Technology advancement in custom orthotics:
The microprocessor stance and swing control orthosis C-brace® improves safety and walking capabilities of KAFO users with leg pareses

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Summary
Patients suffering from pareses of leg muscles, especially those stabilizing the knee, are often dependent on knee ankle foot orthoses (KAFO) to restore their walking ability. Traditionally, KAFOs with locked or posterior off-set orthotic knee joints have been used in these patients. For some decades, stance control orthoses (SCO) that lock the knee joint for stance and release it for free swing have been an orthotic treatment option. Evidence suggests that SCOs deliver remarkable patient benefits as compared to regular locked and posterior off-set KAFOs. As technology advances a microprocessor stance and swing control orthosis (MP-SSCO) – the C-brace® - has been developed to further improve safety and function of KAFO users. This white paper depicts the technology and proven patient benefits of regular KAFOs, SCOs as well as the results of a pilot study conducted with the C-brace® in comparison to standard KAFOs and SCOs. The results suggest that the C-brace® with its new technical features leads to a significant improvement in the subjective perception of safety, perceived difficulty of many activities of daily living, as well as overall orthosis function and satisfaction, ambulation, diseased limb health, and well-being. The greatest improvements were verified for the ADL categories Mobility and Transportation and Family and Social Life. This creates the conditions for further improving patients' independence and participation in family, business and social life.
Introduction
Over centuries, patients who have suffered from paresis or paralysis of the muscles that stabilize the knee, e.g. after acute poliomyelitis, incomplete spinal cord injury, or femoral nerve lesions, etc., have been fitted knee ankle foot orthoses (KAFO) to prevent the paretic or paralyzed leg from collapsing and allow the patient for walking. KAFOs with locked or posterior off-set orthotic knee joints have been the standard assistive devices for a very long time. For some decades now, stance control orthoses (SCO) have been an orthotic option, too. They enable the user to freely swing his leg in the swing phase but are locked for the stance phase, giving the patient the same degree of security as locked knee ankle foot orthoses. However, SCOs have not yet prevailed over locked orthoses to any great extent, mainly due to the fact that their function is still very limited as compared to a sound human leg and even a prosthesis after complete limb loss. A new microprocessor stance and swing control orthosis – the C-brace® – is now aiming at overcoming the traditional technological barriers in orthotics and making the benefits of advanced exoprosthetic technology available to orthotic patients, too. First clinical observations confirm a remarkable gain in safety, function, and walking capabilities when using the C-brace® as compared to regular KAFOs and SCOs. This white paper describes the technology and patient benefits of the different types of KAFOs und SCOs as well as the results of the first clinical observations with the microprocessor stance and swing control orthosis C-brace®.

Mechanism of action and patient benefits of locked Knee Ankle Foot Orthoses (locked KAFOs)
Traditionally, patients who suffer from a paresis or paralysis of the muscles that stabilize the knee resulting in a restriction or loss of walking ability have been fitted with a knee ankle foot orthosis (KAFO) with a locked orthotic knee joint.

In a locked KAFO 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. A locked KAFO 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 by increased pelvic obliquity on the orthotic side during swing and/or unphysiologic plantar flexion on the sound side during stance. Walking on uneven ground is uncomfortable and unsafe as a consequence of the "stiff" orthotic leg. Alternating ramp/hill and stair descent is impossible. The orthotic leg must always make the first step as knee flexion can only be provided by the sound leg.

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

**Mechanism of action and patient benefits of 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 (destabilizing) knee flexion moment during initial 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. 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. 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. Alternating 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.

**Mechanism of action and patient benefits of Stance Control Orthoses (SCOs)**

In contrast to the standard KAFOs described above so called stance control orthoses (SCO) use various technical switching mechanisms to allow for 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 permit a nearly physiologic swing phase. The switching between stance and swing phase may be provided by different technical mechanisms.

Switching mechanisms between stance and swing phase in stance control orthoses:

- weight activated stance control orthoses (e.g. E-knee [Becker Orthopedics], SCOKJ [Horton], NeuroTronic W [Fior&Gentz], SensorWalk [Otto Bock])
- position sensor activated stance control orthoses (e.g. E-MAG Active [Otto Bock], Swing Phase Lock [Basko])
- ankle activated stance control orthoses (e.g. Free Walk [Otto Bock], UTX [Ambroise], Full Stride /Safety Stride [Becker Orthopedics], Neuromatic [Fior & Gentz])

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.

Position sensor activated SCOs lock the orthotic knee for stance phase if it reaches full extension at the end of swing and unlock it at the end of stance if it reaches a preset 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.

Stance control orthoses may also be differentiated by knee angles in which they are able to lock the orthotic knee for stance. Most SCOs available on the market are able to lock the orthotic knee only in full (180°) extension (e.g. Free Walk, UTX, E-MAG Active, Swing Phase Lock). Those orthoses permit safe standing on all kinds of grounds and terrains, but safe walking on level ground only. 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). Alternating ramp/hill and stair descent is not possible with such a SCO. The orthotic leg must always make the first step, knee flexion must be provided by the sound leg.

The E-knee [Becker Orthopedics], die SCOKJ [Horton], Neuromatic, Neuro Tronic W [both Fior & Gentz] as well as the SensorWalk [Otto Bock USA) orthoses are able to lock the orthotic knee in a flexed position. Some also allow for extension of the orthotic knee during stance while the knee flexion lock is still engaged. These SCOs enable safe standing and walking on all different kinds of grounds. However, all stance control orthoses have in common that they do not support knee flexion under
weight bearing. Therefore alternating descent of ramps/hills and stairs is still not possible with SCOs. The orthotic leg must always make the first step, knee flexion must be provided by the sound leg.

A recently published systematic review of the scientific literature on patient benefits of stance control orthoses (1) found that despite the limited methodological quality of the studies, there are clear indications of a medical benefit from stance control orthoses in comparison to locked KAFOs. The great majority of publications tend to produce very similar results, which usually failed to reach the statistically significant level only due to the low number of patients. The medical benefit of a stance control orthosis can be described in three categories (1):

General Benefits
- More physiological gait pattern
- Reduction of compensatory movements
- Greater walking speed
- Lower energy consumption
- Greater patient satisfaction

Benefits for the Affected (Orthotic) Side
- Knee flexion and greater range of motion for the knee in the swing phase with greater ground clearance when walking
- Lower pelvic obliquity

Benefits for the Sound Side
- Plantar flexion to achieve greater ground clearance on the orthotic side is reduced to eliminated
- Elimination of pelvic obliquity in the stance phase
Technical description of the microprocessor stance and swing control orthosis C-brace®

The C-Brace is a microprocessor stance and swing control knee ankle foot orthosis (SSC KAFO). It consists of custom made to measure carbon fibre thigh and calf shells which are connected by a monocentric orthotic knee joint with a linear hydraulic damper (similar to the exoprosthetic C-leg® system). Extension and flexion damping is controlled separately using two valves. These valves are adjusted at a frequency of 50 Hz by servomotors and a planetary gear set. At the calf portion there is a carbon fibre strut connecting the knee unit with the foot part.

Figure 1: The construction of the C-brace®

The hydraulic C-leg® unit controls the knee moments. Thus it is able to control stance phase (to improve safety) as well as swing phase (to harmonize gait) in order to deliver optimal walking function to the patient.

The hydraulic creates braking moments by converting kinetic energy to heat. To prevent excessive heat and burns temperature monitoring is integrated in the system to give an acoustic alarm and stiffen the knee unit in case of excessive heat.
In order to improve energy efficiency the orthosis is equipped with a carbon fibre strut at the dorsal part of the calf shell. That strut is loaded during stance and returns the saved energy at initiation of swing. The hydraulic and electronic components of the C-brace are identical to those used in the C-leg® microprocessor controlled prosthetic knee. Communication between the components works by analogue signals as well as via SPI. The embedded software of the C-brace is the same as for the C-leg®.

The hydraulic damping is microprocessor controlled. The signals of the sensors are converted to target values for the adjustment of the valves by a state machine at a frequency of 20 Hz (current C-leg® technology). So called rule sets define the function of the state machine. The control is programmed in an integrated microprocessor. Input signals for control are the ankle moment measured inside the dorsal carbon fibre strut by integrated strain gauges, the knee angle, the knee angle velocity, and the temperature of the hydraulic.

The C-brace allows for walking with knee flexion under load (weight bearing), i.e. the more physiologic walking with a flexed or even slightly yielding knee joint (shock absorption), safe walking on uneven ground as well as alternating descent of ramps and stairs.

The adjustment of the orthosis to the needs of the patient is done using the C-leg® software that guides the CPO to optimal individual adjustments.

**Mechanism of action and patient benefits of the C-brace®**

The C-brace is a stance and swing control orthosis with a monocentric orthotic knee joint with a microprocessor controlled hydraulic damper as known from exoprosthetics (C-leg®). As the C-brace® uses C-leg® technology it warrants the unmet safety of the safest prosthetic knee joint available (2-4) and prevents the orthotic knee from collapsing while standing and walking on all different kinds of grounds. As it also allows for knee flexion under weight bearing it may enable patients with pareses/paralysis of knee stabilizing muscles for the first time to alternately descend ramps/hills and stairs.
Pilot study with the C-brace®

Patient sample
Six patients using the C-brace (out of 10 who have been fitted globally in total so far) have been followed-up systematically.
Five of these patients were men, one woman, the mean age was 59.2 ± 18.0 years.
Four patients were poliomyelitis survivors, one patient suffered from an incomplete spinal cord injury at the level of T10, and one patient had a peripheral lesion of the femoral nerve as a complication of hip surgery. Manual muscle testing demonstrated a unilateral severe paresis or even paralysis of the quadriceps muscle in all patients, in two patients each combined with a paresis of hip or calf muscles, respectively. All patients were dependent on KAFOs, three patients were using a locked KAFO and three patients a stance control orthosis (2 E-MAG Active [Otto Bock], 1 SPL-2 [Basko]). Average time since first orthosis fitting was 28.8 ± 23.2 years.

Methodology
As there are no validated outcome measures for KAFO use the Prosthesis Evaluation Questionnaire (PEQ) validated for measuring outcomes in lower limb prosthetics was modified for use in lower limb orthotics, creating an Orthosis Evaluation Questionnaire (OEQ). It consists of 81 questions to be answered by the patients on a 100 mm Visual Analogue Scale (VAS) with higher values representing better function and outcome. In addition to the total score and in analogy to the PEQ, the OEQ may be divided into nine sub-scales for ambulation, appearance, frustration, perceived response, diseased limb health, social burden, sounds, utility, and well-being.

Moreover, a questionnaire asking the patients to rate the importance and comparative perceived safety and difficulty to perform 45 activities of daily living (ADL) with their previous orthosis and the C-brace was developed. The 45 ADLs came from five activity categories: Personal Hygiene and Dressing (4 activities), Family and Social Life (12 activities), Mobility and Transportation (19 activities), Sports (4 activities), and Other Activities (6 activities). The individual ADLs are listed in figures 3 to 5.
The importance of the activities of daily living could be rated as

- very important (3 points)
- somewhat important (2 points)
- not important (1 point).

Perceived comparative safety and difficulty could be evaluated as

- much less difficult and/or much safer with the previous orthosis (-2 points)
- less difficult and/or safer with the previous orthosis (-1 point)
- no difference between the two orthoses (0 points)
- less difficult and/or safer with the C-brace® (+1 point)
- much less difficult and/or much safer with the C-brace® (+2 points).

Patients filled out the OEQ at the beginning of this pilot study for their existing locked KAFO or SCO. After 3 months of C-brace® use, they were asked to fill out the OEQ for the C-brace® as well as the questionnaire on comparative safety and difficulty of ADLs with both orthoses.

Statistical analysis of the OEQ was conducted using the Wilcoxon signed rank test with p<.05 and a power of 80% in WIN STAT for MS Excel®.

The results of the comparative questionnaire could be subjected only to a descriptive statistical analysis, as only one value per patient was given for the comparative difficulty and safety, respectively. For this, clinical relevance of the difference was assumed when the group mean value for the respective activity reached at least 25% of the maximum possible difference of +2 points (much less difficult and/or much safer with the C-brace®) or -2 points (much less difficult and/or much safer with the previous orthosis). A clinically relevant gain in function was assumed for the C-brace® when the group mean value was +0.5 or higher and for the previous orthosis when the group mean value was -0.5 or lower. For group mean values between -0.49 and +0.49, it was assumed that there was no clinically relevant difference between the two orthoses.
Results of the Orthosis Evaluation Questionnaire (OEQ)

After 3 months of use of the C-brace® the average OEQ rating over all 81 questions improved insignificantly from 65.7 ± 13.5 for the previous KAFOs/SCOs to 67.8 ± 21.3 with the C-brace® (maximum possible rating is 100).

The results for the nine OEQ sub-scales are reported in table 1.

Table 1: Average VAS ratings of the questions of the nine sub-scales of the OEQ.

<table>
<thead>
<tr>
<th>Sub-scale</th>
<th>Score previous orthoses [Mean±SD]</th>
<th>Score C-brace® [Mean±SD]</th>
<th>p-value</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulation</td>
<td>65.5 ± 31.6</td>
<td>78.1 ± 28.3</td>
<td>.003</td>
<td>+19%</td>
</tr>
<tr>
<td>Appearance</td>
<td>76.4 ± 33.5</td>
<td>71.3 ± 32.8</td>
<td>.72</td>
<td>-7%</td>
</tr>
<tr>
<td>Frustration</td>
<td>63.7 ± 33.1</td>
<td>67.3 ± 34.9</td>
<td>.67</td>
<td>+6%</td>
</tr>
<tr>
<td>Perceived Response</td>
<td>82.7 ± 29.2</td>
<td>78.6 ± 28.1</td>
<td>.25</td>
<td>-5%</td>
</tr>
<tr>
<td>Diseased Limb Health</td>
<td>63.9 ± 35.2</td>
<td>85.5 ± 22.0</td>
<td>.0006</td>
<td>+34%</td>
</tr>
<tr>
<td>Social Burden</td>
<td>79.6 ± 27.5</td>
<td>82.4 ± 27.2</td>
<td>.42</td>
<td>+4%</td>
</tr>
<tr>
<td>Sounds</td>
<td>57.1 ± 38.3</td>
<td>80.3 ± 23.7</td>
<td>.006</td>
<td>+41</td>
</tr>
<tr>
<td>Utility</td>
<td>66.6 ± 29.5</td>
<td>72.6 ± 28.9</td>
<td>.12</td>
<td>+9%</td>
</tr>
<tr>
<td>Well-Being</td>
<td>61.7 ± 26.1</td>
<td>81.3 ± 14.1</td>
<td>.01</td>
<td>+32%</td>
</tr>
</tbody>
</table>

The results of the Orthosis Evaluation Questionnaire (OEQ) demonstrated highly statistical significant improvements after 3 months of C-brace® use in the domains of

- ambulation (p=.003)
- diseased limb health (p=.0006)
- sounds (p=.006)
- well-being (p=.01)

Insignificant deteriorations were seen in the domains of appearance and perceived response which are due to the fact that the hydraulic knee unit of the C-brace® is
bulkier than regular orthotic knee joints. Interviews revealed that most patients would be willing to accept that trade-off for considerable gains in ambulation capacities, diseased limb health, well-being, and reduced noise related to the use of the orthosis.

**Results of the comparative safety and difficulty to perform activities of daily living**

**Importance of the activities of daily living to the patients**
Patients rated the importance of the 45 activities for their daily life at an average of 2.4±0.8. As the maximum possible rating was 3 points ("very important"), it can be concluded from these results that the questionnaire covers a range of important activities of daily living.

**Comparative safety and difficulty in performing the activities of daily living with the previous orthosis and the C-brace®**
For the analysis of the comparative safety and difficulty of the individual ADLs, the threshold described above for a clinically relevant gain in function by the C-brace® (group mean value +0.5 or higher) or the previous orthosis (group mean value ≤0.5 or lower) was used. In the group mean, not one of the 45 ADLs was rated by patients to be safer and only one activity to be less difficult with the previous orthosis. However, 31 ADLs (69%) were rated to be safer to perform and 23 ADLs (51%) were rated to be less difficult to perform with the C-brace® (Fig. 2). A group mean of ≥+1.0 (≥50% of the maximum possible evaluation) was reached for 12 activities (27%) regarding safety and for 4 activities (9%) regarding difficulty.
The greatest functional gain using the C-brace® was achieved in the categories Mobility and Transportation and Family and Social Life. In the category Mobility and Transportation, 17 of the 19 ADLs (89%) were rated safer and 10 of the 19 ADLs (53%) were rated less difficult with the C-brace® (Fig. 3). In the category Family and Social Life, 9 of the 12 ADLs (75%) were rated safer and 8 of the 12 ADLs (67%) were rated less difficult with the C-brace® (Fig. 4). The functional gain was less clear in the categories Personal Hygiene and Dressing, Sports and Leisure Activities and Other Activities (Fig. 5).
Figure 3: Comparison of safety and difficulty of activities in the category Mobility and Transportation between the C-brace® and the previous orthoses. A clinically relevant difference was assumed if the group mean value was at least 25% (-0.5 for the previous orthosis or +0.5 for the C-brace®) of the maximum possible difference in rating (-2 for previous orthosis or +2 for C-brace®) in favor of one orthosis. In the category Mobility and Transportation, 89% of the activities were rated safer and 53% were rated less difficult with the C-brace®.
Figure 4: Comparison of safety and difficulty of activities in the category Family and Social Life between the C-brace® and the previous orthosis. In the category Family and Social Life, 75% of the activities were rated safer and 67% were rated less difficult with the C-brace®.
Figure 5: Comparison of the safety and difficulty of activities in the categories Personal Hygiene and Dressing, Sports and Leisure Activities and Other Activities. In these categories, 64% of the activities were rated safer and 36% were rated less difficult with the C-brace®, whereas only 7% of activities were rated less difficult to perform with the previous orthosis.
**Discussion**

The results of the VAS ratings of the Orthosis Evaluation Questionnaire (OEQ) revealed a significant improvement in ambulation, diseased limb health, sounds, and well-being by the C-brace® as compared to the locked KAFOs or SCOs. Due to the fact that the hydraulic unit of the C-brace® is somewhat heavier and bulkier than standard orthotic knee joints the ratings for appearance and perceived response declined insignificantly, but interviews showed that most patients would be willing to accept that trade-off and prefer the C-brace® over their previous standard locked KAFO or SCO. As there is scientific evidence that patient benefits of stance control orthosis use is superior to that of locked KAFOs (1) it can be assumed that the C-brace® represents a great functional and technological advancement for patients with paresis/paralysis of the muscles that stabilize the knee. As there are no validated outcome measures for custom orthotics, the OEQ has never been used before, and the number and level of orthotic research is generally low the results of this pilot study could no be compared to those of previous research.

When evaluating the performance of activities of daily living, the question that always arises is how many or which activities are representative for the requirements of daily life. To ensure that such questionnaires are practical to fill out as well as to analyze, it is absolutely necessary to select a manageable number of the theoretically hundreds of possible activities of daily living. For this study, the questionnaire was limited to 45 ADLs. The average importance of the activities of daily living that were included was viewed by the patients to be high. In addition, there was the option of naming other very important activities not included in the questionnaire in a free section. However, the patients hardly used this opportunity, which indicates that the ADLs included represented a good cross section. Nevertheless, when analyzing the results, it should be kept in mind that the questionnaires used were no validated instruments.

The extent to which patient surveys can replace objective biomechanical and/or clinical assessment procedures is subject of frequent disputes. Objective measurement results are generally considered to be more significant than subjective
patient statements. The Clinical Assessment Center for Orthopaedic Aids at the University of Muenster, Germany, has found that patient surveys are better than their reputation and should be considered valuable measuring instruments. As early as 2005, Wetz et al. wrote in their study on the indications for the C-leg®, "The results of this (patient) survey closely match the objective biomechanical parameters measured." (5). This statement was confirmed once more in another publication in 2010. "It has been shown that in many cases, the survey leads to the same results as the objective clinical biomechanical examination." (6). Of course, an evaluation should ideally be based on a combination of the results of objective measurements and subjective surveys. As this pilot study was conducted in regular P&O clinics that usually do not have the appropriate equipment to do biomechanical research data collection was limited to patient questionnaires.

Changes in the perceived safety and difficulty of activities within the individual response categories were measured by eliciting a direct comparison of the two orthoses. Specifying the threshold for a clinically relevant difference as a group mean value of at least 25% of the maximum possible difference in evaluation in favour of one of the two orthoses is certainly arbitrary and may give rise to discussion. Here it must be considered that any other specification of a threshold for clinical relevance would have been just as arbitrary. The direct comparison of the two joints showed that on average, patients rated 69% of the ADLs as safer and 51% as less difficult with the C-brace®. The improvements were especially pronounced in the categories Mobility and Transportation and Family and Social Life. Family and Social Life is an inseparable part of participation in society. Increasing the safety and reducing the difficulty of these activities is thus a very good basis for further reducing potential limitations of participation. Improvements in the safety and difficulty of activities in the category Mobility and Transportation contribute to enhancing self-sufficiency and independence of patients. They create the basis for improving patients' participation in business and social life outside their own family. Even though the patients' subjective perception cannot always be explained by objective measurements, it plays a decisive role for the patients' behavior. For instance, it has been scientifically proven that for non-amputees and amputees alike, a reduced subjective sense of
balance and safety is correlated with avoidance of activities of daily living and social participation (15-19). Over time, avoiding activities can lead to a (further) reduction of physical capacity and in turn, of the subjective sense of balance and safety. At the end of this vicious circle, the worst-case scenario is the social isolation of the patient (18, 19). Unfortunately, there are no corresponding studies with orthosis users, but as those findings apply to non-disabled persons and amputees alike it can be assumed that they are also true for patients with pareses/paralyses of leg muscles using custom orthoses.
References


