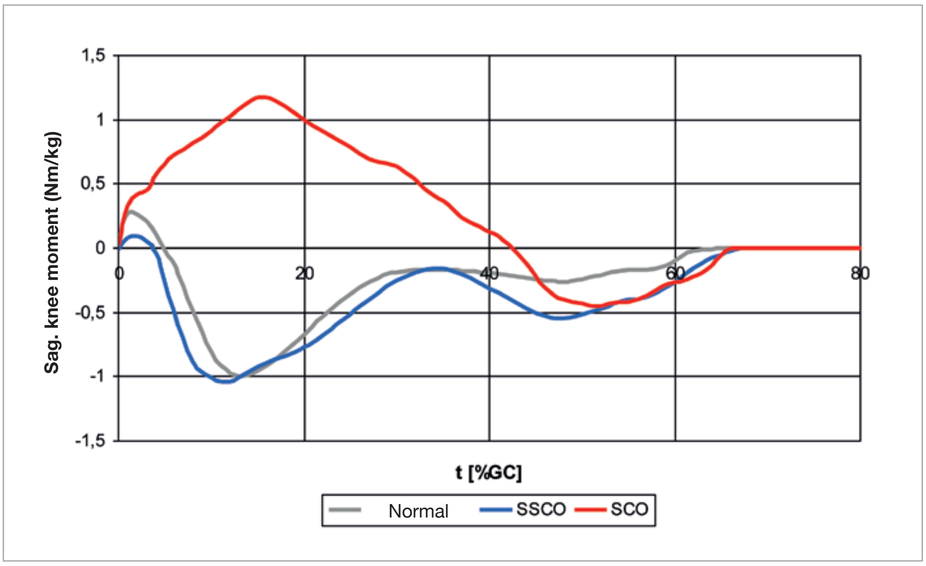


*Fig. 2: Load on the contralateral side while walking down a ramp.*

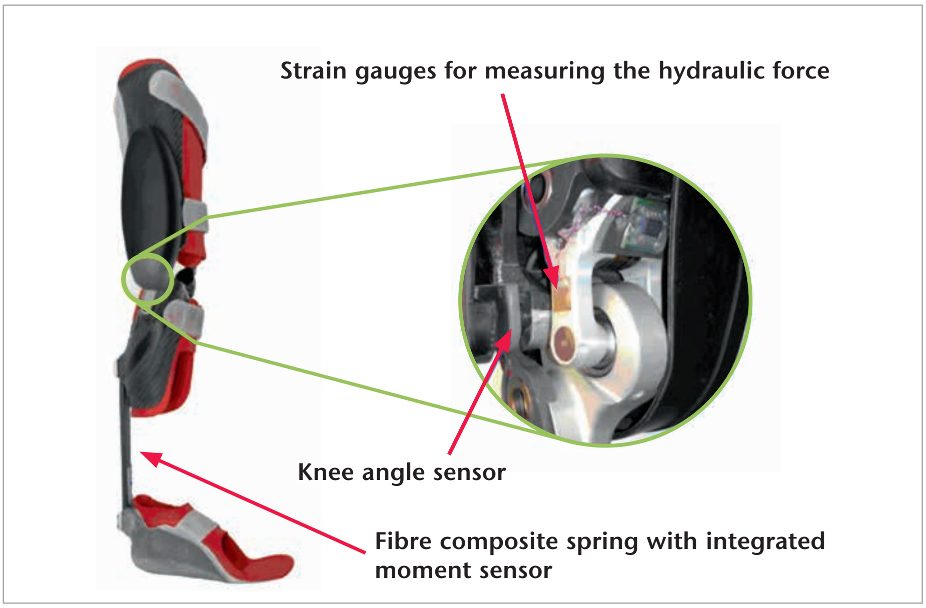


*Fig. 3: Strain gauges for measuring the hydraulic force.*

tional orthoses (where sideways steps are usually used in this situation), this results in a higher walking speed and improved safety.

The biomechanical studies indicate a significant reduction of strain on the contralateral side (which is usually less affected by paralysis).

The diagram below (Fig. 2) shows an example of the sagittal knee moment on the contralateral side for a user walking down a ramp as well as the physiological strain gradient of a healthy person (as a reference). It is striking to note how closely the load situation with the SSCO® approximates the physiological strain gradient, while pronounced deviations are noted with a standard SCO. The unnatural load is unavoidable with the SCO system, since contralateral contact can often be made only with the forefoot due to the lack of stance phase flexion. This shifts the force application point forward, resulting in tremendously high extension moments on the knee joint in the first part of the stance phase. The C-Brace® function that allows knee bending under load can drastically reduce the need for this compensating mechanism, which can cause joint damage over time.

A modified knee joint, which was equipped with additional strain gauges to measure the hydraulic force (Fig. 3) was used on some test subjects.

The applied knee moment was calculated from the hydraulic force and knee angle, allowing conclusions to be drawn about the actual load and energy turnover of the system. The control behaviour was not influenced by these additional sensors.

The measurements with the additional strain gauges showed a significant energy turnover, especially when walking down ramps and stairs. For a user with a weight of 85 kg, approx. 50 joules were dissipated per step in the hydraulics while on the stairs. The maximum output generated to control the knee joint in this case was 262 watts with a maximum knee moment of 89 Nm.

The maximum ankle moment develops when walking up the ramp. With the test subject in question, the maximum moment in this situation was around 61 Nm which corresponded to energy of about 7.5 joules stored in the spring with the system configuration that was used.

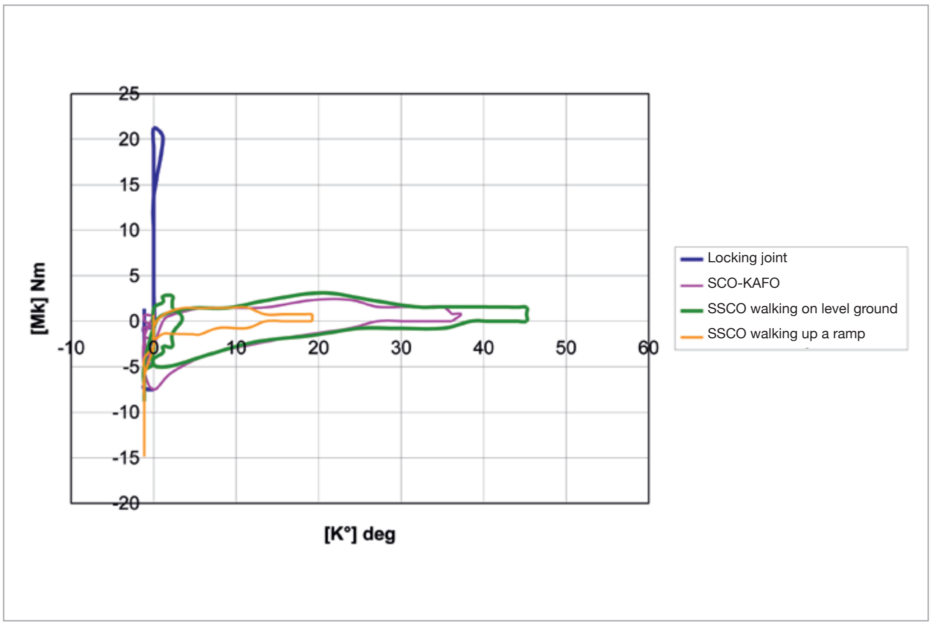


*Fig. 4: Knee moments comparison.*

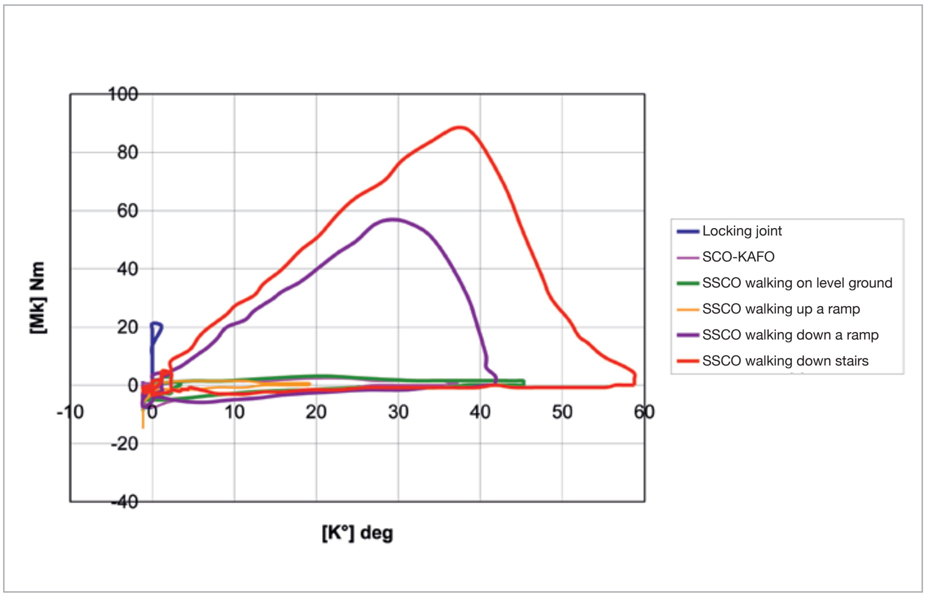


***Fig. 5:** Strain gauges for measuring the hydraulic force.*

This energy is subsequently released to help initiate the swing phase, which provides significant relief for the user due to increased ground clearance during swing-through.

The diagrams that follow illustrate the loads generated during knee flexion in the SSCO® for certain movement patterns (Fig. 4). In the illustrations, the respective knee moment absorbed by the orthosis is applied over the knee angle. Positive moments correspond to knee flexion and negative moments to knee extension.

The blue curve simulates the behaviour of a locking joint where knee flexion was blocked. As expected, the curve is almost a vertical line (constant knee angle). A significant knee flexion moment occurs due to the locked swing phase. This is no longer observed with the remaining tests where a free swing phase was enabled.

The additional small loop in the green curve is interesting (walking on level ground with SSCO® functionality): it illustrates the stance phase flexion cycle while walking on level ground with SSCO® functionality. After heel strike, the knee is flexed briefly and extended again before flexion in the swing phase takes place.

While walking up ramps, an elevated extension moment was observed before initiating the swing phase.

A diagram with a different scale is needed to illustrate the loads while walking down ramps and stairs (Fig. 5).

The data from the preceding diagram (activities on level ground) were entered as well for comparison. The red line represents the measurements while walking down stairs. Here the resulting loads are more than four times as high compared to walking on level ground with a locked joint and the orthosis moves significantly at the same time. The area enclosed by the loop is proportional to the energy turnover of the orthosis.

This also results in entirely new requirements for the structural components of the orthosis. Twisting of the orthosis shells has to be minimized in order to assure the axial alignment of the knee joint and medial support, and in order to avoid problems with excessive joint wear. This is why the orthosis shells, which are individually adapted to the user, have to be fabricated using carbon fibre prepreg technology.

## Area of application for SSCO

The C-Brace® orthotronic mobility system was developed for people with lower limb paralysis symptoms that prevent the secure muscular stabilisation of the knee joint. The following limiting factors for application are currently emerging: lack of torso stability, hip flexor force factor less than 3, sagittal and frontal deviations of more than 10°, passive ankle joint mobility of less than 2°, moderate to severe spasticity, cognitive limitations that prevent secure handling of the system, and orthoprostheses.

The market launch of this orthosis technology is currently being prepared for Europe including Germany. The system is already available in the USA.

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