Reference

Pradon, D., Hutin, E., Khadir, S., Taiar, R., Genet, F., Roche, F.

CHU Raymond Poincaré, Laboratoire d'Analyse du Mouvement, Garches, France.

A pilot study to investigate the combined use of Botulinum toxin type-a and ankle foot orthosis for the treatment of spastic foot in chronic hemiplegic patients

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Products

Walk On additionally to Botulinum toxin (BoNTA)

Major Findings

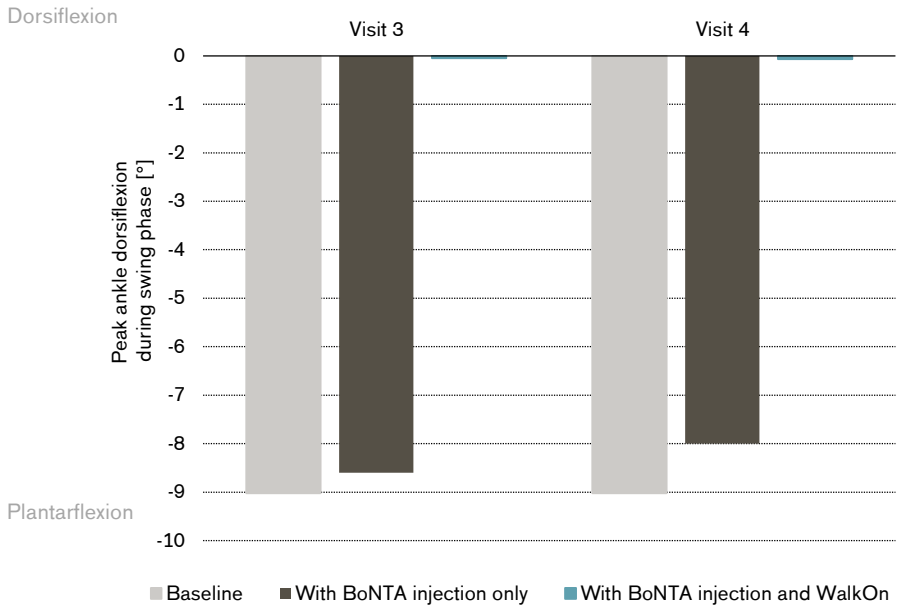
With **BoNTA injection and use of Walk On** compared to BoNTA injection only:

→ **Increase in peak ankle dorsiflexion during swing phase**
→ **Increase in peak plantarflexion moment**

With **Botulinum toxin injection (BoNTA injection)** compared to no treatment:

→ **Increase in gait velocity**
→ **Increase in peak ankle dorsiflexion during stance phase**
→ **Increase in peak knee flexion during swing phase**
→ **Increase in peak plantarflexion moment**

WalkOn significantly increased peak dorsiflexion during swing phase

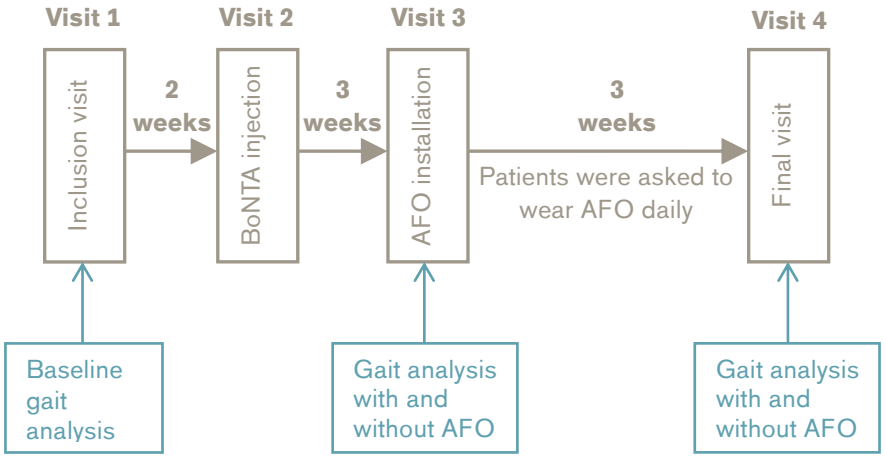


Population

Subjects:	8 chronic hemiplegic subjects following stroke 6 male, 2 female 5 right hemiplegia, 3 left hemiplegia
Mean age:	45 years
Inclusion criteria:	- hemiplegia following stroke (occurring more than 6 months prior to study participation) - spasticity of the triceps surae muscle (1-3 modified Ashworth scale): abnormal electromyogram (EMG) during the swing phase of gait - equinus foot during gait - at least 10 m independent walking without assistive devices - last BoNTA injection at least 4 months prior to study participation

Study Design

Pilot study



Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for BoNTA injection + Walk On (compared to BoNTA injection only)	Sig.*
Biomechanics – Gait analysis	**Kinematic parameters**		
	Peak ankle dorsiflexion during stance phase	No significant differences between BoNTA only and combined use of BoNTA and AFO during visits 3 and 4	0
	Peak ankle dorsiflexion during swing phase	**Significant increase by 99.4% due to AFO use during visit 3 (from -8.6° to -0.05° Plantarflexion)**	++
		Significant increase by 99.1% due to AFO use during visit 4 (from -8.0° to -0.07° Plantarflexion)	++

	Peak knee flexion during swing phase	No significant differences between BoNTA only and combined use of BoNTA and AFO during visits 3 and 4	0
	Dynamic parameters		
	Peak plantarflexion moment (PPFM)	**Significant increase by 13.5% due to AFO use during visit 3 (from 0.89 Nm/kg to 1.01 Nm/kg)**	++
		No significant increase due to AFO use during visit 4	0
	Spatio-temporal parameters		
	Gait velocity	No significant differences between BoNTA injection only and combined use of BoNTA and AFO at visits 3 and 4	0
	Step length (non-paretic side)		0
	Step length (paretic side)		0
	Stride length		0

* no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.)

Category	Outcomes	Results for BoNTA injection only (compared to baseline)	Sig.*
Biomechanics – Gait analysis	**Kinematic parameters**		
	Peak ankle dorsiflexion during stance phase	**Significant increase by 36.1% during visit 3 (from 10.8° to 14.7°)**	++
		Significant increase by 44.4% during visit 4 (from 10.8° to 15.6°)	++
	Peak ankle dorsiflexion during swing phase	No significant chance during visit 3	0
		No significant chance during visit 4	0
	Peak knee flexion during swing phase	**Significant increase by 18.3% during visit 3 (from 30.5° to 36.08°)**	++
		Significant increase by 34.1% during visit 4 (from 30.5° to 40.9°)	++
		Significant increase by 13.4% from visit 3 to visit 4 (from 36.08° to 40.9°)	++
	Dynamic parameters		
	Peak propulsive force	**Significant increase by 30.5% during visit 3 (from 0.059 N/kg to 0.077 N/kg)**	++
		Significant increase by 42.4% during visit 4 (from 0.059 N/kg to 0.084 N/kg)	++
	Peak plantarflexion moment (PPFM)	No significant increase during visit 3	0
		Significant increase by 36% during visit 4 (from 0.75 Nm/kg to 1.02 Nm/kg)	++

Spatio-temporal parameters		
Gait velocity	**Significant increase by 20% during visit 3 (from 0.55 m/s to 0.66 m/s)**	**++**
	Significant increase by 30.9% during visit 4 (from 0.55 m/s to 0.72 m/s)	**++**
	No significant differences between visits 3 and 4	0
Step length (non-paretic side)	**Significant increase by 15.9% during visit 3 (from 0.44 m to 0.51 m)**	**++**
	Significant increase by 18.2% during visit 4 (from 0.44 m to 0.52 m)	**++**
	No significant differences between visits 3 and 4	0
Step length (paretic side)	**Significant increase by 12.8% during visit 3 (from 0.39 m to 0.44 m)**	**++**
	Significant increase by 17.9% during visit 4 (from 0.39 m to 0.46 m)	**++**
	No significant differences between visits 3 and 4	0
Stride length	**Significant increase by 15.5% during visit 3 (from 0.84 m to 0.97 m)**	**++**
	Significant increase by 17.9% during visit 4 (from 0.84 m to 0.99 m)	**++**
	No significant differences between visits 3 and 4	0

* no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.)

Author's Conclusion

"In conclusion, the results of this preliminary study indicate that combined BoNTA injection of the triceps surae and wearing an AFO is more effective than use of BoNTA only. BoNTA injection into the triceps surae improves the gait of patients by increasing ankle dorsiflexion in stance phase, as well as the PPFM. However, BoNTA treatment does not appear to be effective in increasing dorsiflexion during the swing phase. Conversely, use of an AFO increases dorsiflexion of the ankle during the swing phase and does not reduce the benefits gained by use of BoNTA in stance phase. Future studies aimed at quantifying the therapeutic and functional effects of combined BoNTA and AFO are necessary to determine the best management strategy for gait disorders in patients with a motor disability." (Pradon et al., 2011)