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"The Use of the Lokomat System in Clinical Research"

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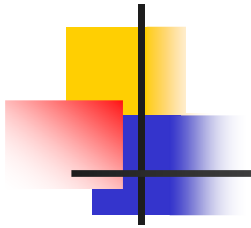


Locomotor Training - Therapists & Robots

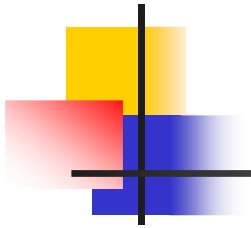
Therapist Driven Body Weight Support Treadmill Training (BWSTT)

Pros:
Intelligent intervention with step to step adjustments, Psychological preference of patients to work with therapists, Step to step variability may lead to improved robustness of training effect

vs.

Cons:
Therapist to therapist differences, Therapist fatigue, Salaries, Difficult to quantify training parameters, independently vary parameters, and control variability in training parameters

But most of all, it's very hard to plug a therapist into a USB port!



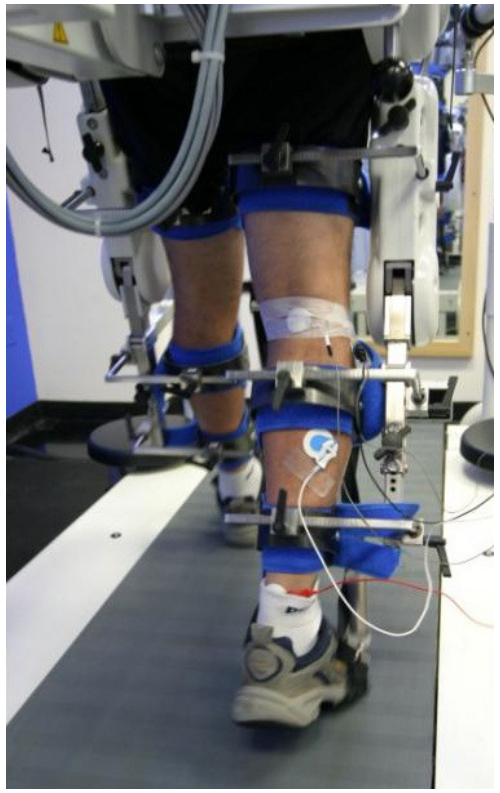
Locomotor Training - Therapists & Robots

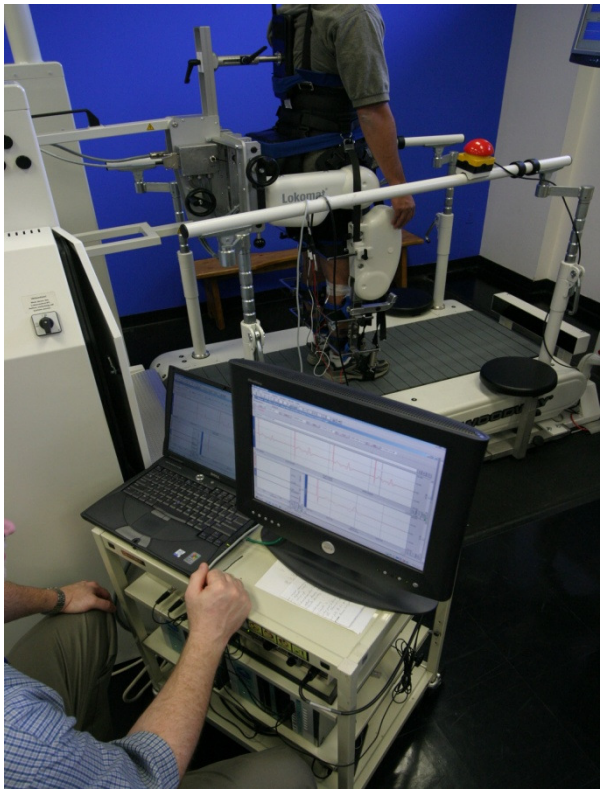
Robot Driven Body Weight Support Treadmill Training (BWSTT)

Pros (clinical):
Consistent and independent (within constraints) control of individual gait training parameters
Ability to train for longer periods
Ability to provide a spectrum of biofeedback to subjects
Ability to be used in conjunction with other therapeutics like FES

Pros (research):
Quantitative tracking of angles, forces, velocities, and timing
Ability to study effects of different specific gait features (body weight support, gait speed, hip vs. knee parameters)
Ability to trigger or control other data collection (EMG, reflexes, other)
Ability to undergo software advances to improve control algorithms
Potential to record or "learn" from therapists or patients

Methods – H-Reflex recording in the Lokomat





Subjects were stepped with 40% body weight support at 1.8 and 2.5 km/hr and H-reflexes (n=50) were recorded at mid-stance and mid-swing of the gait cycle.

The Lokomat in Research

Over 160 devices Worldwide, over 60 in US, unknown number used in research

25 published papers listed on PubMed under “Lokomat”
33 listings under “Robotic Locomotor Training” (some animal studies)

Studies include diagnoses of spinal cord injury, multiple sclerosis, stroke, and cerebral palsy

Most about locomotor recovery but also neural plasticity, muscle strength, joint kinematics, and metabolic measures

Robotic Training of SCI Patients
Patient Selection for Safety and Efficacy

The physical therapy staff in the Spinal Cord Injury Lab offers bodyweight supported treadmill training manually and with the Lokomat® Robotic Ambulation System.

- INCLUSION CRITERIA for Research Candidates:
  - Age between 14 and 65 years old.
  - Stable cardiopulmonary system.
  - No history of long bone fractures secondary to osteoporosis.
  - Without hip or knee degenerative joint disease.
  - Lower extremity joint stability.
  - Sufficient range of motion of the hips, knees and ankles to allow upright stance.
  - Spasticity sufficiently controlled.
  - Males or females of non-child bearing potential (Females of child-bearing potential will be eligible if they had a negative pregnancy test and are using adequate contraceptives.)

- EXCLUSION CRITERIA for Research Candidates:
  - Decubitus ulcer(s) which interfere(s) with harness support or walking (feet).
  - Weight greater than 250 pounds.
  - Bilaterally absent quadriceps and Achilles tendon tap responses.
  - ASIA Impairment Scale A or B (for some studies, not for others).
  - Ventilator dependent.
  - Severe orthostatic hypotension (more than 30 mmHg when moving from sitting to standing).
  - History of traumatic brain injury, CVA or other brain pathology.
  - Cervical or spinal orthosis required.

** Please note that BWSTT, in order to be successful, requires a fairly substantial time commitment on the part of the patient. Research candidates can expect to train for 3 sessions per week, 1 hour per session, and for a 12 week period. It is important that the subject can come to therapy on a regular basis. Research subjects will take priority in treatment schedules. **

Robotic Training of SCI Patients

Training Parameters

Dosing of Training

3 - 5 times per week, 30 - 60 minutes per day,
6 weeks - 3 months - 6 months duration

Training Variables (Lokomat)

- Body weight support
- Treadmill/gait speed
- Hip & knee angles, range of movement
- Choice of biofeedback
- Medications
- Criteria to change variables

Concepts usually agreed upon:
physiological walking speeds are good, loading is important, maintaining good gait kinematics is a goal

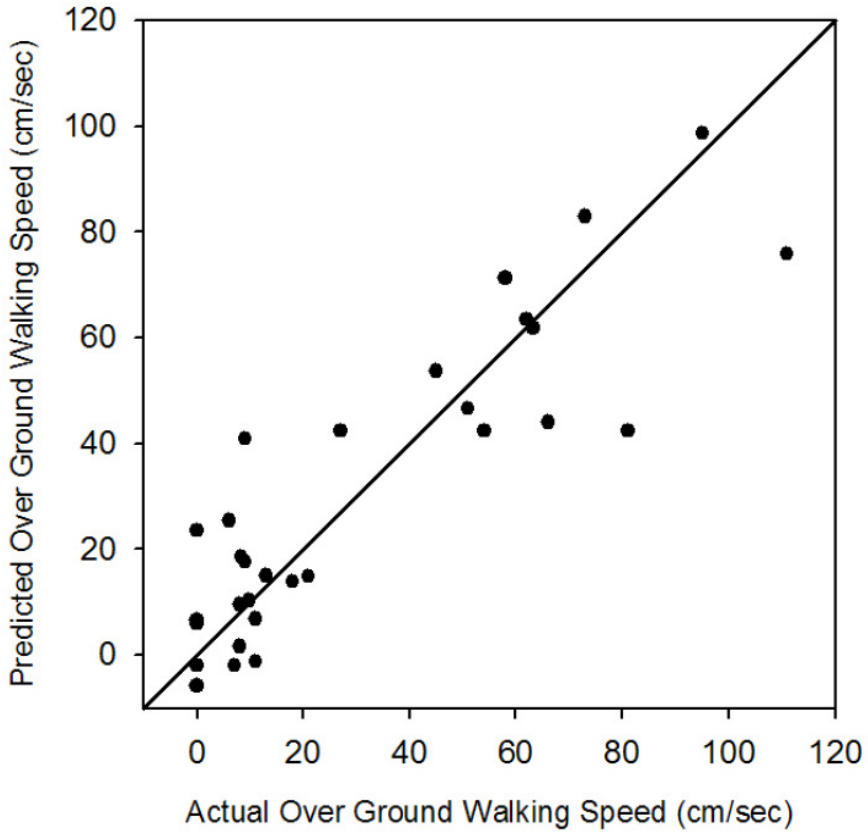
ORIGINAL CONTRIBUTION

A Prediction Model for Determining Over Ground Walking Speed After Locomotor Training in Persons With Motor Incomplete Spinal Cord Injury

Patricia Winchester, PT, PhD[1]; Patricia Smith, PT, PhD[1]; Nathan Foreman, MPT; James M. Mosby, MPT, MS; Fides Pacheco, MD[2]; Ross Querry, PT, PhD[1]; Keith Tansey, MD, PhD[2]

Final over ground walking speed (cm/s) = 21.48
+ (voluntary bowel & bladder voiding x 18.78)
+ (spasticity affecting stance x 14.30)
+ (initial walking speed x 0.87)
– (square root time from injury onset x 6.06)

(Voluntary voiding of B & B: yes=1, no=0; Spasticity affecting stance: yes=0, no=1)

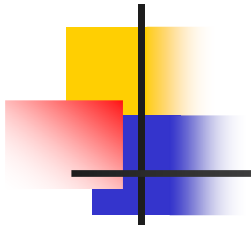


The Lokomat in Research

Unanswered Questions

1)Dosing (Timing Initiation of Therapy, Session Duration and Frequency, Training Duration)
2)Advancing Patients through Training (BWS vs Treadmill Speed)
3)Impact of Specific Gait Parameters (Joint Angles and Positions)
4)Issues of Patient Selection (Gait Kinematics, Medications, etc.)
5)Relationships between Training and Clinical Outcomes
6)Why Do We Get What We Get in Different Patients?
7)Relationships between Functional and Physiological Outcomes
8)Effect of Combining Locomotor Training with Other Therapy

Measures of Gait Recovery with Robotic Training in SCI



"Functional" measures used to date

- ASIA class,
- ASIA lower extremity motor and sensory scores
- Walking Index for SCI II (WISCI II)
- 10 meter walking time/walking speed
- 6 minute walking distance (# steps)
- "timed up and go"
- Functional Independence Measure (FIM)
- Ashworth(less)
- Berg balance score
- gait analysis (Gait Rite, kinematic analysis, other)
- EMG patterns (magnitude and temporal parameters)
- patient surveys

Measures of Gait Recovery with Robotic Training in SCI

Robotic (Lokomat) measures available:

L-ROM (range of motion): a goniometer but a limited relative to a clinical exam out of the Lokomat

L-Force (dynamometer): quantification of isometric forces generated at the hip and knee in the standing position

L-Stiff (tonicity/spasticity?): resistance to movement measured at 3 speeds in static condition, may need faster speed of ranging to distinguish neural from musculoskeletal components

Additional data available from the robot's computer

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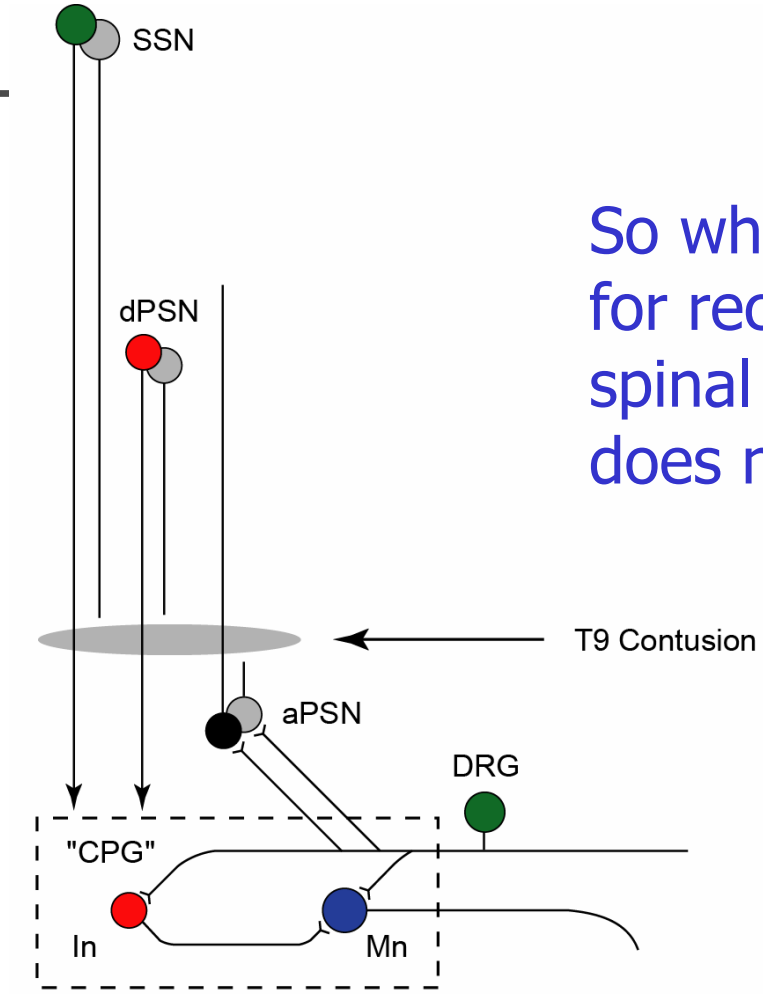
What do we know about locomotor recovery in SCI? (at least the big picture)

	In Animal Models	In Humans
"Complete" Injury	essentially no recovery	essentially no recovery
"Complete" Injury & Locomotor Training	recovery of some stepping	some recovery of balance/standing?
Incomplete Injury	much better recovery of stepping	variable/limited recovery of stepping
Incomplete Injury & Locomotor Training	little enhancement of stepping	enhanced recovery of stepping

Wiring Diagram of Sensory and Supraspinal Inputs to Spinal Central Pattern Generator (CPG) Circuits involved in Stepping after Incomplete Spinal Cord Injury



So what is the neural circuitry for recovered stepping after spinal cord injury and where does neural plasticity happen?

SSN = supraspinal neuron; **In** = interneuron; **Mn** = motoneuron;
DRG = dorsal root ganglion; **aPSN** = ascending propriospinal neuron;
dPSN = descending propriospinal neuron; **CPG** = central pattern generator

The Lokomat in Research

So Many Questions, So Little Time – What to Do?

1)Collaborative Efforts
2)Multi-Center Studies
3)Shared Research “Tool Chest” from Hocoma
4)Other Ideas?

The Lokomat in Research - In Summary

Advantages of the Lokomat as a Research Tool:

1)The Lokomat can train a therapeutic benefit.
2)The Lokomat can measure that therapeutic effect.
3)The Lokomat can be used to set up specific experimental conditions to test hypotheses about locomotor training.
4)The Lokomat can measure the effects of other interventions or combinations of interventions and locomotor training.
5)The Lokomat can guide us to better “evidence based” therapy, perhaps specialized for specific patient “configurations”.
6)The Lokomat can “evolve” in capacity and application.

Gait Recovery with Locomotor Training