Reference

T. Oshima[1], M. Toda[1] and T. Chin[1,2]

Walking Rehabilitation Using Hybrid Assistive Limb (HAL) and Computer-Controlled Long-Leg Orthosis (C-Brace) for an Individual with Chronic Incomplete Spinal Cord Injury: A Case Report

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Products

C-Brace, HAL (Hybrid assistive limb)

Major Findings

With C-Brace (6- month use) after HAL-based walking training in one male adult:

→ Clinically relevant enhanced walking and balance abilities and acquisition of practical walking ability in local community spaces with C-Brace after HAL-based walking training

- Clinically highly relevant improvements in the comfortable walking speed in the 10-minute walk test (10 MWT: MDC 0.13 m/s; MCID = 0.06 m/s) with C-Brace (+0.39 m/s vs. HAL and +0.74 m/s vs. Baseline)
- Clinically highly relevant improvements in the fast-walking speed in the 10 MWT with C-Brace (+0.18 m/s vs. HAL and +0.81 m/s vs. Baseline)
- Clinically highly relevant improvements in the distance of the 6-minute walk test (6 MWT: MDC = +46m/+22%) with C-Brace (+229m vs. Baseline and +140m vs. HAL)
- Clinically relevant improvements in the Berg Balance score values by +5 points (MDC for Baseline values between 45 and 56 = 3.3 points)

→ Clinically relevant reduced risk of falling during daily living activities with C-Brace after HAL-based walking training

- Clincially highly relevant improvements in the Activity Specific Confidence (ABC: MDC = 14.87%) scale (+19,8% with C-Brace vs. Baseline and +8% with C-Brace vs. HAL) → ABC values with C-Brace are over 67% indicating a reduced risk of falling
- BBS values are > 45 points and indicate independent walking and reduced risk of falling

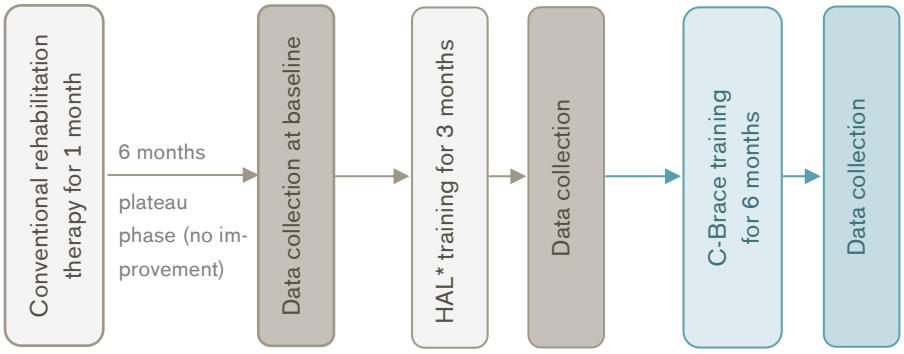
→ Improvements in walking and balance abilities with HAL can be maintained and even further improved to a clinically relevant extent with C-Brace

Population

Subjects:	1 male
Injury & cause:	incomplete cervical spinal cord injury (SCI)
Previous AFO:	right rear strut AFO
Age:	38 years
Time since injury:	5 months

Study Design

Case Report:



*HAL = Hybrid Assistive Limb – a wearable cyborg device that detects and provides mechanical assistance for movement impulses at the hip and knee joints of the wearer

HAL Training protocol: 24 sessions, twice a week for 12 weeks – during this period regular physiotherapy was the same as it was before HAL. Each session lasted for 45 minutes (12 min for equipping, 25 min walking (3 x 6 min with 3 min rest in between) and 5 min HAL removal).

C-Brace training protocol: 30-min sessions 4 times per week for 6 months. For the first 3 months focused on walking training 3 x 6 min with 3 min rest in between. For the last 3 months patient had applied training on uneven ground, stairs and sloped surfaces.

Results

Functions and Activities						Participation	Environment
Biomechanics – Static Measurement	**Biomechanics – Gait analysis**	X-Rays	EMG	**Functional tests**	Clinical effects	Satisfaction	Health Economics

Category	Outcomes	Results for C-Brace	Sig.[a]
Biomechanics (Gait analysis) – time distance parameters	Walking abilities	Clinically highly relevant enhanced walking abilities with C-Brace with improvements by • 0.74 m/s faster comfortable walking speed (CWS) in 10-meter walking test (10 MWT) compared to Baseline and 0.39 m/s faster vs. HAL • 0.81 m/s faster maximum walking speed (MWS) in 10-meter walking test (10 MWT) vs. Baseline and 0.18 m/s faster vs. HAL • 229m longer walking distance in 6-minute walking distance (6 MWT) with C-Brace vs. Baseline and 140m longer vs. HAL	++

	Baseline	HAL (3 mo.)	C-Brace (3 mo.)	C-Brace (6 mo.)
10 MWT CWS	0.4 m/s	0.75 m/s	0.80 m/s	1.14 m/s
10MWT MWS	0.52 m/s	1.15 m/s	1.19 m/s	1.33 m/s
6MWT	195 m	284 m	360 m	424 m

No improvements for conventional rehabilitation therapy (physical and occupational therapy).	++

At Baseline he was able to walk 10-meters with one Lofstrand crutch and right rear strut ankle foot orthosis.

After HAL Training he was able to walk indoors on level ground in a stable manner but unstable on slopes, stairs and uneven terrain and was afraid of falling. For outdoors a wheelchair was required.

After 6 months of C-Brace use the patient acquired the ability to walk stably while wearing C-Brace with one crutch in all environments necessary for daily life, including rough terrain, stairs, and slopes. He was able to walk continuously for more than 1000 m.

Category	Outcomes	Results for C-Brace	Sig.[a]
Functional tests	Berg Balance Scale (BBS)	Enhanced BBS Values with C-Brace by 5 points vs. Baseline and by 3 points vs. HAL → BBS values > 45 points indicate independent walking and reduced risk of falling	++
		Baseline: 48 / HAL (3 mo.): 50 / C-Brace (3 mo.): 50 / C-Brace (6 mo.): 53	
	Activity Specific Balance Confidence (ABC) Scale	Clinically highly relevant enhanced ABC Scale Values with C-Brace with values over 67%, indicating reduced risk of falling	++
		Baseline: 56.3 % / HAL (3 mo.): 62.5 % / C-Brace (3 mo.): 65.6 % / C-Brace (6 mo.): 67.5 %	

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.) significance was additionally assessed based on Minimal detectable change (MDC) / Minimally clinically important difference (MCID) for SCI patients for the specific outcomes (*10 MWT: MDC 0.13 m/s; MCID = 0.06 m/s; 6 MWT: MDC = +46m/+22%; BBS: MDC for mixed conditions with Baseline values between 45 and 56 = 3.3 points; ABC: values < 67% indicating increased fall risk)*

Author's Conclusion

"We experienced a case in which HAL and C-Brace training proved effective as practical walking reacquisition therapy at the local community level for a patient with chronic incomplete cervical SCI associated with ambulatory impairment. The combination of HAL and C-Brace technologies is a novel, effective therapeutic strategy for walking rehabilitation in chronic SCI patients. Further proof with additional cases is necessary for verification of these results" (Oshima et al., 2022)

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