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The Effects of the Norsk Funktion-Walking Orthosis on the Walking Ability of Children With Cerebral Palsy and Severe Gait Impairment

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ABSTRACT

The purpose of this study was 1) to test whether an orthosis, which provides postural stability of the trunk and guides the leg movements during walking (Norsk Funktion-walker orthosis [NFWO]), would enable nonambulant children with cerebral palsy with poor or no leg coordination and with little or no trunk control to walk on their own, 2) to investigate if there is an increase in motor function and activity while using a NFWO, and 3) defining requirements for a successful provision. Ninety-three children (39 girls, 54 boys; mean age 7.6 years; 67 with bilateral spastic, 10 with dyskinetic, 10 with mixed, 6 with ataxic cerebral palsy; Gross Motor Function classification System level 4: 45, level 5: 48) were provided with a NFWO. The following assessments were carried out immediately before and 3 months after using the NFWO: WeeFIM walking score; independence rating by parents or caregivers; aims or expectations of parents or caregivers; at a mean interval of 265 days after provision: mean daily walking distance (meters). With the NFWO, 78 children (84%) became ambulatory, 10 children (11%) used it exclusively as a dynamic standing frame only, and 5 children (5%) returned the NFWO. The mean daily walking distance was 99 m (2–463 m). The mean WeeFIM walking score of 1.99 (SD 0.83) without the NFWO increased to 4.42 (SD 1.00) with the NFWO indoors and to 3.71 (SD 1.24) ($p < 0.001$) outdoors. Independence rating by parents or caregivers reflected a highly significant increase in independent mobility with the NFWO compared with locomotion without ambulatory aides ($p < 0.001$) and of bilateral hand function ($p < 0.001$). No significant increase in the mobility was found when comparing former mobility aides (wheelchair, tricycle) with the NFWO. The ability to cross obstacles did neither significantly increase with the NFWO. Successful indication for a NFWO depends on 1) the child's motivation to walk and the support of the environment to achieve independent walking mobility through the use of this assistive tool, 2) the ability for selective reciprocal leg movements, and 3) no flexion contractures of hips and knees above 20° and a foot dorsiflexion of at least neutral-0°. The NFWO proved to be a useful ambulatory aid in the children with cerebral palsy with severe gait impairment to increase independent mobility. (*J Prosthet Orthot.* 2009; 21:138–144.)

KEY INDEXING TERMS: orthosis, walking orthotics, gait impairment

Independent walking is difficult for a large number of children with cerebral palsy due to impaired postural control, abnormal muscle tone, and pathological muscular coordination of the legs.[1,2] Until recently, there has been a lack of a walking orthosis, which would enable severely impaired children with poor postural control of head and trunk to walk. The ORLAU Locomotor Guidance System was developed as a rear support walking frame, to provide ambulation for patients with total body involved cerebral palsy.[3]

The Norsk Funktion-walker orthosis (NFWO; initially called the David Hart walker orthosis; Fig. 1A, B) is an individually adjustable device, which assists children with severe gait impairment to attain independent mobility. It combines an adaptable body weight support with a high amount of postural control. Its two main components are a modular hip-knee-ankle-foot orthosis with trunk support and a wheeled carrier. The brace is secured height-appropriately with a posterior support attachment. The carrier's support mechanism offers the child a regulated and individualized amount of weight-bearing support and gait guidance during walking. The steering is designed, so that the carrier's front wheels turn in the child's intended direction of travel when the child turns the body. Hence, children with severe motor disability may walk independently without needing to use their hands for support. It provides maximal independence and improves the quality of life by enabling the child to participate in activities, including being able to play with peers. Regular walking training improves general fitness, bone density, muscle strength, and control of trunk and lower limbs, ameliorates

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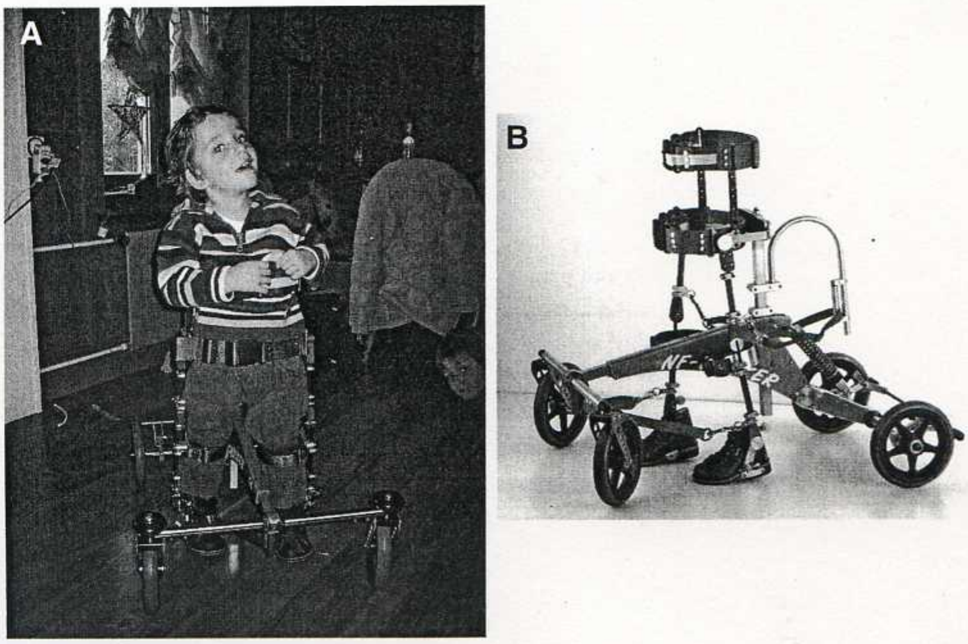

Figure 1. The Norsk Funktion-walker orthosis.

muscle balance by reducing spasticity, and promotes coordination of leg and trunk movements as demonstrated in patients after stroke[4] and under treadmill walking.[5,6]

A study of four children with cerebral palsy using a NFWO for 12 months were investigated sequentially through gait analysis (eight times) during this period.[7] All children improved regarding their kinematic data, especially with decreasing knee flexion angle toward normal gait. The electromyography data changed little, which may indicate that improvements occurred due to the mechanical guidance and motor learning and less due to a decrease of spasticity (which was neither a goal nor expected). An observational study of five children (age 3–10 years) examining the use of the NFWO and the impact of the use of their hands during a 3-month period showed quantitative improvements and an increase in activity and participation levels.[8] A further study performed by Canadian physiotherapists investigated the use of the NFWO to improve the walking capacity in 20 children (age 4.0–12.8 years) with bilateral spastic cerebral palsy. After 12 months, 11 children were able to walk ≥30 m within 360 seconds, whereas the other nine partially completed the 30 m within this time. Not only their walking abilities (GMFM) improved but also their directional abilities improved.[9]

Despite the evidence for efficacy of the NFWO in these previous studies, no investigation has studied its effects on independent walking ability in a larger population of children with cerebral palsy with severe gait impairment.

Therefore, we carried out a prospective longitudinal study of consecutive cases to investigate the ability of severely gait impaired children with cerebral palsy to walk with a hip-knee-ankle-foot orthosis with trunk support (NFWO).

The following questions were addressed:

Would an orthosis, which provides postural stability of the trunk and guides the leg movements during walking (NFWO), enable nonambulant children with cerebral palsy with poor or no leg coordination and with little or no trunk control to walk on their own?

Is there an increase in motor function (b770 gait pattern) and activity (d465 moving around using equipment) according to International Classification of Functioning, Disability and Health (ICF),[10] children and youth version to be observed while using a NFWO?

What are the requirements for a successful provision?

METHODS

All consecutive children with cerebral palsy[11] with severe gait impairment (Gross Motor Function classification System [GMFCS] 4–5)[12] in Switzerland who got a NFWO between January 2003 and April 2004 were included in this study. Parents underwent informed consent to participate in this study to evaluate use of the NFWO. Exclusion criteria were as follows: children with cerebral palsy who could walk with less support (GMFCS 1–3) and children with profound developmental retardation and lack of motivation to move. The data of the children enrolled are displayed in Table 1. Ninety-three children (39 girls and 54 boys, mean age of 7.6 years, range 1.8–18.0 years) were eligible. Sixty-seven (72%) had bilateral cerebral palsy, 10 (11%) had dyskinetic cerebral palsy, 10 (11%) had a mixed form of cerebral palsy, and 6 (6%) had ataxic cerebral palsy, with a GMFCS value of level 4 in 45 children and level 5 in 48 children.

Of the ninety-three children included in the study, 51 (55%) demonstrated initial foot contact with toes during

Table 1. Demographics of patients provided with a NFWO

Diagnosis	All	Bilateral spastic	Dyskinetic	Mixed	Ataxic
Sex (%)	93 (100)	67 (72)	10 (11)	10 (11)	6 (6)
Female (n)	39	28	2	6	3
Male (n)	54	39	8	4	3
Age (years)					
Range	2–18	2–18	3–10	3–12	2–11
Mean (±SD)	7.54 (3.20)	8.19 (3.36)	5.91 (2.22)	6.70 (2.45)	6.41 (2.89)

NFWO, Norsk Funktion-walker orthosis.

assisted walking (51% to 100% body weight support). Twenty-eight children (30%) demonstrated full plantar initial foot contact and 14 (15%) did not weight bear at all. Most of the children showed either a hind foot valgus or an equinus deformity. Contractures of the lower limbs were present in 44 children (47%; hip and knee flexion contracture less than 20°; equines with passive foot dorsiflexion with extended knee at least to the neutral 0° position). Five children (5%) used knee-ankle-foot orthoses, 57 (61%) wore ankle foot orthoses, and 18 (19%) foot orthoses. Seventy-three children (78%) used a standing support frame, 79 (85%) had a wheelchair (manual or electric), and 36 (39%) used a tricycle before the provision of the NFWO. All but one child had regular physiotherapy (mean 2.0 sessions/week, range 1–4 sessions/week). The therapy setting remained unchanged during the investigation period. Twenty-three children (25%) have been treated previously with botulinum toxin (>6 months ago). The walker was refitted every 3 months to adapt for growth (adaptations of length) and increase in abilities (decrease of body support by the NFWO). Instructions regarding the intensity of use were given by the authors and the treating physiotherapists. The use of the NFWO was integrated into the child's daily physical mobility program and was carried out either at the home or at the school during term. Parents or caregivers or both recorded hours and type of wear in a dairy.

Eighty-eight children completed the investigation period of 3 months. The NFWO was returned by five children (5%) (one due to death because of a respiratory tract infection), four due to limited motivation of the child or reduced compliance of caregivers and/or parents).

The outcome measures listed below were chosen to assess the use of the NFWO. They were administered before the start of and 3 months after the study by the two authors and the treating physiotherapists.

Independence of locomotion (WeeFIM Walking Score)[13,14] cf. Appendix 1.

Independence rating by parents and/or caregivers. This assessment was developed by ourselves and is not validated. It is based on our experience of the development of independence in children with a neuromotor disability. Four well-defined areas of motor development (for items and score see Table 4) are assessed.

Open questionnaire on aims and expectations regarding independent motor activities completed by parents or caregivers and physiotherapists.

It was decided to add the following assessment criteria poststudy start as a key outcome measure:

Walking distance per day (meters) independent or with a clearly defined support. To calculate the total walking distance, the orthotist mounted a counter to one of the back wheels of the NFWO. The calculated walking distance was divided by the number of days the counter was mounted for the total distance measurement.

Statistical analysis was performed with SPSS 13.0 software (SPSS Inc. Headquarters, Chicago, IL); significance level was set at 0.05 for all tests.

Nonparametric statistics were used in case the distribution of interval and ratio scaled data seemed to be not normally distributed and in those cases where the data scales were nominal or ordinal. They were applied for the observed results of parental independence rating and WeeFIM Locomotion score using the Wilcoxon Test. With a Friedman two-way analysis of variance (ANOVA), we additionally compared the conditions WeeFIM Locomotion without/with former mobility aid/with NFWO indoors and outdoors. Baseline values were compared with values acquired after the study phase of 3 months using the NFWO.

RESULTS

The NFWO was used as a walking aid for 78 participants (84%) and for 10 (11%) as a dynamic standing support (4 of these children started walking with the NFWO 6 months after study begin). The walker was regularly used at home in 73 patients (78%), although 53% of the parents (n = 49) rated the use of the walker to be laborious. In average it was used 5 times a week for 0.8 hours per day (2–7 times per week, 0.2–2.5 hours/day).

In Table 2, walking distances in relation to diagnosis are reported. Distance measurements were taken for 73 children during a mean period of 31 days (range 6–92 days, SD 14). No distance measurements were taken for 5 children. The interval between the initial fitting of the NFWO and the measurements was 265 days (range 0–559.0, SD 143 days). The mean

Table 2. Walking distance (meters) per day with NFWO

	All	Bilateral spastic	Dyskinetic	Mixed	Ataxic
n	73	47	10	10	6
Distance (m/day)					
Range	2–463	2–457	6–463	5–324	19–328
Mean (±SD)	98.5 (110.6)	96.2 (103.5)	117.8 (159.9)	98.9 (106.9)	110.9 (112.9)

NFWO, Norsk Funktion-walker orthosis.

Table 3. Distribution of WeeFIM locomotion ability without/with different mobility aides/mean walking ability (WeeFIM)

WeeFIM score	(n=88)	Walking without aid	Locomotion without aid indoors	Locomotion without aid outdoors	Locomotion with former mobility aid indoors	Locomotion with former mobility aid outdoors	Walking with NFWO indoors	Walking with NFWO outdoors
Total dependence	1–2	70	41	64	41	47	10	14
Modified dependence	3–4	18	22	8	12	13	41	43
Supervision only	5	0	8	2	7	6	25	17
No helper, with device	6	0	7	4	18	12	12	4
Mean (SD)	1.99 (0.83)	1.62 (1.70)	1.73 (1.35)	2.95 (2.15)	2.58 (1.97)	4.42 (1.00)	3.71 (1.24)	

NFWO, Norsk Funktion-walker orthosis.

walking distance was 98.5 m per day (range 2–463, SD 110.6). Reports from parents give evidence of a further increase of walking distances after closure of the study.

In Table 3, the distribution of locomotion ability according to the WeeFIM locomotion and walking ability scores without aid, former mobility aid (wheelchair or tricycle), and NFWO indoors and outdoors is displayed. When looking at walking abilities with the NFWO indoors, 78 children (84%) were able to walk with the NFWO with moderate to no assistance (WeeFIM walking score 3–6). Four children were able to walk with little to no assistance/dependency indoors (walking with NFWO level 1-outdoors 14 vs. indoors 10). Either they had no opportunity to walk outdoors due to environmental factors during the observation or study period of 3 months or they were only able to walk on even ground with a smooth surface. Thirty-seven of the included children (40%) were able to walk independently for the first time in their lives (WeeFIM walking scores 5 and 6). The group of 10 children (11%) who stayed at WeeFIM score 1 or 2 (Walking with NFWO indoors) used the device as a dynamic standing frame only. This group failed to show a significant increase of their walking ability (WeeFIM walking score remained 1–2) within the observation time. However, a more dynamic standing in terms of balance reaction (in anterior-posterior, lateral, and axial direction) was observed.

Comparing the WeeFIM walking abilities without and with the NFWO indoors and outdoors, a highly significant increase ($p < 0.001$) of walking ability is observed in the whole sample. Maximal assistance, which was necessary when walking assisted without NFWO (WeeFIM walking mean score 1.99), reduced to minimal assistance or supervision when walking with NFWO (WeeFIM walking mean score indoors 4.42 and outdoors 3.71). When matching WeeFIM locomotion scores indoors and outdoors without aid (creeping and crawling) to the locomotion ability with a former mobility aid, a significant increase is recognized outdoors ($p = 0.002$) versus a nonsignificant increase indoors ($p = 0.3$). When comparing WeeFIM locomotion scores indoors and outdoors with former mobility aid to NFWO, a highly significant increase of the WeeFIM locomotion score is seen ($p < 0.001$). Comparing the conditions of WeeFIM locomotion scores (without aid/with former aid/with NFWO) indoors and outdoors using the Friedman two-way ANOVA, we saw significant differences between conditions and highest values for NFWO-locomotion (mean rank WeeFIM locomotion indoors (1.58/1.88/2.53; χ^2 43.00) and outdoors (1.51/1.93/2.56; χ^2 53.26).

The questionnaire of independence rating by parents and caregivers (Table 4) focused on locomotion (creeping and crawling) indoors of at least 5–10 m and locomotion outdoors of more than 10 m on a uneven surface with a slight slope, to cross an obstacle, such as doorstep, and bilateral hand function such as opening a door, using a switch or washing hands. The situation was assessed initially without and with the former mobility aid (tricycle or wheelchair) and at follow-up after using the NFWO for 3 months. In the children who walked with the NFWO, highly significant results were found for mobility using the NFWO compared with no mobility aid

Table 4. Mobility and independence rating (parents/caregivers) for n = 78

	Without aid	With former aid	With NFWO
I. Locomotion indoors[a]	0.35	0.65	0.95
II. Locomotion outdoors[b]	0.17	0.49	0.59
III. Ability to cross obstacles (a doorstep, a carpet, to get into a lift)	0.22	0.47	0.45
IV. Bilateral hand function (to open doors, to switch on lights, to wash hands independently, to grasp objects)	0.42	0.69	1.04

Rating: 0, fully dependent (25% to 100% contact help); 1, supervision or contact help <25%; and 2, independent.
[a]Locomotion 5–10 m on even surface.
[b]Locomotion >10 m on uneven surfaces.
NFWO, Norsk Funktion-walker orthosis.

Table 5. Aims and expectations

	Exceeded	Fulfilled	Not fulfilled
Parents expectations (n = 88)	21	54	13
Physiotherapists expectations (n = 88)	33	46	9
Postural control improved (n = 88)	11	49	28
Initiation of steps (n = 88)	25	50	13

for locomotion indoors (5–10 m) and outdoors (>10 m), as well as for bilateral hand function ($p < 0.001$). Comparing the NFWO with the former, mobility aid results were less clear: a significant improvement of locomotion indoors with the NFWO compared with the former mobility aid ($p = 0.03$), but not outdoors ($p = 0.63$). No improvement was found for crossing obstacles with the NFWO compared with no aid and to former aid ($p = 0.11$ and $p = 0.74$, respectively).

Table 5 contains the results of the open questionnaire, which consisted of a form completed before the study including expectations and aims and a second form completed at the end of the 3-month study. Parent's expectations were exceeded in 21 children (23%), fulfilled in 54 (58%), and not reached in 18 (19%). The aims of physiotherapists were exceeded in 33 (35%), met in 46 (51%), and not achieved in 14 (14%). According to their estimation, postural control improved in 60 children (65%) and initiation of steps (selective reciprocal leg movements) in 75 children (81%).

DISCUSSION

This observational study evaluates the use of the NFWO of the first 93 children with cerebral palsy in Switzerland provided with this ambulatory aid. The use of this walking device in children with cerebral palsy and severe motor impairment (GMFCS IV and V) with WeeFIM walking scores 1–2 in 70 children (51% to 100% body support in walking), WeeFIM walking score 3 in 14 children (26% to 50% body support), and WeeFIM walking score 4 in 4 children (1% to 25% body support) enabled 78 (84%) to walk with significantly less support as reflected by the significant increase of the WeeFIM walking score (Table 3). Motor function scores as contained in the WeeFIM correlate well with activities of daily living in terms of dependence.[15] Therefore, the improvements in motor function have an impact on all aspects of activity and participation.

When including all forms of mobility as done in the parent or caregiver mobility and independence rating (Table 4), a significant improvement of mobility with the NFWO was achieved in comparison with no mobility aid. In contrast, there were no significant increases to the independence rating of the NFWO when compared with the former ambulatory aid. It may well be that the parent or caregiver mobility and independence rating is not sensitive enough to detect changes in dependence. In comparison, the WeeFIM locomotion scores demonstrate significant differences between locomotion with NFWO compared with both the former mobility aides and no aides. Crossing obstacles, such as carpets, doorsteps, getting into lifts, remain a difficult task with a NFWO and no significant differences compared to former mobility aides were found. The advantages of the decreased need for direct body assistance were outweighed by an increase of control and help with steering. The highly significant increase of bilateral hand function observed with the NFWO compared with no mobility aid and to a former walking aid is explained by the fact that a child in a NFWO is able to remain in an upright position and to move without being held, holding onto a walker or self-propel a wheelchair. The hands are released and can now be used to carry and handle objects bimanually. Through increased daily activity in the upright position, postural control and thereby the prerequisites for bilateral use of hands improve. These findings correspond with an observational study in children of 3–10 years using a NFWO during a period of 3 months, where improvements of use of hands reflected by an increase of the level of activity and participation are reported.[8]

The distances which the children walked within 1 month (Table 2) with this new type of walking aid demonstrates a gain in functional walking because none of the children were able to independently walk before. According to the parents and physiotherapists, an ongoing improvement of walking after the fitting with the NFWO was observed poststudy.

According to the parents and therapists, aims and expectations were met or exceeded in 81% and 86%, respectively (Table 5). Although application of the NFWO is laborious, the satisfaction and enthusiasm of many of the children outweigh this disadvantage. These findings agree well with the study investigating the parent's view of and their experiences with the NFWO.[9] According to their estimation, postural control (not further specified) and selective reciprocal leg movements improved in 65% in 81% of the children. This is another indication of the training effect that the regular use of the NFWO may have.

As an effect of the postural, strength, and gait training, six children, who used the NFWO during the study, further developed their walking abilities, and postural control, no longer need the NFWO and progressed to a posterior walker. Thus, the NFWO can serve as a tool to promote motor abilities in children with severe gait impairment and support heir development toward higher motor abilities according to their potential.

A weakness of this study is that measurements were taken after the 3-month study period. The high variability of the interval between provision and the duration of measurement does not allow us to make any statements regarding the daily distances walked by the children regarding to the different types of cerebral palsy, functional levels, and amount of use of the NFWO. To show the effect of continuous training, a second measurement of walking distance at a set interval after provision is necessary. It can only be assumed that differences in the daily time spent in the walker have a direct influence on the development of walking abilities. However, a 3-month time period after provision may be too short to measure training effects.

It is a further methodological weakness, that in 5 of the 78 children using the NFWO to walk, no distance measurements were taken. However, when comparing the distribution of diagnoses and WeeFIM locomotion abilities in these children to the whole sample group, no significant differences could be detected.

There are a considerable number of children ($n = 10$) who did not achieve walking ability with the NFWO (within the observational time of this study) but used it merely as a dynamic standing device. Motivation for walking was low in 6 children. The other four children with higher motivation were thrilled about the device allowing for a different body position but were initially less interested in discovering their environment by walking. After closure of the study, those four children started walking with the NFWO.

Unexplained aims and motivational problems of the (social) environment (parents, caregivers, and therapists) were predominant in four of five children who gave the NFWO back. This leads to the important conclusion that initial interdisciplinary agreement of aims and possibilities of the NFWO is a prerequisite for a successful provision.

The costs of the NFWO are similar to those of ordinary wheeled walking aides with a high amount of postural support. Some costs can be saved by the lack of need for additional standing or walking devices or functional (ankle-)foot-orthoses. Adaptations at regular intervals (every 3 months to adjust for height increases and decreases of the amount of weight support) are a prerequisite for an appropriate fit and continuing progress. Because the walker is adjustable over a large size range, it can be used to provide daily independent walking opportunities for several years.

The magnitude of flexion contractures of hips, knees, and ankles should not exceed the range we have chosen. An equinus contracture with a dorsiflexion of less than 0° and a hip and knee contracture of above 20° considerably limit the use of the NFWO to achieve independent walking.

The questions of this study could be answered as follows:

1. In 78 children (83%) nonambulant children with cerebral palsy with little or no trunk control were able to walk with the NFWO with moderate to no assistance (WeeFIM walking score 3–6). This rate can be increased when the requirement for a successful provision (cf. answer to question 3) are met.
2. An increase in body function (achievement of heel-toe gait within the NFWO) and activity (moving around using the NFWO) according to the ICF was achieved.
3. The requirements for successful indication are a) motivation of the child to walk and the support of the environment to achieve independent walking mobility by the use of this assistive tool, b) neurological prerequisites are met (ability for selective reciprocal leg movements), and c) orthopedic preconditions are fulfilled (no flexion contractures of hips and knees above 20°, a foot dorsiflexion of at least neutral-0°).

CLINICAL MESSAGE

The NFWO is a highly effective walking device for the children with severe gait impairment and low levels of motor ability, who need a high amount of postural control of trunk, pelvis, and legs to be able to walk.

The NFWO allows severely gait impaired children to practice walking daily, which results in an increase of independent mobility. By enabling them to walk with little to no assistance, they can participate in social activities and improve independence.

APPENDIX 1

WeeFIM WALKING (WITHOUT AID/WITH NFWO)

WeeFIM Levels

No helper

7. Complete independence: the child runs a distance of at least 50 m without any aides. Secure performance.
6. Modified independence: the child walks a distance of

at least 50 m but needs an orthosis or prosthesis, orthopedic shoes, walking sticks, or a walking aid; it needs additional time than normal or there are safety concerns.

Helper-modified dependence

5. Supervision: the child walks only short distances (at least 17 m) without or with a walking aid. It possibly needs more time than normally or there are safety concerns.
4. Minimal assistance: the child brings up most of the effort (75% or more) to walk at least 50 m.
3. Moderate assistance: the child brings up half or more of the effort (50% to 74%) to walk at least 50 m.

Helper-complete dependence

2. Maximal assistance: the child brings up less than half of the effort (25% to 49%) to walk at least 17 m. It needs the assistance of 1 person.
1. Total assistance: the child brings up little or no effort (less than 25%) to walk or it needs the help of two persons or it is not able to walk at least 17 m.

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