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# Genu Neurexa





# **Clinical Study Summaries**

This document summarizes clinical studies conducted with the Genu Neurexa. 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).

Reference		Category						
		Functions and Activities					Participation	
Author	Year	Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction
Portnoy	2015		x		x	x		x
Total number: 1		0	1	0	1	1	0	1

# 2 Summary of individual study

On the following pages you find the summary of the study that researched Genu Neurexa. 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

Portnoy, S., Frechtel, A., Raveh, E., & Schwartz, I.

Department of Physical Medicine and Rehabilitation, Hadassah Medical Center, Mount Scopus, Jerusalem 91240, Israel; Department of Occupational Therapy, Tel Aviv University.

## Prevention of Genu Recurvatum in Poststroke Patients Using a Hinged Soft Knee Orthosis

American Journal of Physical Medicine & Rehabilitation 2015: 1-10.

### **Products**

### **Genu Neurexa**

### **Major Findings**

With Genu Neurexa compared to wearing no orthosis:

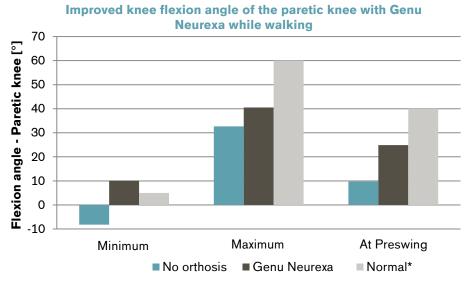
### → Prevention of hyperextension and higher knee flexion angle while walking

### → Significant improvement in all Functional Tests when using Genu Neurexa:

→ Berg Balance Scale (BBS): + 7.0%
 → 6-Minute Walk Test (6MWT): +16.5%
 → 10-Meter Walk Test (10MWT): + 6.9%
 → Timed Up and Go Test (TUG): +10.6%

### → High user satisfaction with an OPUS-Satisfaction with Devices score of 13.8 ± 3.9 (9=very satisfied, 36=very dissatisfied)

(Average score of the 9 questions is  $1.5 \pm 0.4$ , where 1 reflects very satisfied and 4 very dissatisfied)



\*Perry, J. (2010). Gait analysis. Normal and Pathological Function, 2nd edition.

### **Population**

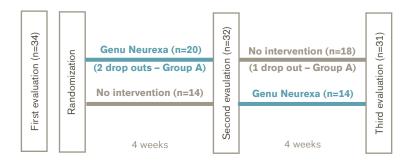
Subjects: 31 (23 men, 8 women) Mean age:  $59.9 \pm 15.1$  years Mean body mass:  $76.1 \pm 11.7$  kg Time after stroke:  $6.1 \pm 6.7$  years NIHSS:  $7.5 \pm 2.1$ 

(National Institute of (Total range from 0 (normal function) to 42

Health Stroke Scale) (severe impairment))

### **Study Design**

Interventional, single crossover with randomization:



### **Results**

Functions and Activiti	es	Participa	tion		
	Biomechanics – X-Ray Gait analysis	EMG Functional tests Clinical effects Satisfac	tion		
Category	Outcomes	Results for Genu Neurexa	Sig.*		
Biomechanics – Gait analysis	Sagittal angle of paretic knee	The flexion angle of the paretic knee was significantly higher with Genu Neurexa compared to wearing no orthosis:			
		Minimum: The hyperextension was prevented with Genu Neurexa compared to wearing no orthosis.  Maximum: The maximum flexion angle increased by 23.9% with Genu Neurexa compared to wearing no orthosis.  At Pre-swing: A significantly higher flexion angle (+156.7%) was recorded			
at Pre-swing with Genu Neurexa c orthosis.		at Pre-swing with Genu Neurexa compared to wearing no orthosis.			
	Spatiotemporal parameters and gait symmetry	No significant differences for the recorded spatiotemporal and gait symmetry results were found.			
EMG	Activation time and Peak RMS (root mean square)	No differences for paretic and non-paretic leg were found when comparing Genu Neurexa to wearing no orthosis.			
Functional tests	Berg Balance Scale (BBS)	The BBS was significantly improved by 7% with orthosis compared to wearing no orthosis.			
	6-Minute Walk Test (6MWT) [m]	The covered distance within 6 minutes increased by 16.5% with Genu Neurexa compared to no orthosis.			
	10-Meter Walk Test	The users were significantly faster by 6.9% with Genu	++		

Functions and Activities					Participation	
Biomechanics – Static measures	Biomechanics – X-Ray Gait analysis	EMG	Functional tests	Clinical effects	Satisfaction	
Category	Outcomes	Results for Genu Neurexa				
	(10MWT) [s]	Neurexa compared to wearing no orthosis.  The TUG was performed significantly faster by 10.6% ++ with Genu Neurexa compared to wearing no orthosis.				
	Timed Up and Go Test (TUG) [s]					
Satisfaction	OPUS-(Orthotics and Prosthetics User's Survey) — Satisfaction with Devices	The users rated to be very satisfied with the orthosis with an score of 13.8 $\pm$ 3.9, where 9 reflects great satisfaction and 36 great dissatisfaction.  (Questionnaire included 9 questions about the orthosis, with an average score of 1.5 $\pm$ 0.4)				

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

### **Author's Conclusion**

"Using a hinged soft knee orthosis to prevent genu recurvatum after stroke may be considered a viable option to prevent falls and fall-related injuries by restoring balance and confidence in the patient and increasing foot clearance" (Portnoy et al. 2015)

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