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Rapid-HTA: Robot-Assisted Gait Therapy

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Introduction

- Robot Assisted Gait Therapy (RAGT) involves the use of a robot orthotic device to help the patient retrain motor coordination by performing well-focused and carefully-directed repetitive practice[1].
- There are two main types of devices available
  - A robotic exoskeleton which is used in conjunction with a treadmill (e.g. Lokomat™)
  - Footplates placed on a double crank and rocker gear system (e.g. Gait Trainer)

Picture of the Lokomat™ [2]

Picture of the Gait Trainer[3]

Introduction

- RAGT systems are stated to have the following advantages:
  - Hesse states that there is a reduced number of rehabilitation staff needed to assist the patient in gait training[4]
    - Normally, 2-3 staff are needed to support the body weight of the patient, while also assisting the patient's leg movements
  - Westlake states that there is a non-trivial risk of injury to the human trainers during physiotherapy[5]
  - Hidler reports that as therapists fatigue during the session, the patient has to adjust to the changing assistance of the physiotherapist in addition to their impairment[6]

Introduction

- In Singapore, Stroke
  - Is the 4th leading cause of death, comprising 8.3% of all deaths[7]
  - Is the 8th leading cause of hospitalisation, comprising 2.1% of all discharges[8]
  - Incidence rate of 1.8 per 1000 person-years in 2000[9]
  - Prevalence rate of 4.05% in 2005[10]
- In addition, 40% of all residents in long term care facilities are stroke patients[11]
- Over 50% of stroke patients were assessed to require physical rehabilitation[12] upon discharge from acute hospitals
- At present, there is one RAGT available in Singapore
  - The price of an one hour session on the Lokomat™ approximately twice as much as an one hour session in physiotherapy

Objectives

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- The purpose of this report is to examine the literature on effectiveness of RAGT with stroke patients as compared to physiotherapy using the Population, Intervention, Comparison, Outcomes (PICO) framework

Population	Hemiplegic/hemiparetic stroke patients
Intervention	RAGT or RAGT plus physiotherapy or RAGT plus physiotherapy plus FES
Comparison	Conventional Physiotherapy
Outcomes	Walking ability (Functional Ambulatory Category (FAC)*) and Walking speeds

About the Outcome Measures

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- FAC
  - Staff-completed tick box of 5 broad categories of walking ability[13]

FAC	Definition
0	Patient cannot ambulate and requires more than one person's physical assistance to ambulate safely
1	Patient requires one person to continuously be in physical contact to support body weight and maintain balance or assist coordination during ambulation
2	Patient requires one person to be in physical contact assist the balance and coordination during ambulation
3	Patient can ambulate on level services without manual assistance but requires supervision for safety
4	Patient can ambulate independently on level surfaces but not on stairs, inclines and other non-level surfaces
5	Patent can ambulate independently on all surfaces

- Walking Speed
  - Measured by calculating the time taken by the patient to cover a specified distance using their walking equipment[14]
    - Also called Self-Selected Walking Speed
  - Patients unable to walk without assistance are considered to have a walking speed of 0 m/s

Methodology

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- A search was conducted using the following databases:
  - PubMed
  - Ovid
  - Cochrane
  - NHS Centre for Reviews and Dissemination Database (CRD)
  - National Guidelines Clearinghouse

- Search terms: (Robot Assisted Gait OR Lokomat OR Gait Trainer) AND Stroke AND physiotherapy.

- Non-English papers and those without abstracts were excluded. Search results were also checked for relevance to the above PICO.

Results

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- TEN publications were reviewed
  - 1 Systematic Review,
  - 4 Randomised Clinical Trials (RCT),
  - 2 Case-Control,
  - 2 Case Series
  - 1 Review

- Clinical Questions addressed

Results: Systematic Review (1)

- Hesse, Merholz & Werner reviewed articles on lower limb rehabilitation after stroke on articles from 1980 to 2007 [4].

First Author (Year)	Device	Therapy Arms	Initial FAC	Term FAC	Follow-up* FAC	Type of Patients
Tong (2006)	GT1	RAGT + FES+PT RAGT + PT PT	1 (0-1) 1 (0-1) 1 (0-2)	**4 (1-4)**** **3 (1-3)**** **2 (0-2)****	-	50 Acute initially non-ambulant patients
Pohl (2006)	GT1	RAGT + PT PT	1 (0-2) 1 (0-2)	**4 (0-2)**** **2 (0-2)****	**5**** **3****	156 Acute initially non-ambulant patients
Husemann (2007)	LokomatTM	RAGT+PT PT	0 (1-4) 0 (1-4)	1 (1-4) 1 (1-4)	-	30 Acute initially non-ambulant patients
Mayr (2007)	LokomatTM	RAGT PT	2 (1.5-2) 2 (2-3)	3 2.5	-	16 Acute initially non-ambulant patients
Paurela (2005)	HGT1	RAGT+FES+PT RAGT+PT PT	4 (3-4) 4 (3-4) 4 (3-4)	-	-	45 Chronic, moderately affected patients

* Follow-up after 6 months
** Statistically significant finding

Results: Systematic Review (2)

First Author (Year)	Device	Therapy Arms	Initial Walking Speed (m/s)	Term Walking Speed (m/s)	Follow-up* Walking Speed (m/s)	Type of Patients
Tong (2006)	GT1	RAGT + FES+PT GT + PT PT	0.0 ±0 0.0 ±0 0.0 ±0	**0.63 ±0.37**** **0.47 ±0.21**** **0.24 ±0.3****	-	50 Acute initially non-ambulant patients
Pohl (2006)	GT1	RAGT + PT PT	0.13 ±0.17 0.14 ±0.19	**0.44 ±0.47**** **0.32 ±0.36****	0.53 ±0.31 0.36 ±0.42	156 Acute initially non-ambulant patients
Husemann (2007)	Lokomat TM	RAGT+PT PT	0.12 ±0.02 0.14 ±0.19	0.12 ±0.02 0.14 ±0.03	-	30 Acute initially non-ambulant patients
Mayr (2007)	Lokomat TM	RAGT PT	0.11 0.13	0.13 0.14	-	16 Acute initially non-ambulant patients
Paurela (2005)	HGT1	RAGT+FES+PT RAGT+PT PT	0.23 0.25 0.25	0.28 0.33 0.31	-	45 Chronic, moderately affected patients

* Follow-up after 6 months
** Statistically significant finding in red

Results: Systematic Review (3)

- Of the 5 clinical trials found and reviewed in the study, 2 studies (Tong and Pohl) with larger sample sizes showed significant improvement in both walking ability, with median FAC improving by 3-4 points and walking speed improving by .44 to .63 m/s.
  - Mayr however showed that a RAGT+PT +RAGT group had significant outcomes compared to the PT+RAGT+PT group
- The 3 smaller studies did not show significant improvement
- The difference of outcome between RAGT and RAGT + FES was not significant
- The authors conclude that additional studies were needed to establish if the effectiveness of RAGT and were unable to conduct a pooled meta-analysis due to the heterogeneity of the study results.

Results: Randomised Clinical Trials (1)

- 4 RCTs were found, 1 in 2008 (Ng et al[15]) and 3 published in 2009 (Hidler et al[6], Schwartz et al[16] and Westlake et al[5])

First Author (Year)	Device	Therapy Arms	Type of Patients
Ng (2008)	GT1	RAGT + FES+PT RAGT + PT PT	54 Patients < 6 weeks post stroke with FAC < 3
Hidler (2009)	Lokomat™	RAGT PT	72 Patients < 6 months post stroke with initial walking speed of 0.1 to 0.6 m/s
Schwartz (2009)	Lokomat™	RAGT+PT PT	67 Patients < 3 months post stroke with condition severity between 6 and 20
Westlake (2009)	Lokomat™	RAGT PT + Body Weight Supported Treadmill Training (BWSTT)	16 Patients < 6 months post stroke categorised as unlimited household ambulators

Results: Randomised Clinical Trials (2)

- Ng showed significant improvement in RAGT+PT and RAGT+FES+PT after 6 months of follow up
- Schwartz also showed significantly better results with 54% in the Lokomat^{TM} arm showing FAC of 3 or better

First Author (Year)	Device	Therapy Arms	Initial Mean FAC	Term Mean FAC	Follow-up* FAC
Ng (2008)	GT1	RAGT + FES+PT RAGT + PT PT	1.3 1.3 1.4	**3.4**** 3.2 2.5	**4.2**** **4.0**** 3.0
Hidler (2009)	Lokomat TM	RAGT + PT PT	3.3 3.7	4.0 4.4	4.0 4.7
Schwartz (2009)	Lokomat TM	RAGT+PT PT	0 0	**54% FAC ≥3**** 29% FAC ≥3	-

- Westlake did not use FAC is an outcome measure

* Follow-up after 3 months for Hidler and 6 months for Ng
** Statistically significant finding

Results: Randomised Clinical Trials (3)

- Only two out of the 4 studies reported significant improvements in gait speed using RAGT

First Author (Year)	Device	Therapy Arms	Initial Mean Gait Speed (m/s)	Term Mean Gait Speed (m/s)	Follow-up* Gait Speed (m/s)
Ng (2008)	GT1	RAGT + FES+PT RAGT + PT PT	1.3 1.3 1.4	**3.4**** 3.2 2.5	**4.2**** **4.0**** 3.0
Hidler (2009)	Lokomat TM	RAGT + PT PT	0.34 0.35	**0.46**** **0.60****	**0.49**** **0.65****
Schwartz (2009)	Lokomat TM	RAGT+PT PT	0 0	0.31 0.37	-
Westlake (2009)	Lokomat TM	RAGT PT + BWSTT	0.62 0.62	**0.72**** **0.65****	- -

* Follow-up after 3 months for Hidler and 6 months for Ng
** Statistically significant finding

- Hidler reported that physiotherapy was produced superior results to RAGT for Gait Speed

Results: Randomised Clinical Trials (4)

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- Other results reported in the studies.
  - Ng reported that RAGT and RAGT with FES scored when compared to physiotherapy scored better Elderly Mobility Scale Scores (EMS) when compared to PT
    - At 4 weeks: 0.9 and 0.87 higher Elderly Mobility Scale (EMS) Scores
    - At 6 months: 0.86 and 1.14 higher EMS scores
  - Schwartz et al. reported improved stair climbing ability in the RAGT with PT arm after 6 weeks
  - Westlake et al. reported
    - RAGT arm had significant improvements in:
      - Fast Walking Speeds
      - Absolute Step Length Ratio
      - Berg Balance Scale
    - BWSTT arm had significant improvements :
      - Berg Balance Scale

Results: continued

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- There were no economic evaluations performed on RAGT

- There were no clinical guidelines published on RAGT

- Of the remaining studies found (case-control and case series), it was found that:
  - New enhancements to the robotic exoskeleton or with virtual reality augmented RAGT improve stroke survivors gait patterns[17] and walking speeds [18]
  - Chronic hemiparetic stroke subjects still exhibited abnormal joint torque patterns in spite of being trained in physiologically symmetric gait patterns[19]
  - RAGT subjects were able to consume less oxygen and increase walking time duration during therapy when compared to floor walking[20]

Patients. At the Heart of All We Do

Conclusion

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- The evidence that either RAGT with PT is more effective than conventional PT is mixed.
  – However, RAGT with PT is effective for patients less than 3 months post stroke, in improving their FAC
  – In addition, RAGT with PT appears effective for patients with low FAC
  – 2 papers which used RAGT with FES and PT show that it is more effective than PT alone
- However, the evidence does not indicate that RAGT alone as a treatment option is superior to PT
- More studies will have to be done to assess effectiveness and cost-effectiveness of RAGT in stroke rehabilitation

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