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The effect of overground gait training using wearable exoskeletal robot in children with cerebral palsy: a single-blinded RCT

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BACKGOURND & OBJECTIVES

- **Cerebral palsy** (CP): most common developmental motor disorder in children, causing walking and activity limitation.
- Robot-assisted gait training (RAGT) using wearable exoskeletal robot can offer intensive overground walking experience.
- **Aim:** To investigate the effects of an **overground RAGT** using an **untethered torque-assisted wearable exoskeletal robot** in children with CP.

SUBJECTS

- **Design:** Single-blinded, randomized controlled trial
- **Inclusion criteria**
  - Children with spastic cerebral palsy
  - Aged 6 to 18 years
  - GMFCS level **II~IV**
- **Exclusion criteria**
  - Patients who are difficult to perform each assessment due to cognitive impairment
  - Torque assisted wearable exoskeletal robot within 3mo, Trajectory controlled gait robot within 6wks
  - Orthopedic surgical management within 6mo
  - Lower limb botulinum toxin injection within 3mo
  - Unstable medical condition

METHODS

A single-blind randomized controlled trial was conducted at 5 rehabilitation institutions. Nighty children with CP in Gross Motor Function Classification System (GMFCS) levels II-IV were randomly assigned to the RAGT and control groups. The RAGT group received gait training using a torque-assisted wearable exoskeletal robot (Angle legs M20, Angel Robotics, Korea) for 30 min/session 3 times/week for 6 weeks. The control group received conventional physical therapy (PT) for the same frequency and duration.

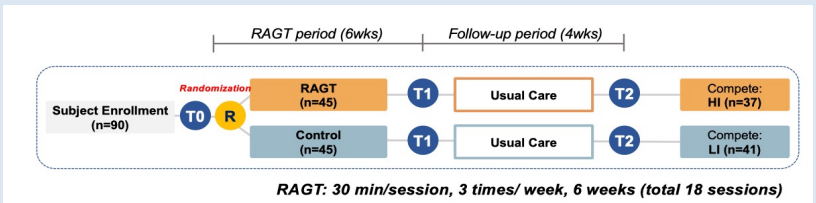

Figure 1. Study Flow chart

Figure 2. Torque-assisted, overground walking robot (Angel legs M20, *Angel Robotics, Korea*)

ASSESSMENT

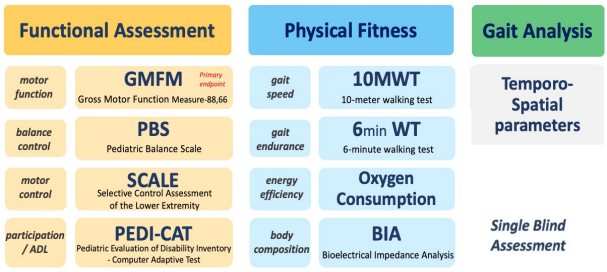

Figure 3. Assessments profile

RESULTS

Seventy-eight participants completed the intervention. In the RAGT group, gross motor functions measured by GMFM-88, responsibility in daily living measured by PEDI-CAT were significantly improved after intervention compared with the control group ($p<0.05$). Balance and selective motor control function significantly improved in both groups without group differences. Regarding gait endurance, the total distance measured by the 6mWT significantly improved only in the RAGT group. In the gait analysis, the duration of single support was increased, while double support was decreased, indicating improvements in gait pattern with significant differences between the groups.

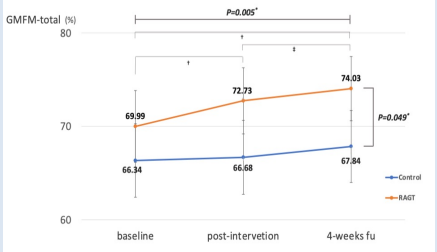

Figure 4. GMFM-total score at baseline, after intervention, and at 4 weeks FU (primary endpoint)

Table 1. GMFM, PEDI-CAT, Gait analysis at baseline, after intervention, at 4wks FU

Variable	Group	Baseline	Post-intervention	4-week FU	*P*-value Time x Group
Gait ability					
10MWT (m/s)	RAGT Control	0.66 (0.08) 0.58 (0.07)	0.78 (0.11) 0.75 (0.11)	0.70 (0.08) 0.69 (0.09)	0.622
6min WT (m)	RAGT Control	196.34 (18.89) 166.87 (19.83)	204.69 (18.50) 183.35 (21.65)	**215.04**†‡ (19.19) 184.16 (21.59)	0.377
Borg during 6MWT	RAGT Control	13.85 (0.52) 14.79 (0.52)	13.88 (0.51) 14.27 (0.53)	13.74 (0.50) 14.24 (0.50)	0.565
Gait analysis					
Single support –more involved (%)	RAGT Control	29.59 (1.66) 30.14 (2.29)	30.31 (1.72) 30.54 (2.69)	**32.07**† (1.58) 30.05 (2.36)	0.144
Single support –less involved (%)	RAGT Control	32.12 (1.85) 29.07 (2.59)	33.07 (1.82) 31.14 (2.50)	34.10 (1.66) 32.42 (2.66)	0.663
Double support (%)	RAGT Control	33.04 (4.06) 38.62 (5.37)	32.09 (3.70) 34.11 (5.39)	**27.83**†‡ (3.22) 34.62 (5.30)	**0.047***

Variable	Group	Baseline	Post-intervention	4-week FU	*P*-value Time x Group
GMFM					
GMFM-88 D	RAGT Control	50.24 (5.69) 44.25 (5.58)	**52.67**† (5.73) 44.84 (5.67)	**54.68**† (5.58) 45.56 (5.73)	0.095
GMFM-88 E	RAGT Control	43.17 (5.34) 36.86 (5.55)	**45.50**† (5.54) 37.29 (5.61)	**47.07**† (5.48) 38.14 (5.74)	**0.033***
GMFM-88 total	RAGT Control	69.99 (3.84) 66.34 (3.93)	**72.73**† (3.54) 66.68 (3.96)	**74.03**†‡ (3.44) 67.84 (3.85)	**0.049***
GMFM-66	RAGT Control	61.97 (2.90) 57.65 (3.04)	**63.82**† (3.03) 58.19 (3.02)	**64.41**† (2.96) 59.13 (3.00)	0.069
PEDI-CAT					
Daily activity	RAGT Control	52.62 (0.91) 52.63 (1.05)	**53.59**† (0.84) 53.02 (1.06)	**53.85**† (0.92) **53.56**† (1.07)	0.340
Mobility	RAGT Control	57.16 (1.18) 55.22 (1.18)	57.68 (1.13) 55.63 (1.20)	57.02 (1.14) **57.29**† (1.07)	0.155
Social cognitive	RAGT Control	65.46 (1.07) 64.68 (1.02)	66.05 (1.13) 65.27 (1.01)	66.17 (1.05) 65.07 (1.08)	0.813
Responsibility	RAGT Control	47.51 (1.65) 48.22 (1.19)	48.87 (1.50) 47.05 (1.17)	49.66 (1.30) 47.51 (1.18)	**0.018***

Values are Least square mean (standard error)
* p <0.05 by linear mixed model , † p <0.05 by Bonferroni adjusted post hoc analysis, compared with baseline assessment
‡ p <0.05 by Bonferroni adjusted post hoc analysis, compared with post-intervention assessment

CONCLUSION

Overground RAGT using wearable robot remained superior in improving gross motor function, participation in daily living, and gait parameters. This new torque-assisted wearable exoskeletal robot, based on assist-as-needed control, may effectively complement standard rehabilitation by providing adequate assistance and therapeutic support for children with CP.

ACKNOWLEDGEMENT

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