

# Evidence Summary

## LKAFO, KAFO, SCO, C-Brace

### Locked Knee Ankle Foot Orthoses (LKAFOs)

Traditionally, patients with paresis or paralysis of the muscles that stabilize the knee, resulting in a restriction or even loss of walking ability, have been fitted with a knee-ankle-foot-orthosis with a locked orthotic knee joint (LKAFO).

In a LKAFO, the orthotic knee is locked during stance as well as swing phase. Thus, the patient has to walk permanently with a fully extended or “stiff” leg. The orthotic knee joint is only unlocked manually for sitting down and locks again after getting up from sitting. An LKAFO allows for safe standing and walking on level ground. It must be considered, however, that foot clearance of the orthotic leg is remarkably limited and must be compensated for by increased pelvic obliquity, hip hiking and circumduction on the orthotic side during swing (1-3) and/or unphysiologic plantar flexion on the sound side (vaulting) during stance phase (2, 4, 5). Walking with an LKAFO is therefore slower (2-4, 6, 7), requires more metabolic energy (3, 5, 8), and results in higher mechanical stress to the sound leg (2, 3) than walking with an unlocked orthosis. Walking on uneven terrain, slopes, and stairs is uncomfortable and unsafe as a consequence of the “stiff” orthotic leg, as it becomes increasingly difficult to provide sufficient toe clearance. Physiologic, reciprocal ramp/hill and stair descent is impossible with an LKAFO. The orthotic leg must always make the first step as knee flexion during weight bearing can only be provided by the sound leg, resulting in a high risk of stumbling and falling when negotiating non-level surfaces. These technical limitations result in lower patient satisfaction as compared to unlocked orthoses (6, 7, 9).

As the effectiveness of LKAFOs to restore walking ability in patients with paresis/paralysis of the knee stabilizing muscles has been obvious in clinical practice over centuries, no clinical studies to demonstrate their patient benefits could be identified.

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### **Knee Ankle Foot Orthoses (KAFOs) with a posterior off-set knee joint**

In a KAFO with a posterior off-set orthotic knee and an orthotic ankle joint with dorsiflexion stop, the fulcrum of the orthotic knee is off-set posteriorly to the fulcrum of the anatomical knee of the patient. Thus, the vector of the ground reaction force (GRF), which is normally positioned behind the fulcrum of the knee resulting in a (de-stabilizing) knee flexion moment during early stance, is shifted in front of the fulcrum of the orthotic knee joint. That creates a (stabilizing, securing) extension moment on the orthotic knee resulting in extension and stabilization of the orthosis and thus the paretic leg. The dorsiflexion stop in the orthotic ankle joint prevents ventral movement of the calf during mid and terminal stance as well as dorsiflexion of the foot, creating a stabilizing extension moment acting on the orthotic knee joint. All mechanisms depicted above prevent the orthotic knee joint from collapsing during the entire stance phase and allow for safe standing and walking on level ground. During swing, the orthotic knee joint is free allowing for the calf to swing forward. However, the posterior off-set of the orthotic knee joint and the dorsiflexion stop in the orthotic ankle joint result in a too early extension of the orthotic leg during early stance. Moreover, the patient must develop a lot of muscle force to overcome the stabilizing knee extension moment in order to initiate swing. Therefore walking with such an orthosis is exhausting and uncomfortable. A KAFO with a posterior off-set orthotic knee and dorsiflexion stop in the orthotic ankle joint warrants safe standing and walking on level ground only. Standing and walking on uneven ground requires good patient knowledge of the function of the orthosis. As the orthotic knee is not locked and its posterior off-set as well as the dorsiflexion stop in the orthotic ankle joint result in considerable changes in gait biomechanics, the patient has to learn to adapt his/her gait pattern to uneven ground in a way that the orthosis allows for safe standing and walking. That is the more difficult the rougher the terrain becomes. Physiologic, reciprocal ramp/hill and stair descent is not possible with such a KAFO. The orthotic leg must always make the first step, knee flexion must be provided by the sound leg.

As KAFOs with a posterior off-set orthotic knee joint have proven their effectiveness to restore walking ability in patients with paresis/paralysis of the knee stabilizing muscles in clinical practice over more than a hundred years, no clinical studies to demonstrate their patient benefits could be identified.

#### References

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### Stance Control Orthoses (SCOs)

In contrast to the standard KAFOs described above, there are stance control orthoses (SCO), which use various technical switching mechanisms to allow locking the orthotic knee joint during stance for safe standing and walking as well as unlocking it at the end of the stance phase to allow for a free swing phase. The switching between stance and swing phase may be provided by different technical mechanisms (weight, gait, or ankle activated).

Weight activated SCOs lock the orthotic knee joint as soon as there is a weight load on the foot detected by pressure sensors in the insole of the foot part. The orthotic knee is unlocked for swing phase if the foot is relieved or the weight load falls short of a pre-defined threshold or the orthosis detects a shift in weight loads from heel to forefoot that can be attributed to walking.

Gait activated SCOs lock the orthotic knee for stance phase when they reach full extension at the end of swing phase and unlock it at the end of stance when it reaches a pre-set angle relative to the ground (Swing Phase Lock) or hip (E-MAG Active) of the patient.

Ankle activated SCOs are controlled by movements of the tibia relative to the foot resulting in unlocking the orthotic knee at the end of stance for swing. The orthotic knee is locked for stance if the unloaded orthosis reaches full extension.

A systematic review of the scientific literature on patient benefits of stance control orthoses (1) found that, compared to locked KAFOs (LKAFO), SCOs reduce or eliminate the need for compensatory movements such as pelvic obliquity, hip hiking and circumduction on the orthotic side (2-4), vaulting on the sound side (1, 3, 5, 6), allow for higher walking speed (1, 3-5, 7, 8) and reduce metabolic energy consumption (1, 4, 6, 9) and mechanical stress to the sound limb (1, 3, 4). These benefits result in a higher patient satisfaction with SCOs than with LKAFOs (1, 5, 7, 10). However, all of these studies have only been conducted in level walking, reflecting the fact that stance control orthoses allow for safe and comfortable walking on level ground with nearly constant stride length only. Steps of varying lengths and changes in walking direction may prevent the orthotic knee from reaching the relocking position and may thus cause failure to lock for a safe loading response, resulting in knee collapse. When walking on uneven ground, especially in very rough terrain, it may become very difficult to bring the orthotic knee to full extension in order to lock it for stance. In addition, unlocking the orthotic knee for swing becomes more and more difficult with increasing roughness of the terrain, making walking on uneven ground with that kind of SCOs limitedly safe (weak roughness) to unsafe (strong roughness). Reciprocal ramp/hill and stair descent is not possible with SCOs. The orthotic leg must always make the first step, knee flexion must be provided by the sound leg. That is why many SCO users lock their orthosis for walking on non-level terrain and operate them like an LKAFO.

#### References

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### C-Brace

The C-Brace is a microprocessor stance and swing control leg orthosis. It consists of custom-made carbon fibre thigh and calf shells which are connected by an orthotic knee joint with a microprocessor controlled linear hydraulic damper. The sophisticated control algorithms are fed with 100 Hz inputs an accelerometer, knee angle and hydraulic force sensors. Thus, the microprocessor is able to control two separate valves for knee extension and flexion damping, respectively, using servomotors and a planetary gear set. The C-Brace is the first leg orthosis to allow for stance phase control including nearly physiologic stance flexion during level walking to reduce or even eliminate compensatory movements, knee flexion during weight bearing as required for reciprocal slope and stair descent and negotiation of uneven terrain, and stumble recovery. Its advanced swing phase control supports walking with a wide variety of different gait velocities. The adjustment of the orthosis to the needs of the patient is done by a certified orthotist using specialized control software.

With its microprocessor controlled hydraulic unit, the C-Brace makes the well-known benefits of microprocessor controlled hydraulic prosthetic knee joints to above-knee amputees now available to leg orthosis dependent patients for the first time. In a first study that compared the benefits of using the C-Brace with the use of locked knee-ankle-foot (LKAFO) and stance control orthoses (SCO), all patients were able to walk with the C-Brace without problems. Compared to only relative movements between the limb and the orthosis in locked and stance control orthosis use, a nearly physiologic stance knee flexion (mean value  $11^{\circ} \pm 5.6^{\circ}$ ) was seen in level walking with the C-Brace. The maximum swing knee flexion with the MP swing controlled C-Brace was close to the value of  $65^{\circ}$  in sound subjects and thus more physiologic than in the free but uncontrolled swing phase in stance control orthoses ( $66^{\circ} \pm 8.5^{\circ}$  vs  $74^{\circ} \pm 6.4^{\circ}$ ). Control of maximum knee swing flexion is necessary to provide

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sufficient toe clearance and prevent tripping and stumbling. Unlike with locked and stance control orthoses, all patients were able to descend ramps and stairs using reciprocal gait with the C-Brace (flexion angles  $64.6^{\circ} \pm 8.2^{\circ}$  and  $70.5^{\circ} \pm 12.4^{\circ}$ , respectively).

In conclusion, the results of this study demonstrate that users of locked and stance control orthoses are able to utilize the situation-dependent knee flexion during weight bearing offered by the C-Brace with a high level of confidence (1).

Another study surveyed the perceived orthotic function as well as perceived difficulty and safety of performing activities of daily living with the C-Brace as compared to LKAFO and SCO use. Orthotic function as measured with the modified Prosthesis Evaluation Questionnaire demonstrated significant improvements by C-Brace use in the overall orthotic function ( $p=.02$ ) as well as in the subdomains of ambulation ( $p=.001$ ), paretic limb health ( $p=.04$ ), sounds ( $p=.02$ ), and well-being ( $p=.01$ ). The analysis of the mean perceived difficulty of 45 ADLs showed that 22 activities were rated significantly easier to perform with the C-Brace than with the previous devices combined. In the subgroup of previous SCO users, 5 activities were significantly easier to execute with the C-Brace, and another 13 activities showed a trend towards easier execution with  $p$ -values  $\leq .09$ . The previous LKAFO users rated 12 activities as significantly easier to perform with the C-Brace, while another 9 activities presented a trend towards greater ease of execution with  $p$ -values  $\leq .09$ . Of the responses for perceived comparative safety, 59% demonstrated a safer execution of ADLs with the C-Brace (2).

A recently finished, yet to be published study with 18 subjects found that the C-Brace, compared to locked KAFOs and SCOs, reduced the number of self-reported falls, significantly improved balance as assessed with the Berg Balance Scale, increased self-selected walking speed and distance walked in the 6-minute walk test, and improved the quality of slope and stair ambulation.

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