NORTHERN NEW JERSEY SPINAL CORD INJURY SYSTEM

Spinal Cord Injury Grand Rounds Series

This packet contains materials presented as part of the Spinal Cord Injury Grand Rounds Series hosted by the Northern New Jersey Spinal Cord Injury System with support from the National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Grant #H133N110020.

The SCI Grand Rounds Series is a forum in which to learn about innovative research and cutting-edge clinical practice from experts in the field. We hope you will find these materials to be informative and helpful.

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sciresearch@kesslerfoundation.org

The NNJSCIS is a cooperative effort of Kessler Foundation, Kessler Institute for Rehabilitation, Rutgers New Jersey Medical School and University Hospital, Newark.

"Lokomat Robotic Training: Who is the appropriate patient?"

Natalie Cavadini, PT, DPT
Kessler Institute for Rehabilitation

Grand Rounds- April 15, 2015

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Presentation Goals

- To educate others on how Kessler is currently utilizing the Lokomat Pro.
- To explain the general indications and contraindications for use
- To increase the number of appropriate referrals for the Lokomat program
- To begin to show that the Lokomat is an adjunct PT intervention appropriate for many different diagnoses

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Hocoma

Lokomat® Pro

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The Referral Process

- Referral can come from **either** the MD or the PT
- All patient's must have **written** MD clearance that specifically notes **"Lokomat"** on Rx
- All patient's then undergo PT evaluation
- If appropriate, PT and pt determine **frequency and duration** of Lokomat

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Options of Lokomat Utilization

Option 1: The patient is enrolled into PT for LOKOMAT ONLY training (2-3x/week for 3 months duration??)

Option 2: The patient can utilize the Lokomat as an adjunct intervention while in PT (1, 2 or 3x/week for varied duration)

Option 3: The patient can self-pay for the use of the Lokomat ($$ price = specialty program rate)

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The Current Use of the Lokomat Pro at Kessler Institute for Rehabilitation

August 2011 to present

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How many and what types of patients have we seen?

- At least 108 **different** patients on the Lokomat to present date
- 50 females; 58 males
- Total # of sessions to present >1100
- At least 10 different diagnoses

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How many and what types of patients have we seen?

- Age ranged from **13 to 80 y.o.** (9 y.o. female - manual training only)
- Treatments/patient ranged from 2 to 55 sessions/patient
- First patient utilized Lokomat at KIR in **August 2011**
- Kessler was the **first** site in the nation to utilize the **"Pro"** version of the Lokomat

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GENERAL INDICATIONS

AKA:Who is appropriate?

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General Indications that the Lokomat may be appropriate

- Your patient can support his/her head
- Your patient tolerates standing for 30 minutes (Standing frame is acceptable)
- Your patient's ROM is grossly WFL
- Your patient can follow one to two step commands
- Your patient's height and weight are appropriate for the device (*see next slide)

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The Lokomat can be adjusted to fit a variety of "shapes and sizes"

The Lokomat IS adjustable/appropriate for:

1. Small Leg length discrepencies 1-3" (with built-in shoelift)
2. Weight limit = 290 lbs.
3. Height restrictions= approx 5' to 6.2'
   (*35 cm > Upper leg length <47 cm*)
4. Each lower extremity can be set at a different ROM and/or offset

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What types of diagnoses have we treated on the Lokomat?

- SCI (complete and incomplete)
- Multiple Sclerosis
- Cerebral Palsy
- Muscular Dystrophy
- Transverse Myelitis
- Spina Bifida
- Spinal Surgeries
- Stroke
- Traumatic Brain Injury
- Chiari Malformation
- Guillain-Barré Syndrome

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What other populations might benefit from Lokomat training?

- Parkinson's disease
- Orthopedic population
- General de-conditioned patient
- Can you think of any others???

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GENERAL CONTRAINDICATIONS

AKA- Who isn't/may not be appropriate for the Lokomat?

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Contraindications

- Orthosis cannot be adjusted to fit the body (lower limbs)
- Body weight greater than 135 kg (290 lbs)
- Severely fixed contractures
- Bone instability (non-consolidated fractures, unstable spinal column, severe osteoporosis)
- Open skin lesions in the area of the lower limbs and torso
- Circulatory problems
- Cardiac contraindications
- Hip, knee and ankle arthrodesis

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Contraindications

- Uncooperative or self-harming behavior, such as transitory psychotic syndrome
- Severe cognitive deficits
- Patients with (long-term) infusions
- Mechanical ventilation
- Patients with extremely disproportionate growth of the legs or spinal column(e.g. bone or cartilage dysplasia)
- Severe vascular disorders of the lower limbs
- General, patients who have been ordered to remain in bed or immobile (e.g. osteomyelitis or other inflammatory/infectious disorders)

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Possible barriers limiting use of Lokomat

- High Tonicity
- DF contractures (neutral ankle DF is desirable)
- Fragile skin
- Pre-pubescent child??
- Significant leg or abdominal girth
- Hypersensitivity and/or high levels of pain
  - Patient will be supported 100% of BWS during set up of Lokomat

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Special Features of the Lokomat

How we can use the Lokomat to individualize PT sessions?

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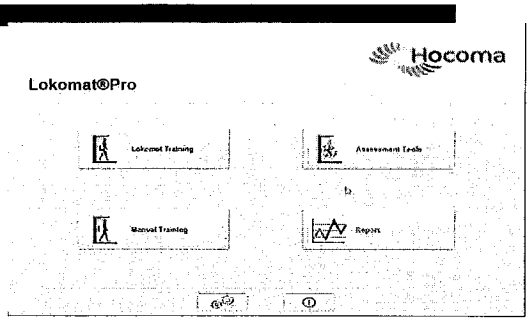
Different Options for Training



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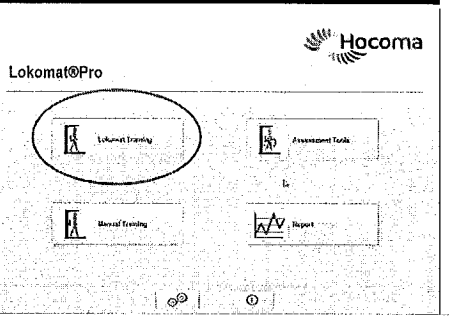
Mode #1: Lokomat Training



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Lokomat Training

"Lokomat is an electrically powered gait orthosis consisting of ahip adjustment and two gait orthoses. The gait orthoses are each equiped with a hip and knee joint drive. Lokomat is mounted on a swivel door via parallelogram. It is used together with a treadmill and a body weight support system. Lokomat is controlled via a PC."

Http://www.hocoma.com/products/lokomat

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#1 Parameters that individualize treatment

Varying BWS – ideal unloading =40-60%

GOAL: maximize weight bearing

Varying speed – max speed = 2.0 mph

Average walking speed = 1.2 mph (0.5 m/s)

Random speeds and BWS (different programs available- PT sets min/max speed/BWS)

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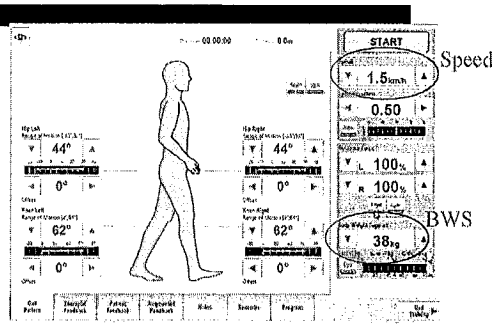
Gait Pattern Parameters (Screenshot)



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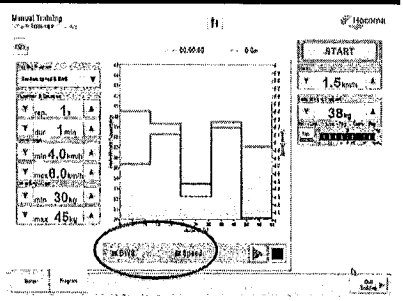
Random Speeds and BWS



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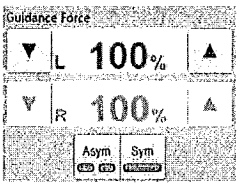
#2 Parameters that individualize treatment

Guidance force-- the amount of assistance that the orthosis provides during ambulation

(can be set asymmetrically for Right versus Left)



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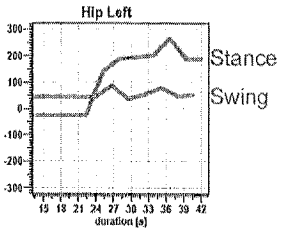
Parameters that individualize treatment

Biofeedback-- provides information on **stance** and **step** phases of gait on right and left legs

*Patients get an idea of how much they are able to assist at both his/her knees and hips.



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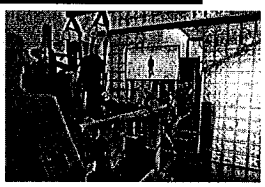
Parameters that individualize treatment

Augmented Feedback-- allows for the patient to interact with different environments

* Patients can control the avatar on the screen with his/her own movements.



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Lokomat Training-Special Feature: Augmented Feedback

Benefits of using Augmented Feedback

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"It's how you get there: walking down a virtual alley activates premotor and parietal areas" *Wagner J, 2014*

- Participants: 11 healthy volunteers (26 +/- 7 years) with no past or current neurological or locomotor defticts
- Design: Participants walked with the Lokomat under five different visual feedback conditions. Each condition lasted 4 min and was repeated 2x during experiment

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Wagner J, 2014

Four feedback conditions consisted of:

- **NoFB**- participants walked while looking at black screen
- **GAZE**- participants looked at a white graphical objects sequentially appearing (for 3 s) in different locations on a black screen
- **MIRROR**- participants watched themselves in a mirror while walking in the orthosis
- **3rdP VE and 1stP VE**- Participants walked in a 3D Virtual Environment in 3rd and 1st person view. Using augmented feedback game "Alley Walk"

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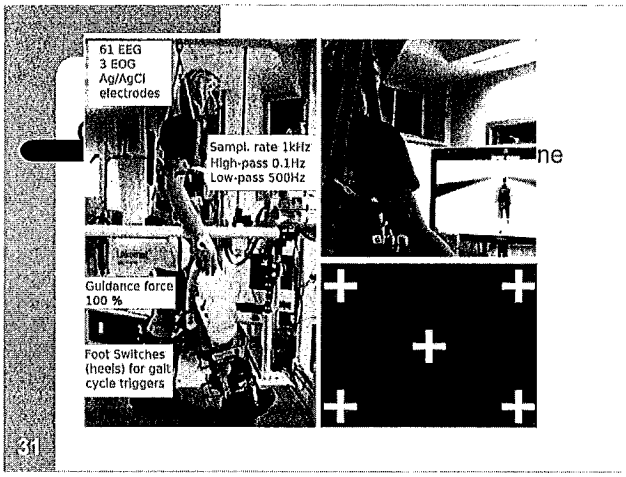

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Wagner J, 2014

- *"The task of active gait adjustment in the VE required enhanced motor planning and increases activity in the premotor cortex. This is in line with numerous studies that relate increased activity in the premotor area to the planning of single limb movements."*
- *"Recent studies have demonstrated that the premotor areas are also activated during gait initiation and adaptation."*

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Wagner J, 2014

- *"Our findings that an interactive gait adaptation task activates premotor and parietal areas is especailly interesting as these areas have been related to motor intention and motor planning."*
- *"Our results are relevant for gait rehabilitation after stroke and may help to better understand the cortical involvement of human gait control."*

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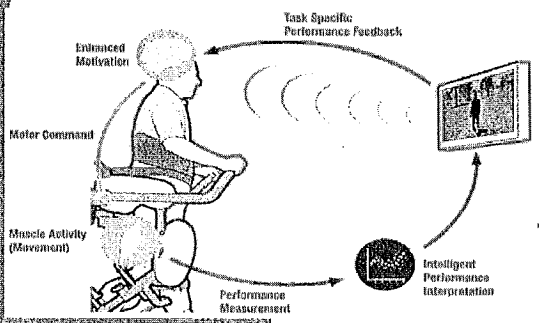
Augmented Feedback



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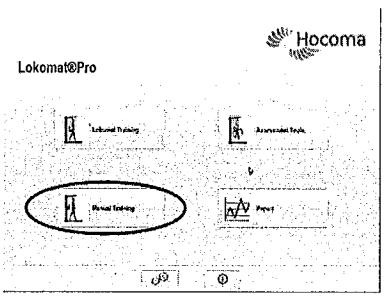
Mode #2: Manual Training



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Manual Training with the Lokomat

The Lokomat can be performed **without the use of orthosis for Locomotor Training**

A harnessed environment is a safe and effective environment to work on:

- GAIT KINEMATICS
- GAIT ENDURANCE
- STANDING TOLERANCE
- BALANCE

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Manual Training with the Lokomat

- May choose to use manual training if:
  - The patient is too short (or too large) to fit into orthosis
  - If you are unable to safely support a patient overground (and a harness would improve their safety)
  - If you are unsure how the patient will tolerate Lokomat training
  - To perform locomotor training to the non-NRN patient

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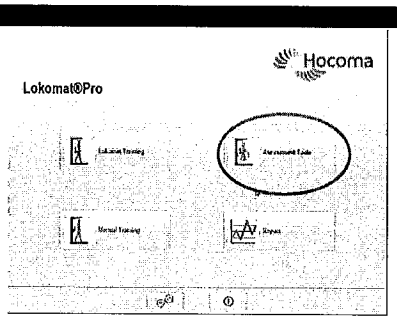
Mode #3: Assessment



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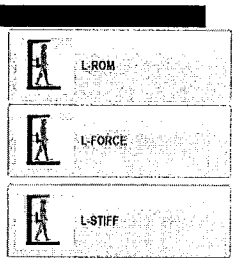
Assessment Tools

- **L ROM: Range of motion of flexion/extension in hip and knee joints.**
- **L Force: Isometric force of flexion/extension muscle groups in hip and knee joints**
- **L-Stiff: Mechanical stiffness in hip and knee joints at different speeds**



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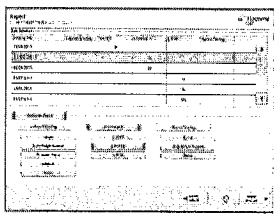
Mode #4: Reports

- The Lokomat keeps track of every training session and summarizes the results in graphs and reports!!!



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Lokomat Set-Up

Let's see the Lokomat in action!

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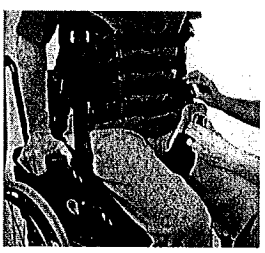
Lokomat Set-Up (con't)

1. The patient is harnessed either seated on the mat or in a standing position. (padding may be applied for increased comfort)



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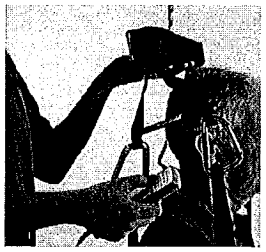
Lokomat Set-Up (con't)

2. The patient is wheeled up the ramp/walks up ramp and harness is connected to overhead support

3. Patient is supported to 100% of his/her BWS



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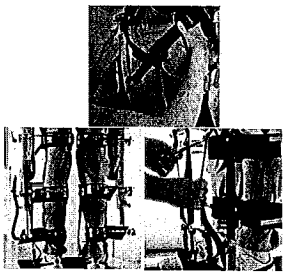
Lokomat Set-Up (con't)

4. The orthosis is closed behind patient and is then attached to patient.

5. Hip and knee ROM and appropriate amount of DF is adjusted to fit patient.

(**setup is approx 10-15 minutes and can be done with 1 PT but is most efficient with 1 PT and 1 assistant**)



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Lokomat Set-Up (con't)

6. Patient begins "walking" in the air and is slowly lowered down until they are on the treadmill

7. Speed, BWS, are set but may be changed at any time during session.

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Lokomat Set-Up (con't)

8. Ideally, the patient's performs 30 minutes of facilitated gait training

9. Ideally, the patient then comes off Lokomat, and performs 10-15 minutes of overground activity (overground walking or appropriate functional activity)

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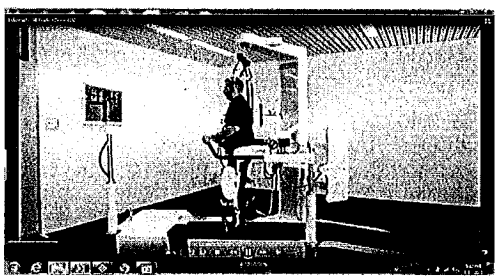
Video of Lokomat Pro



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Progression with the Lokomat

BWS

Guidance force

Duration

Speed

★ Try Adding- Biofeedback and Augmented Feedback ★

** Note:Which parameter you change first, second, etc. depends on the patient's goals and the goal of the treatment session!**

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Outcome Measures

- Modified Ashworth Scale
- **Modifed Functional Reach**
- Berg Balance Scale
- Timed Up and Go
- 10 Meter Walk Test
- 6 Minute Walk Test
- Pain
- MMTs and ROM as appropriate

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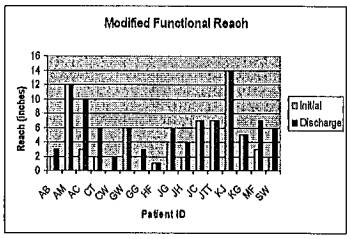
Modified Functional Reach -Kessler Preliminary Data



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Modified Functional Reach

- MDC for SCI population) = 1.5" (T1-T12 SCI)- 1.9" (C5-C6 SCI) Lynch et al, 1998, SCI
- 7/21 persons tested were able to improve on MFR from IE to Discharge
- 6/21 made a change that was greater than 1.9" (MDC).

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What about the evidence supporting Lokomat training?

SCI and Stroke populations

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Lokomat robotic-assisted versus overground training with 3 to 6 months of incomplete spinal cord lesion: randomized controlled trial

Alcobendas-Maestro M, 2012

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Alcobendas-Maestro M, 2012

Inclusion Criteria: Spinal cord injury (SCI), AIS C and D (upper-motor neuron only); traumatic, nontraumatic, nonprogressive lesions; levels C1 and T12; onset < 6 months; age 16-70 years; **having achieved assisted standing a minimum of 1 week previously; informed consent.**

How many subjects agreed to participate: 80

Authors Stated Purpose: To compare conventional overground training to a walking reeducation program using the Lokomat for individuals with both traumatic and nontraumatic SCI.

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Alcobendas-Maestro M, 2012

Treatment Group 1 : Conventional training: underwent 1 hour duration walking on each of 40 walking training sessions. **Also: joint mobilization below lesion level, strengthening, muscle stretching and postural relaxation techniques for spasticity, stabilization, and self-care training.**

Treatment Group 2 : The Lokomat group completed 30 minute sessions with the Lokomat during each of the 40 walking sessions. Initial BWS= 60% ;Progression: BWS decreased as their tolerance increased but not less than 25% was provided. **Also: joint mobilization below lesion level, strengthening, muscle stretching and postural relaxation techniques for spasticity, stabilization, and self-care training.**

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Alcobendas-Maestro M, 2012

Results	Covnvention Group	Lokomat Group
Walking speed (initial)	0.3 m/s	.3 m/s
Walking speed (end)	0.3 m/s	0.4 m/s
WISC II (initial	4 pts.	4 pts
WISC II (end)	9 pts	16 pts
6 MWT (initial)	82.3 m	110.1 m
6 MWT (end)	91.3 m	169.4 m

*WISC=Walking Index for Spinal Cord Injury
*6 MWT= 6 minute walk test (meter)

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Alcobendas-Maestro M, 2012

Authors Conclusions: Although Lokomat training improves walking ability in patients 3 to 6 months after onset of an incomplete spinal cord injury, **the functional results of speed and quality of walking were not found to be superior to conventional overground walk training;** however, the Lokomat system did have **better results for lower-limb strength and endurance compared to the conventional overground reeducation.**

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Multicenter randomized clinical trial evaluating the effectiveness of the Lokomat in subacute stoke

Hidler J, 2009

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Hidler J, 2009

Inclusion: Hemiparesis resulting from unilateral ischemic or hemorrhagic stroke; no prior stroke; time since stroke onset <6 months; age >18 years; ability to ambulate 5m without physical assistance and a self-selected walking speed 0.1 to 0.6 m/s

How many subjects agreed to participate: 72

Authors Stated Purpose: To determine whether persons with subacute stroke, who receive robotic-assisted gait training, improved their walking ability greater than those who received conventional gait training with therapist assistance.

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Hidler J, 2009

Treatment Group 1 : Conventional Gait Training: Early--static and dynamic posture, trunk positioning, LE and UE ROM, overground walking! Progression-- more difficult tasks of balance and gait (walking speed tasks, stair climbing, treadmill training-no facilitation)

Treatment Group 2 : Lokomat Gait Training: Early--initial parameters <40%BWS and 0.42 m/s. Progression--increasing walking speed and duration and by decreasing the level of body-weight support. Participants received biofeedback about performance at their hips and knees.

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Hidler J, 2009

Results	Covnvention Group	Lokomat Group
Walking speed (initial)	0.35 m/s	0.34 m/s
Walking speed (end)	0.6 m/s	0.46 m/s
6 MWT (initial)	440.7 m	387.8 m
6 MWT (end)	714.7 m	552 m

*6 MWT= 6 minute walk test (meter)

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Hidler J, 2009

Authors Conclusions: "The results of this study indicate that conventional gait training, when compared with Lokomat gait training, yields greater improvements in overground walking speed and distance in individuals with moderate to severe gait impairments following subacute, unilateral stroke. Thes results need to be interpreted cautiously...subjects in the Lokomat group received only robotic-assisted training.

In a clinical setting, gait training would likely involve both robotic-assisted training and conventional training."

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Electromechanical-assisted Training For Walking After Stroke (Mehrholz J, 2013)

BY THE COCHRANE COLLABORATION

Objectives of study: to investigate the effects of automated electromechanical and robotic-assisted gait training devices for improving walking after stroke

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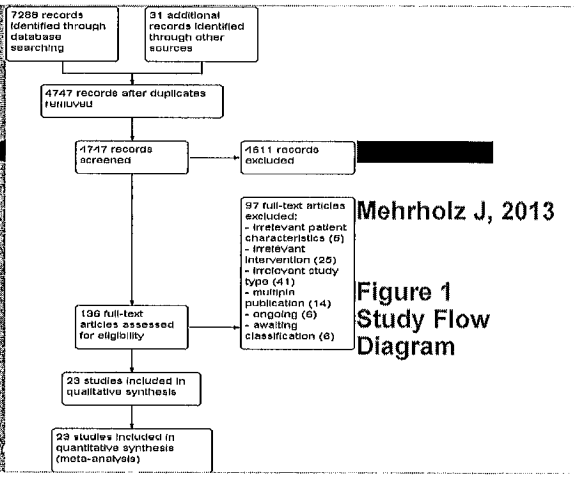

Mehrholz J, 2013

Figure 1 Study Flow Diagram

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Mehrholz J, 2013

Main results: (The review included 23 trials involving 999 particpants.) *"Electromechanical-assisted gait training in combination with physiotherapy* ***increased the odds of participants becoming independent in walking*** *(odds ration 2.39, 95% CI, 1.67-3.43; P <0.00001) but did not significantly increase walking velocity (mean difference = 0.04 m/s) or walking capacity (3 meters walked in 6 minutes)."*

65

Mehrholz J, 2013

Authors' Conclusions:

#1: People who receive elctromechanical-assisted gait training in combination with physiotherapy after stroke are **more likely to achieve independent walking than people who receive gait training without these devices.**

#2: People in the **first three months after stroke** and **those who are initially not able to walk** seem to benefit most from this type of intervention.

#3: **The role of this type of device is still not clear.** Further research should consist of: What frequency or duration of electromechanical-assisted gait training might be most effective? How long does the benefit last."

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Cochrane Review (Mehrholz J, 2013)

THE COCHRANE COLLABORATION®

The authors conclude that every fifth dependency in walking after stroke could be avoided if electromechanical assisted devices were used.

(Number needed to treat to benefit = 5)

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Mehrholz J, 2013

Study Limitations:

1. Of the total population of 999 participants, approx. 45% were independent walkers at the start of the study
2. No definitive conclusion can be drawn for a longer-lasting effect of the use of electromechanical devices (in terms of independent walking at **follow- up** or walking velocity at **follow-up**)

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Mehrholz J, 2013

"Adverse events, drop-outs and deaths do no appear to be more frequent in participants who received electromechanical or robotic-assisted gait training."

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Take Home Point

Based on these results and what I see clinically, the Lokomat is proving to be **widely used, safe, challenging, useful and appropriate in the rehabilitation of many different persons.**

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Who may be the most appropriate candidates for Lokomat training?

Based on what we're seeing in the clinic and the evidence

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So, Who is the appropriate patient?

1. Complete SCI- If the patient has a very weak trunk/poor sitting balance but has good head control, the Lokomat may be appropriate
2. Incomplete SCI- If the patient is just beginning to walk/stand overground but they are not yet strong enough to perform these tasks without maximal/moderate assist.

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So, Who is the appropriate patient?

3. Stroke- within first 3 months post-stroke; and possibly largest effect for those who are not yet walking (based on results of Cochrane Review)

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So, Who is the appropriate patient?

4. All diagnoses- Use augmented feedback and biofeedback as means of improving interaction and possibly motor planning

5. All diagnoses- vary **guidance force** to challenge patient and make intervention ACTIVE

6. **All diagnoses- Use the Lokomat as an adjunct intervention in order to improve a patient's trunk stability, gait kinematics and overall endurance**

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FYI: What's New!?!

New software and Hip Orthosis

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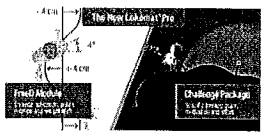
New Software: **Challenge Package!**

- New games supporting "specific therapy goals for optimized patient challenge!"



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New add-on! **FreeD Module (Hips)**

I'm NEW!!

- "Supports weight shift and balance activation through lateral and rotational movements of the pelvis."

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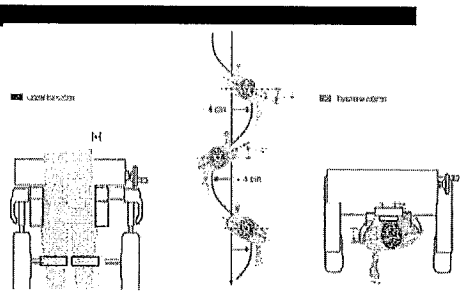
Fig. 1: Adjustable lateral translation of up to 4 cm (left) and transverse rotation of the pelvis of up to 4° (right) to each side during walking (center).



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THANK YOU!!

Questions???

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Work phone: 973-324-3617

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