ottobock.

Walk On





Clinical Study Summaries

This document summarizes clinical studies conducted with the Walk On. The included study was identified by a literature search made on PubMed and within the journals Orthopädie-Technik, Medizinisch Orthopädische Technik, Neurologie & Rehabilitation and Journal of Pediatric Orthopaedics.

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1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Defe					Category			
Reference Functions and Activities				Participation				
Author	Year	Biomechanics – Static measures	X-Kav EMG Eurotional tests Clinical effects					
<u>Pradon</u>	2011		x					
Total number: 1		0	0 1 0 0 0 0 0				0	

2 Summary of individual study

On the following pages you find the summary of the study that researched Walk On. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of the summary you also can read the original study authors' conclusions.

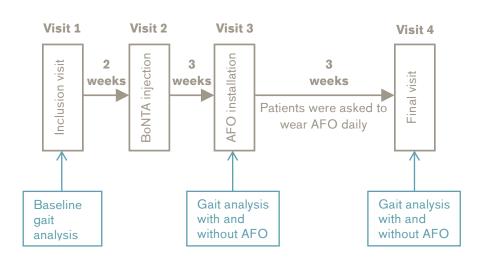
Reference				r, R., Genet, F., & d'Analyse du Moi		hes, France.	
	Botulinu for the hemiples Clinical Biome	m to trea gic p	oxin type- tment of		kle foot	orthosis	
Products			/ to Botulinum 1				
Major Findings	With BoNTA injection and use of Walk On compared to BoNTA injection only: → Increase in peak 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 						
	Walk On signi swing phase	ificantl	y increased pea	ak dorsiflexion c	during		
	Dorsiflexion		Visit 3		Visit 4		
		0 -1					
	_	-2					
	lexion tse [°	-3					
	dorsif g pha	4					
	ankle j swin	-5					
	Peak ankle dorsiflexion during swing phase [°]	· -6 ······					
	E O	-8					
	Plantarflexion	-9					

Baseline With BoNTA injection only With BoNTA injection and WalkOn

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



Pilot study



Results

Functions and Activit	ies				Participatio	on
Biomechanics – Static measures	Biomechanics – X-Ray Gait analysis	EMG		Clinical effects	Satisfacti	
Category	Outcomes		NTA injection BoNTA injecti			Sig.*
Biomechanics – Gait analysis	Kinematic parameters					
	Peak ankle dorsiflexion during stance phase	No significant differences between BoNTA only and combined use of BoNTA + AFO during visits 3 and 4			,	0
	Peak ankle dorsiflexion during swing phase	-	-	9.4% due to A o -0.05° Plantar		++
		-	-	9.1% due to A o -0.07° Plantar		
	Peak knee flexion during swing phase	•		etween BoNTA o O during visits 3		0

Peak plantarflexion mo- ment (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		
Spatio-temporal parame	eters	0	
Gait velocity			
Step length (non-paretic side)	No significant differences between BoNTA injection only and combined use of BoNTA and AFO at visits		
Step length (paretic side)	3 and 4		
Stride length	_		

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

Functions and Activit	ies		Participation			
	Biomechanics – X-Ray Gait analysis	EMG Functional tests Clinical effects	Satisfaction			
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	No significant chance during visit 3	0			
	during swing phase	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 mo-	No significant increase during visit 3	0			
	ment (PPFM)	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			

	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 t	rrend (-), 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, BoN-TA 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. 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)

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