

## Smart Mobility

# Summary of Keeogo Clinical Trials

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## Keeogo's Patient Population

- Stroke
- Parkinson's Disease
- Knee Osteoarthritis
- Multiple Sclerosis



## Keeogo Clinical Trials

Author/Date	Publication	Patient Population
Mcleod et al., 2017	Evaluation of the Keeogo Deroskeleton	1) Mixed 2) Stroke
USFDA, 2019	The Evaluation of the Effectiveness and Safety of Keeogo Deroskeleton in Subjects with Mobility Impairments Due to Stroke	Stroke
Cantin, 2012	Study of balance and walking capacity in patients with Parkinson's Disease	Parkinson's disease
McGibbon et al., 2018	Evaluation of the Keeogo exoskeleton for assisting ambulatory activities in people with multiple sclerosis: an open-label, randomized, cross-over trial	Multiple sclerosis
McGibbon et al., 2017	Effects of an over-ground exoskeleton on external knee moments during stance phase of gait in healthy adults	Knee Osteoarthritis

## Evaluation of Keeogo Part I

### Evaluation of the Keeogo™ Dermoskeleton

*(Mcleod et al., 2017)*

**Subjects:** 13 individuals with neurological impairments

#### **Objectives:**

- (1) Determine the functional characteristics of individuals with neurological impairments that may predict successful use of Keeogo
- (2) Quantify the specific benefit Keeogo provides to a regular user of the device



## Evaluation of Keeogo Part I: Subjects

Table 1. Participant characteristics.

Subject ID	Gender	Age	Impairment/injury	Severity	Time from injury/ impairment (years)
1	M	65	iSCI	T10; ASIA: A	1
2	M	65	MS	EDSS: 6	4
3	F	20	CP	GMFCS: 1	n/a
4	F	57	MS	EDSS: 2	14
5	F	55	MS	EDSS: 4	24
6	M	65	Stroke	Spinal	2
7	F	20	Stroke	n/a	3
8	M	50	MS	EDSS: 6	6
9	F	56	MS	EDSS: 6.5	21
10	M	44	MS	EDSS: 2	19
11	M	65	CA	Progressive	12
12	M	55	iSCI	C2;ASIA: D	2
13	F	45	MS	EDSS: 2	19

iSCI: incomplete spinal cord injury; ASIA: American Spinal Cord Injury Association; MS: multiple sclerosis; EDSS: expanded disability status scale; CP: cerebral palsy; GMFCS: gross motor function classification system; n/a: not available; CA: cerebellar ataxia.

# Evaluation of Keeogo Part I: Outcome Measures

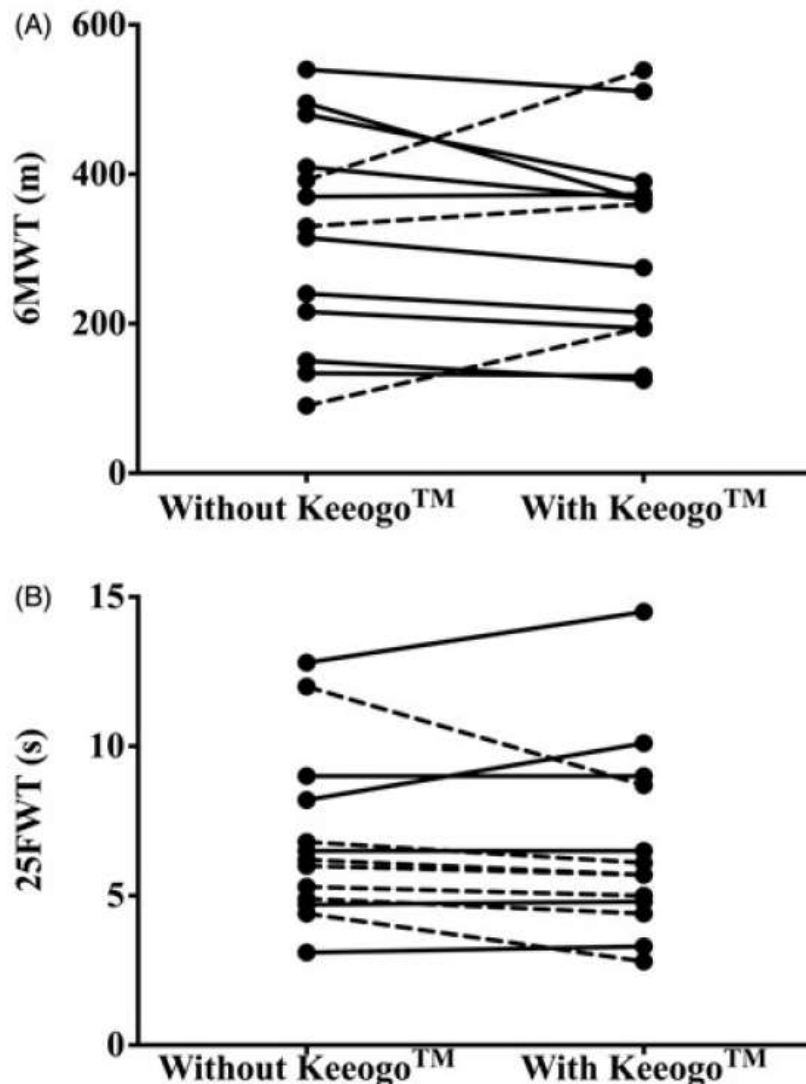
## Primary Outcome Measures

- 6-Minute Walk Test (6MWT)
  - 25-Foot Walk Test (25FWT)
- } Assess patient performance  
WITH and WITHOUT Keeogo

## Secondary Outcome Measures

- Timed Up-and-Go (TUG)
  - Berg Balance Scale (BBS)
- } Identify patient baseline characteristics

## Evaluation of Keeogo Part I: Outcome Measures



### Primary Outcome Measures

- 6-Minute Walk Test (6MWT)
- 25-Foot Walk Test (25FWT)
  - Improvement of  $\geq 5\%$  in performance while wearing Keeogo → “responders”
  - Improvement of  $< 5\%$  while wearing Keeogo → “nonresponders”



## Evaluation of Keeogo Part I: Results & Conclusions

**Table 3.** Clinical criteria for responders and non-responders to Keeogo™ on primary outcome measures.

	6MWT		25FWT	
	Responders	Non-responders	Responders	Non-responders
TUG (s)	10.1 ± 2.2	12 ± 6.9	11.1 ± 4.4	12.1 ± 8.2
BBS (score)	50 ± 6	48 ± 6	50 ± 5	48 ± 8

6MWT: 6-min walk test; 25FWT: 25-foot walk test; TUG: timed up and go; BBS: Berg Balance Scale.

- Association between “**responders**” and “**non-responders**” for 6MWT, 25FWT and TUG, BBS



## Evaluation of Keeogo Part I: Results & Conclusions

**Table 4.** Clinical criteria for responders, high-end- and low-end non-responders to Keeogo™.

	Non-responders	Responders	Non-responders
TUG (s)	<8	8–12	>12
BBS (score)	<46	46–51	>51

TUG: Timed Up and Go; BBS: Berg Balance Scale.

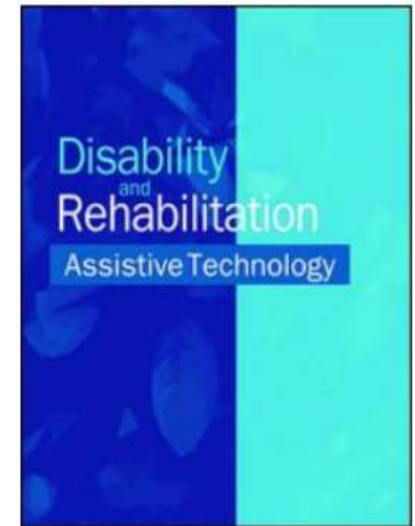
- **Berg Balance Scale and Timed Up-and-Go test can be used to measure baseline characteristics of good responders to Keeogo**
- Individuals with too severe or too **do not benefit** from Keeogo
- Individuals with **moderate impairment** → respond **best** to Keeogo

## Evaluation of Keeogo Part II: Case Study

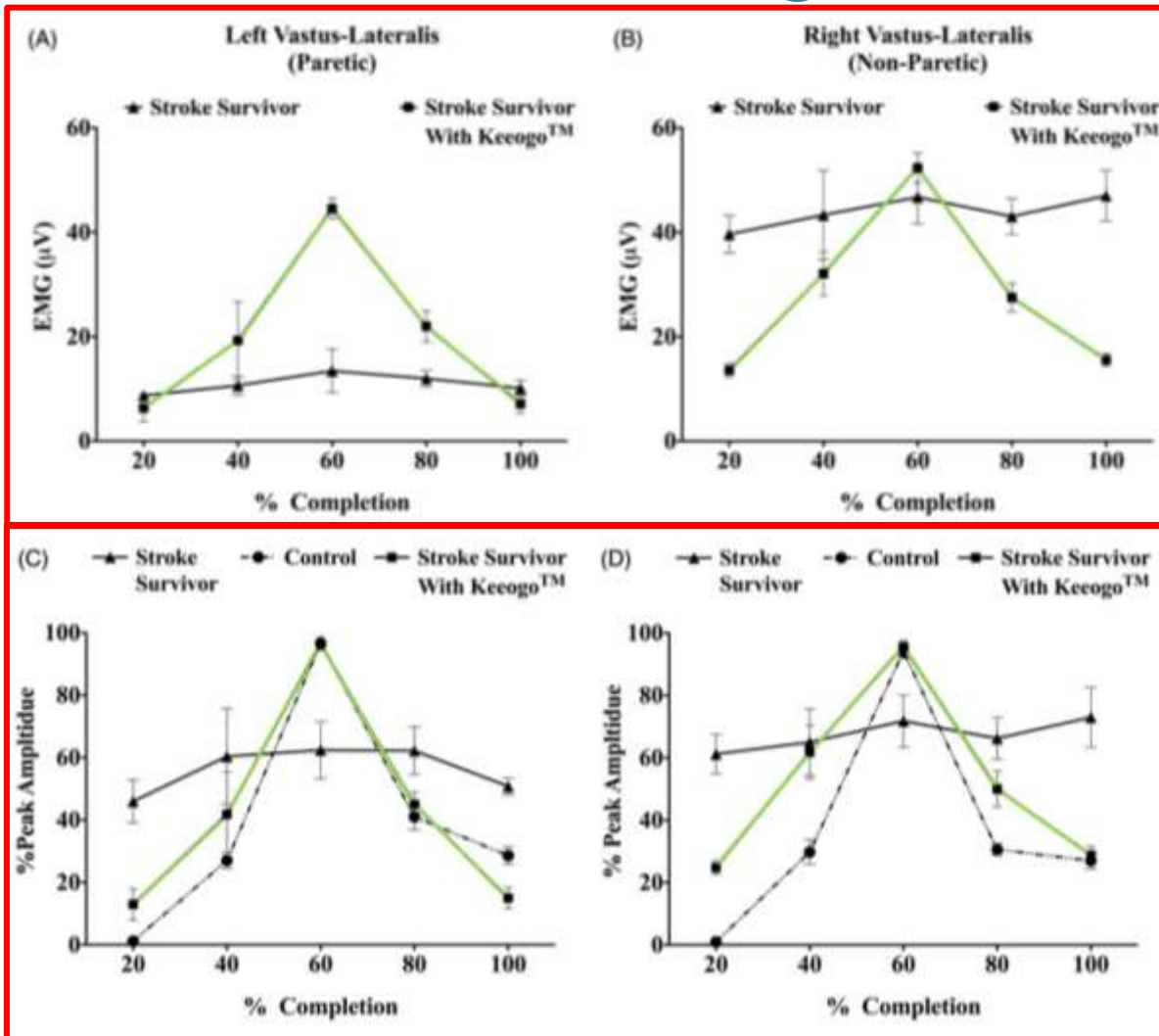
**Subject:** 20 year old stroke survivor (left hemiparesis)

**Objective:** To assess functional benefits (stair climb test and 30-second chair stand test) gained when wearing Keeogo™ on day-to-day basis for 12 months under two conditions:

- With Keeogo
- Without Keeogo



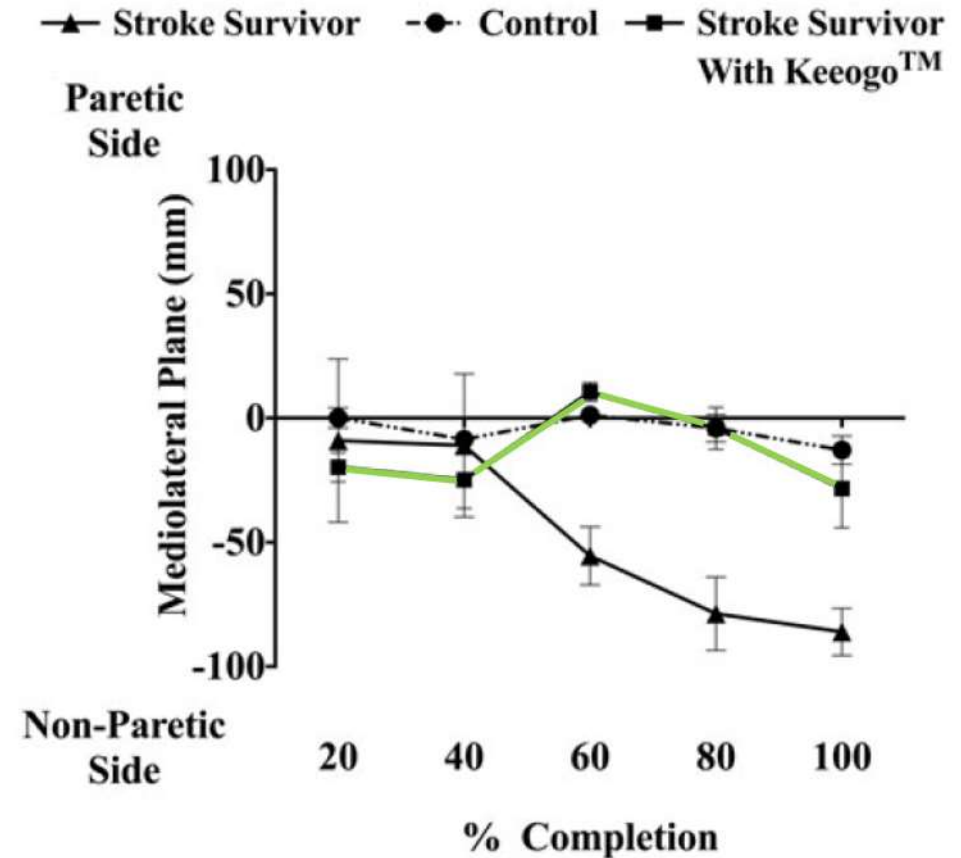
## Evaluation of Keeogo Part II: Results



- **Increased knee extensor activity** in paretic limb
- Knee extensor activation pattern more closely matched that of healthy control
- **Increased confidence**
- More direct effort in activating paretic limb

## Evaluation of Keeogo Part II: Results

- CoP sway typically towards **non-paretic limb**
- Keeogo help **corrects sway**
- **Increased load** on paretic limb → **improved postural control**



(Mcleod et al., 2017)

## Evaluation of Keeogo Part II: Results & Conclusions

	Stroke survivor		
	Control	Without Keeogo™	With Keeogo™
SCT (s)	6.92	47.83	8.83
30CST (# of reps)	16	8	13

SCT: stair climb test; 30CST: 30-s chair stand test.

- Improved **symmetry in lower extremity muscles** during sit to stand
- Capable of **loading more weight on paretic limb** → rise from chair in more symmetrical fashion with Keeogo

## Keeogo in Stroke (USFDA): Unpublished Study

**The Evaluation of the Effectiveness and Safety of Keeogo Dermoskeleton in Subjects with Mobility Impairments Due to Stroke**  
*(USFDA, 2019)*

**Subjects:** 48 chronic stroke patients (ages  $58 \pm 10$ , median 40 months since CVA, 23 female)

**Objective:** To evaluate the safety of Keeogo and its effectiveness in chronic stroke patients

- Safety for patient and PT
- Device effectiveness

## Keeogo in Stroke (USFDA): Study Design

- **Multi-site study**
- **Open-label** study (no blinding, masking, or random assignment)
- **Intra-subject** comparison
- **No control group**
- **Intervention duration: 9 days**

Week 1  
(Visit 0)

- Subject enrollment

Week 1  
(Visit 1-3)

- Familiarization and baseline data collection (**no Keeogo**)

Week 2  
(Visit 4-6)

- Fitting and familiarization **with Keeogo** (3 sessions)

Week 3  
(Visit 7-9)

- **Performance assessments with Keeogo** (3 sessions)



## **Keeogo in Stroke (USFDA): Outcome Measures**

- **Walking performance** (Wisconsin Gait Scale, WGS)
- **Patient Rated Outcomes (PRO)**
- **Clinician Rated Outcomes (ClinRO)**
- **Knee strength** (30 second chair test, 30SCT)
- **Stairs ability** (Timed stair test, TST)
- **Spatiotemporal variables**
- **Disability measures** (FMA-LE, BBS, MAS)

## Keeogo in Stroke (USFDA): Results and Conclusions

- **Improved gait**
  - 2.6 improvement in Wisconsin Gait Scale (15% above MCID)
  - 37% reduction in gait deficit
- **Improved stability against falls**
- **Improved stair performance for 70% of patients**
  - Improved time (decrease by 7.15 s, compared to baseline 36.6 s)
- **Improved knee strength\***
  - Increased repetitions (11 to 15) for 30SCT

\* = statistically significant

## Keeogo in Parkinson's Disease

### Study of balance and walking capacity in patients with Parkinson's Disease (*Cantin, 2012*)

**Subjects:** 3 patients

**Objective:** To evaluate walking capacity and balance under 3 conditions:

- Without Keeogo
- With Keeogo (free mode)
- With Keeogo (assist mode)



- 53 years old
- Diagnosed  $\approx$  10 yrs
- Medicated



- 56 years old
- Beginner
- Slightly medicated

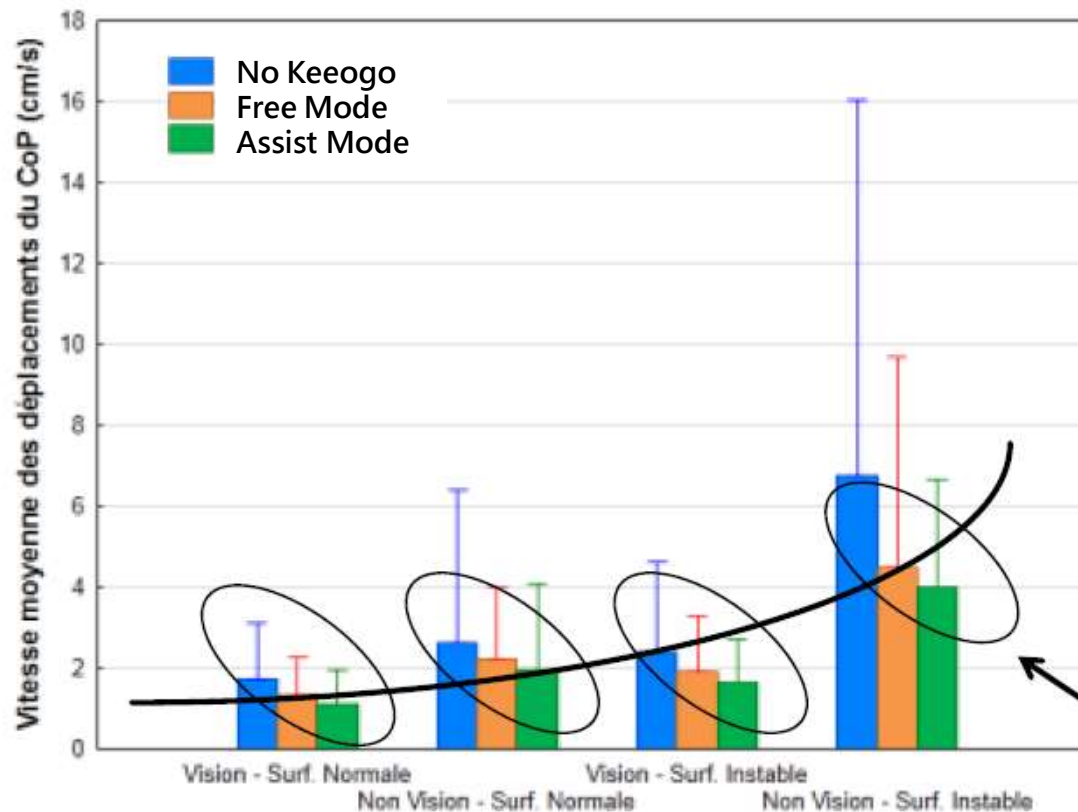


- 61 years old
- Diagnosed  $\approx$  5 yrs
- Not medicated

# Keeogo in Parkinson's Disease: Results

## Oscillation Speed

- Reduction in oscillation speed for most of the cases



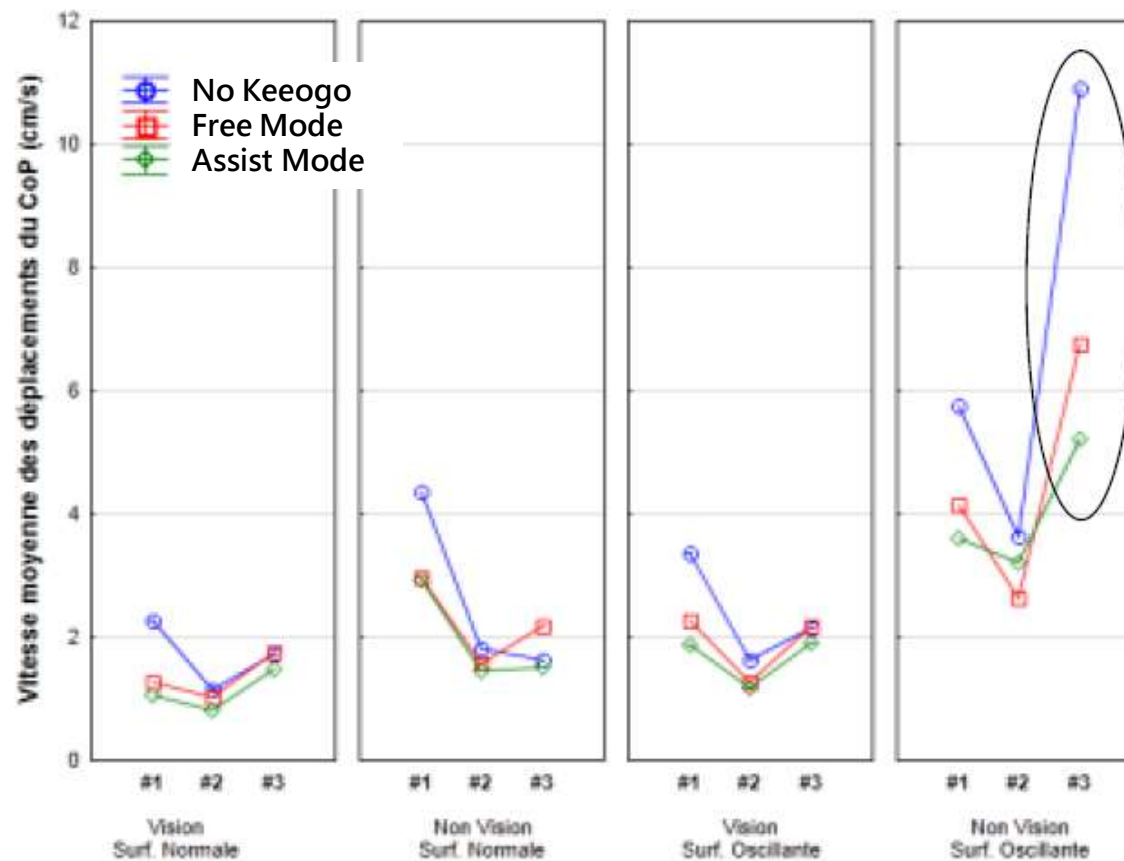
**POSITIVE TREND** towards improvement in balance when wearing Keeogo in assist mode (green bars)

**NOTE:** Decrease in average oscillation speed for all of the conditions.

# Keeogo in Parkinson's Disease: Results

## Oscillation Speed

- Trend between disease severity and dermoskeleton efficiency

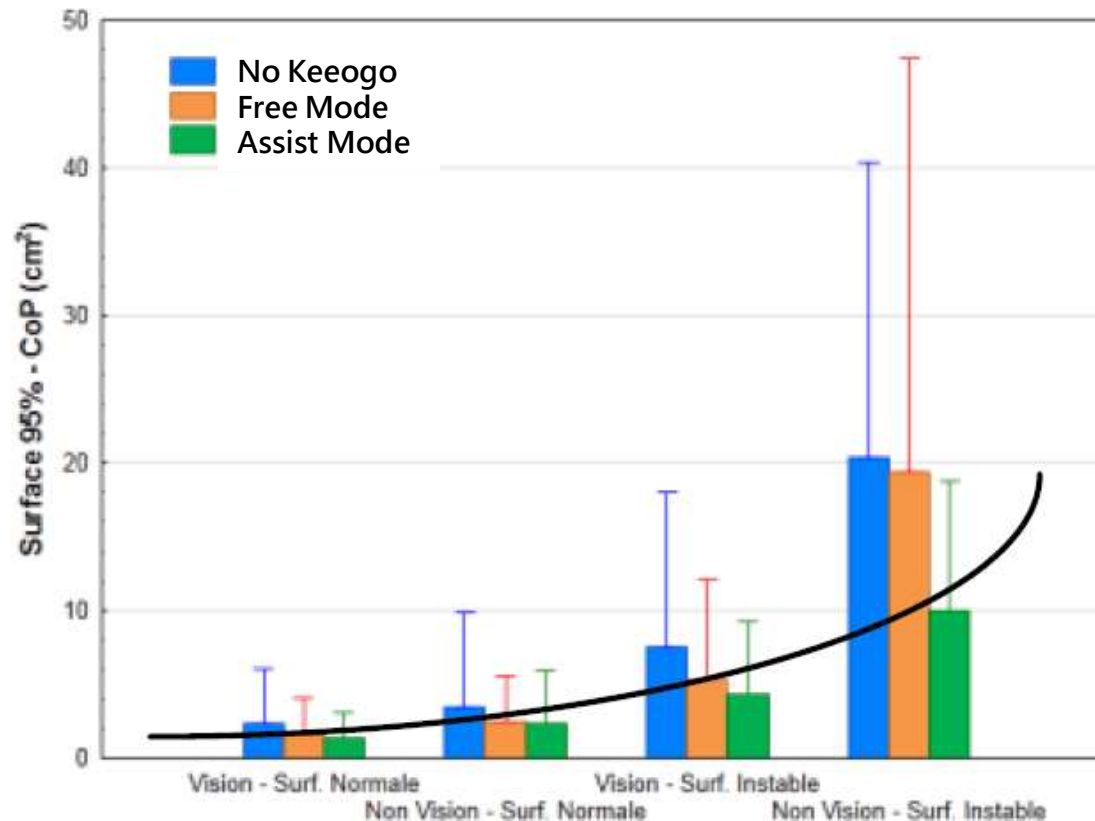


**NOTE:** Subject 3 with most severe PKS benefits the most in the most difficult condition (unstable surface and non-vision)

# Keeogo in Parkinson's Disease: Results

## Oscillation Surface

- Decreased oscillation surface (sway) when wearing Keeogo in assist mode



**NOTE:** Trend in decreased oscillation surface across the board in assisted mode.

## Keeogo in Parkinson's Disease: Conclusions

- **Keeogo on assist mode → improvement in balance**
- **Trend between disease severity and dermoskeleton efficiency**
- **Straighter more stable posture**
- **More solid ankles**
- **Less hand tremor**



## Keeogo in Multiple Sclerosis

**Evaluation of the Keeogo exoskeleton for assisting ambulatory activities in people with multiple sclerosis: an open-label, randomized, cross-over trial**  
*(McGibbon et al., 2018)*



**Subjects:** 29 patients with MS (randomized into group A and B)

**Objective:** Examine the immediate performance effects when using Keeogo and the potential benefits of using Keeogo at home for 2 weeks

- Performance Effect
- Activity Effect
- Rehab Effect
- Training Effect

## Keeogo in Multiple Sclerosis

### Performance Effect

Improvements in physical performance **while wearing Keeogo**

### Activity Effect

Improvements in physical activity levels **while using Keeogo at home for 2 weeks**

### Rehab Effect

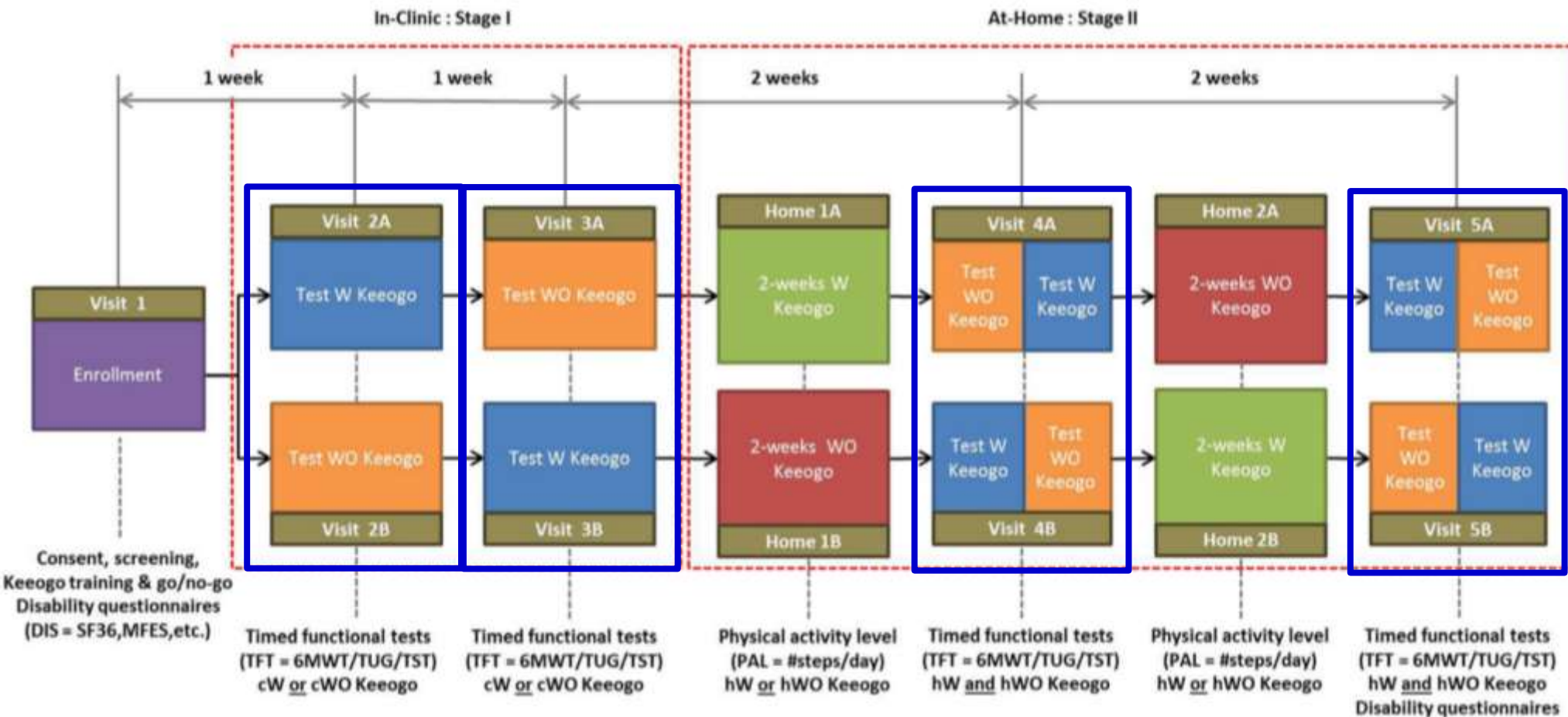
Improvements in physical performance **without Keeogo AFTER using Keeogo at home for 2 weeks**

### Training Effect



Improvements in physical performance **with Keeogo AFTER using Keeogo at home for 2 week**

# Keeogo in Multiple Sclerosis: Study Design

## 2x2 cross-over approach

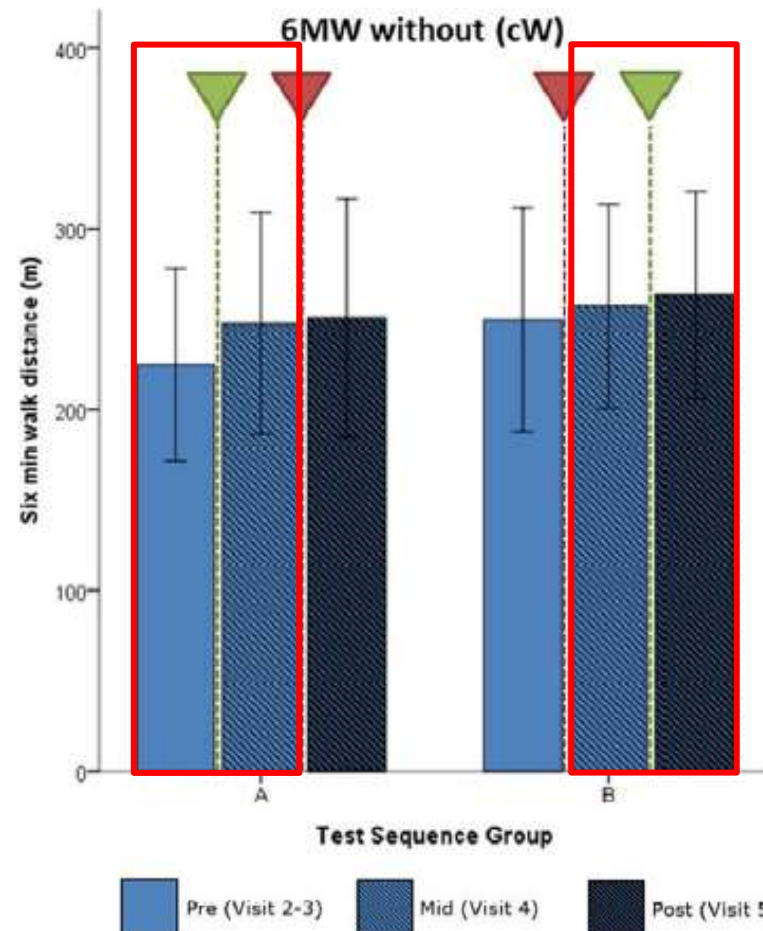
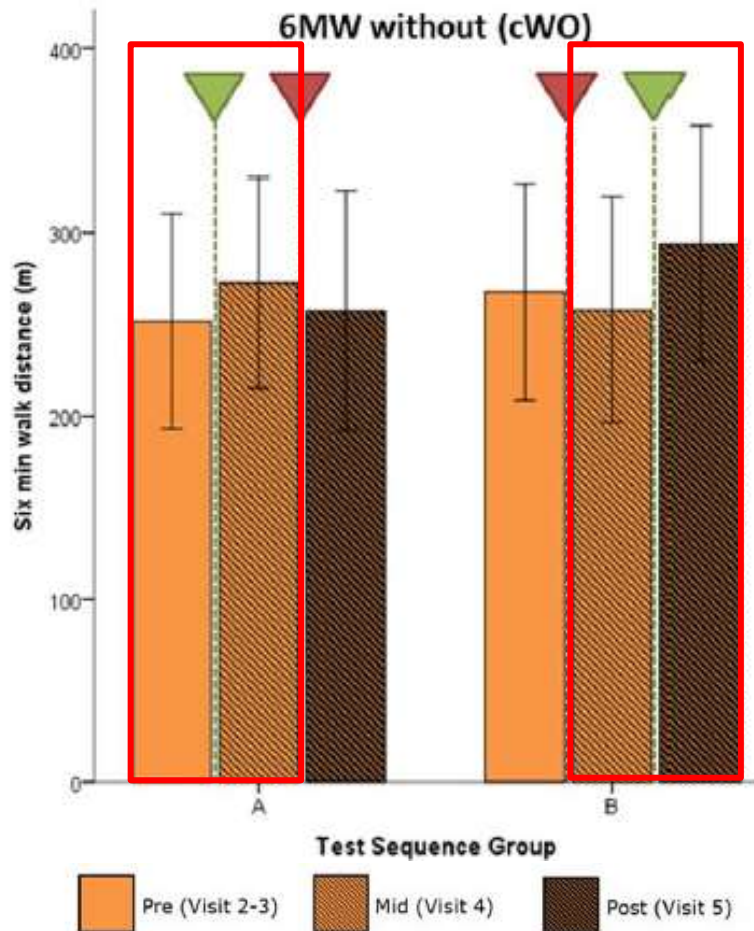


# Keeogo in Multiple Sclerosis: Results

Home with (hW)   
Home without (hWO) 



Rehab effect

Training effect



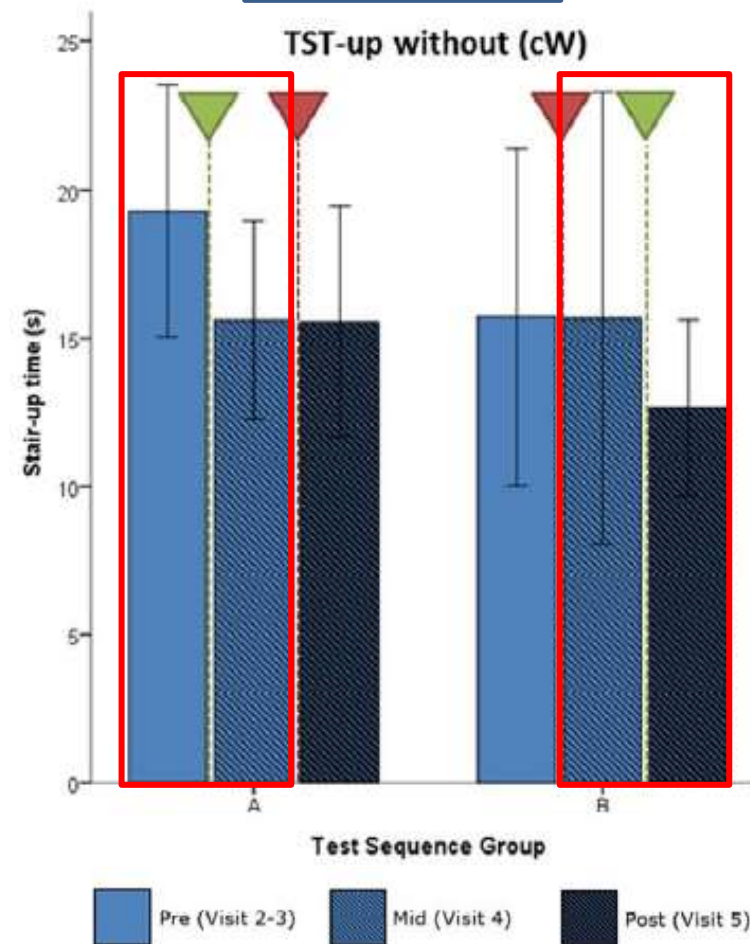
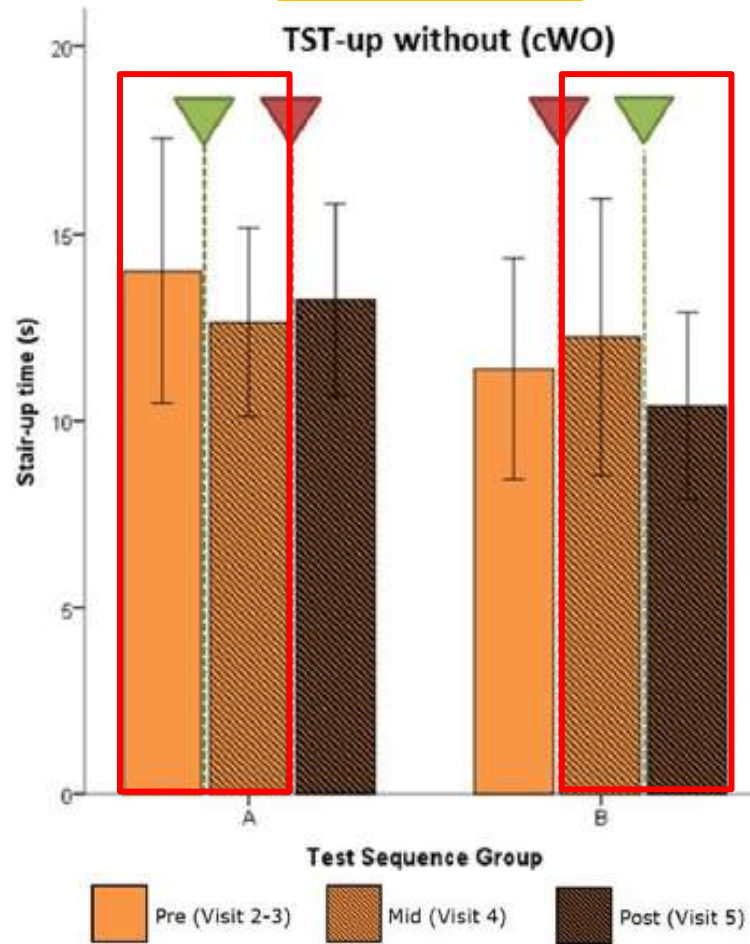


# Keeogo in Multiple Sclerosis: Results



Home with (hW)   
Home without (hWO) 

Rehab effect

Training effect

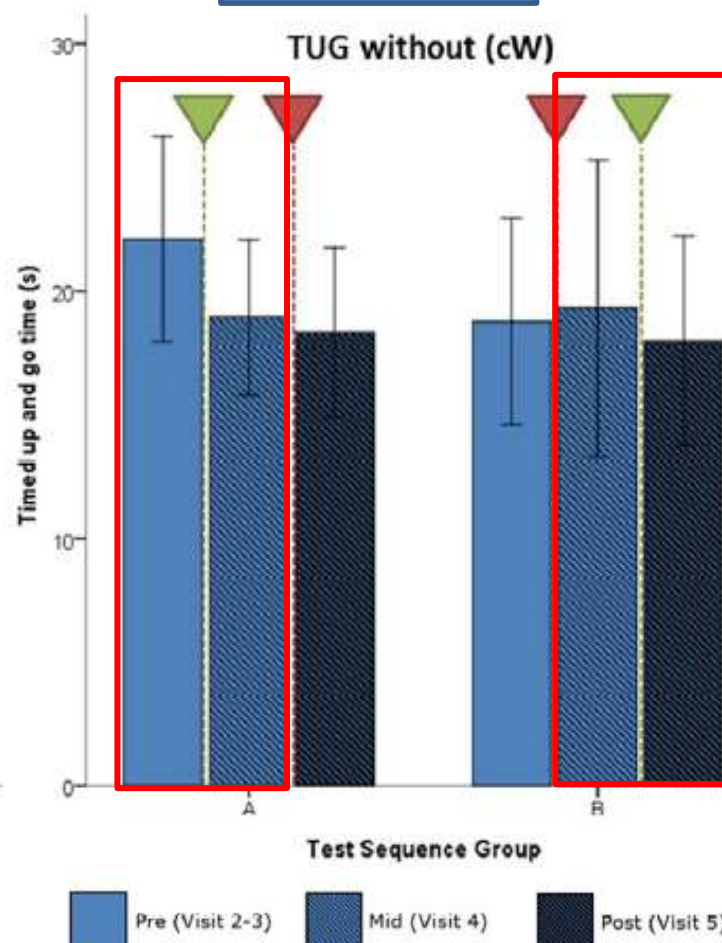
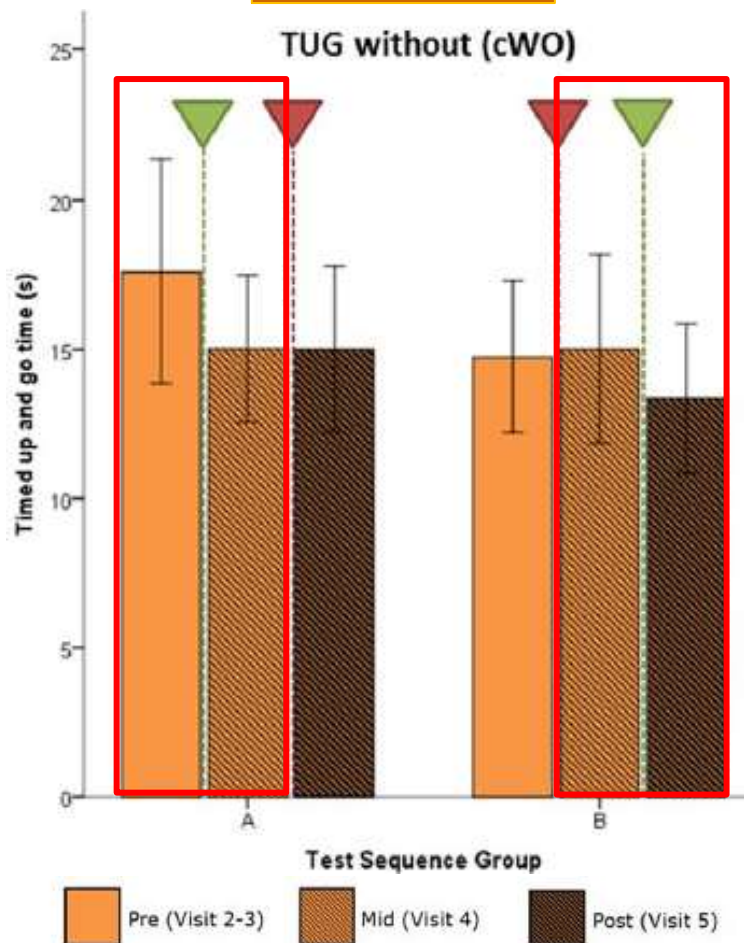


# Keeogo in Multiple Sclerosis: Results

Home with (hW)   
Home without (hWO) 

Rehab effect

Training effect



## Keeogo in Multiple Sclerosis: Results

Improved unassisted walking endurance  
Improved unassisted stair climbing performance



Rehab  
Effect

Improved use of Keeogo during functional activities



Training  
Effect



## Keeogo in Multiple Sclerosis: Conclusions

- Patients walked **slower** when wearing Keeogo
- Increased use of Keeogo at home → improvement in unassisted physical function
- Patients **improved use** of Keeogo in performing functional activities
- Rehab and Training effects **positively correlated** with Keeogo training

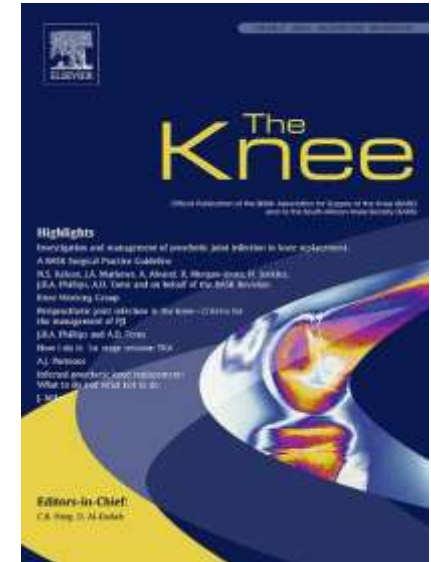
## Keeogo in Knee Osteoarthritis

**Effects of an over-ground exoskeleton on external knee moments during stance phase of gait in healthy adults** (*McGibbon et al., 2017*)

**Subjects:** 13 healthy participants

### Objective:

- (1) Quantify and evaluate how Keeogo modifies knee biomechanics
- (2) Apply in the context of knee osteoarthritis



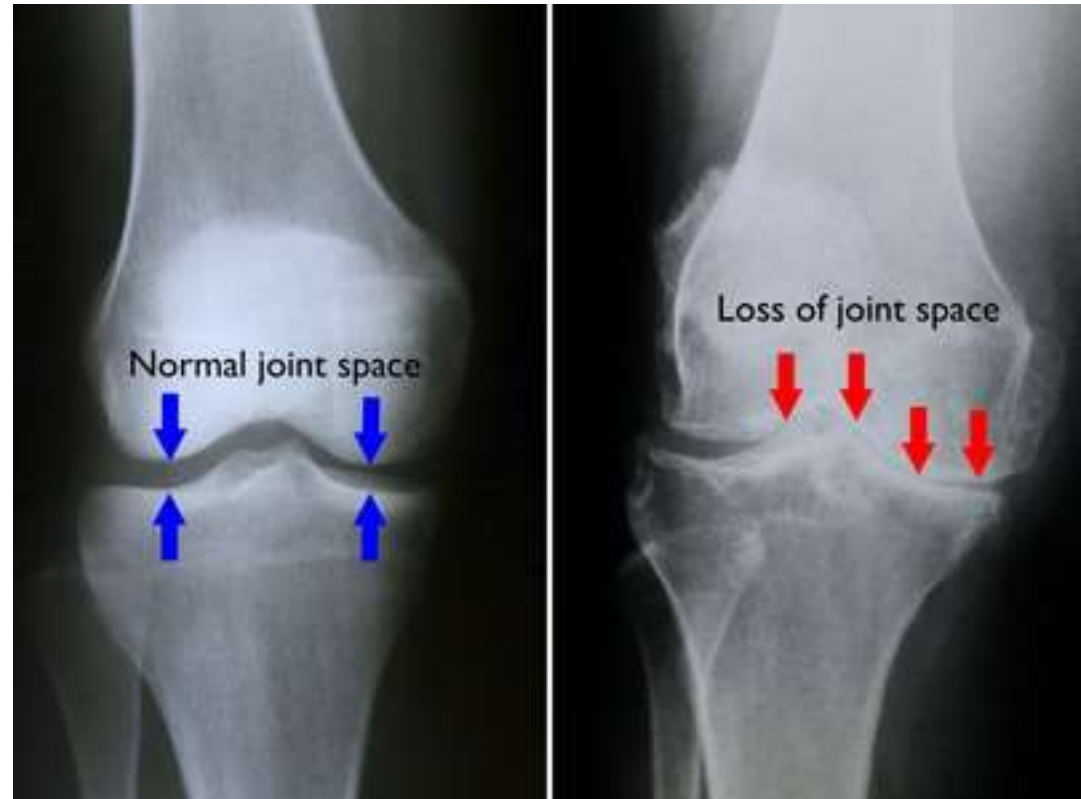
## Keeogo in Knee Osteoarthritis: Results

- Patients took shorter, wider steps
- Keeogo decreases knee adduction moment → favorable biomechanical environment for the OA knee



## Keeogo in Knee Osteoarthritis: Conclusions

- **Frontal plane misalignment** in KOA causes increased knee adduction moment (KAM)
  - Strong predictor of progression of medial compartment KOA
  - Non-responsive to muscle strengthening
- **Reduction of KAM** creates **favorable circumstances** for conservative management



(Image source: <https://roberthowells.com.au/conditions-and-treatment/knee-osteoarthritis-overview/>)

## Keeogo in Knee Osteoarthritis: Conclusions

- **Reduces muscle co-contraction → beneficial for neuromuscular training**
- **Reduce knee loading**
- **Enable greater physical activity**
- **Modifies of knee biomechanics → favorable for conservative management of KOA**

## Applicable Outcome Measures

- **Walking performance**
  - Gait speed (10-Meter Walk Test or 25-Foot Walk Test)
  - Endurance (6-Minute Walk Test)
  - Timed Up-and-Go
- **Stairs ability**
  - Timed Stair Test
  - Stair Climb Test (SCT)
- **Lower body strength**
  - 30 Second Chair Stand Test (30CST)
  - 5 Times Sit-to-Stand (FTSST)
- **Disability measures (FMA-LE, BBS, MAS)**

## Concluding Remarks

- Safe for **chronic stroke, Parkinson's disease, multiple sclerosis, and knee OA patients**
- Improvement performance in **gait and stairs**
- Improved **stability** and **balance** in lower extremities
- Improved **symmetry in lower extremity** muscle activation and weight-bearing
- Increased use of Keeogo → **greater improvement in unassisted physical function**
- Increases **confidence** in the user



## Concluding Remarks: Limitations

- More **familiarization time with Keeogo** may be needed
- Inherent stiffness may lead to **slower walking speed** and **widening of base of support**

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Thank You