Clinical Studies
In this presentation:

- Total number of studies
- Publications
- Key clinical studies
  - Israel: sub acute stroke
  - Germany: sub acute stroke
  - Italy: chronic stroke
  - Japan: sub acute stroke
- New article
- General conclusions
- Ongoing studies
The ReoGo was launched in rehab centers in 2007
Clinical studies focused on Efficacy, Safety and patients satisfaction
New directions in ReoGo therapy include combined use with EEG or EMG
In many cases we only learn about such studies after they are published
In this presentation we will discuss the main publications
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Total number of studies: 13
- 9 completed
- 4 ongoing

No. of patients: ~350

Sites: USA, Japan, Italy, Germany, Israel
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- New article
- General conclusions
- Ongoing studies
Multiple clinical studies have been performed worldwide (US, Europe, Japan, Israel) to test the feasibility and the efficiency of the post-stroke rehabilitation provided by ReoTherapy platform.

Publications
The American Journal of Occupational Therapists, 2012, USA
Top Stroke Rehabilitation, 2011, Germany
Journal of Neuroengineering and Rehabilitation, 2011, Italy
Journal of rehabilitation Medicine, 2009, Italy
European Journal of physical and Rehabilitation, 2008, Israel
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Robot-assisted therapy for neuromuscular training of sub-acute stroke patients

A feasibility study

I. Treger, S. S. Faran, H. Ring,

Israel, 2008

European Journal of physical and Rehabilitation Medicine
Objective:

- Preliminary assessment of patient acceptance of an upper extremity ReoGo Robot Therapy

Design:

- 10 sub acute stroke patients
- 15 sessions of 45 minutes of ReoGo treatment in addition to physical and occupational therapy
Motor impairment was significantly improved in the Robot-assisted upper arm therapy.
### TABLE I.—Results of acceptance feedback questionnaire, Fugl-Meyer and Manual Function Test.

<table>
<thead>
<tr>
<th></th>
<th>Mean values</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>After 1 week of treatment</td>
<td>After 3 weeks of treatment</td>
</tr>
<tr>
<td>Acceptance of Reo™ Therapy System</td>
<td></td>
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<tr>
<td>Feedback Questionnaire (max. value = 75)</td>
<td></td>
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<tr>
<td>Pretreatment</td>
<td></td>
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</tr>
<tr>
<td>Fugl-Meyer Test</td>
<td>35.0</td>
<td>43.5</td>
</tr>
<tr>
<td>Manual Function Test (proximal part only)</td>
<td>8.2</td>
<td>10.3</td>
</tr>
<tr>
<td>Manual Function Test (distal part only)</td>
<td>5.0</td>
<td>8.7</td>
</tr>
<tr>
<td>Manual Function Test (overall)</td>
<td>13.2</td>
<td>19.0</td>
</tr>
</tbody>
</table>

*Statistically significant.
Conclusions

- Motor impairment was significantly improved in the ReoGo upper arm therapy.
- Excellent patients compliance.
- High patient motivation led to a high number of repetitions of functional movement per session.
What is the average number of repetitions per session of ReoGo therapy vs. physiotherapy?
Average Repetitions Per Session

- **210 (SD 54)**: 23 min. (SD 6)
- **32* (20-44)**: 36 min. +/- 14

*Increased number of repetitions, better brain recovery*

*Archives of physical medicine and rehabilitation, 2009*
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- New article
- General conclusions
- Ongoing studies
Active and repetitive robot assisted training improves the functional recovery of the arm in sub-acute stroke patients

S. Faran, S. van Kaick, C. Eickhoff, K-H. Mauritz

Germany, 2008

International Stroke Conference, New Orleans, LA
Objective:

- To determine whether motor training with the ReoGo for 60 minutes daily as compared to splint therapy will lead to significant improvement in:
  - Selective arm motor control
  - Arm activities

2008, Germany
Design:

- 20 sub-acute stroke patients, with first ischemic stroke onset 3 weeks - 3 months prior to treatment
- Two groups

Treatment protocol:

- Daily therapy sessions
- 4 weeks
- 20 sessions of one hour
- ReoGo or air splint therapy
Main Outcome Measures:

- Fugl Meyer (FM) test
- Action Research Arm Test (ARAT)

The tests were performed at baseline and after 4 weeks.
Results:

- **FM:**
  Significant improvement in the ReoGo treatment (11.09 points)

- **ARAT:**
  Significant improvement in the ReoGo treatment (14.3 points)

**FM and ARAT Vs Motor Power Scale at Baseline:**
Improvement (delta from baseline) in the Reo therapy was considerably higher for patients entering the therapy with higher motor power.
Conclusions:

- **Motor recovery of the upper limb** in hemiplegic stroke patients can be significantly improved through additional sensori-motor training in the **sub-acute phase**.

- The score of the Fugl-Meyer in the Reo group improved by 18.2%, a difference that can be considered to be **clinically relevant**.
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- New article
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Robot-aided therapy for upper limbs in patients with stroke-related lesions. Brief report of a clinical experience

2011, Italy

F. Bovolenta, M. Goldoni, P. Clerici, M. Agosti, M. Franceschini

JOURNAL OF NEUROENGINEERING AND REHABILITATION
Objectives

- To verify the improvement of the motor impairment and functionality after a rehabilitation treatment with the ReoGo™

- To verify the persistence of the effects after 1 month.

- To evaluate patients’ degree of acceptance and compliance with the treatment
Design:

- 19 patients (13 males, 6 female) with chronic hemiparesis
- Average age 55.74 (±12.6) years
- First acute event of cerebrovascular stroke
- Unsuccessful conclusion of a previous rehabilitation program

Treatment protocol:

- 20 sessions with ReoGo robotic system
- 45 min each
- 5 days a week, 4 weeks
Main Outcome Measures:

- Fugl-Meyer (FM) test,
- Medical Research Council (MRC),
- Ashworth scale
- Visual Analogue Scale pain
- Frenchay Arm test
- Box and Block test,
- FIM motor
- Time up and Go test
- Euro Quality of Life
- Visual Analogue scale satisfaction
# Results

## 2011, Italy

<table>
<thead>
<tr>
<th>Table 3 Performance at the clinical assessment tasks</th>
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</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Fugl-Meyer Test (n = 18)</td>
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<tr>
<td>Upper Limb</td>
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<tr>
<td>Mean ± Std Dev.</td>
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<tr>
<td>Median</td>
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<tr>
<td>Min; Max</td>
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<tr>
<td>31.33 ± 17.42</td>
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<td>33.5</td>
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<tr>
<td>5;54</td>
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<tr>
<td>Ashworth Scale (n = 18)</td>
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<tr>
<td>Shoulder</td>
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<td>Mean ± Std Dev.</td>
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<td>Min; Max</td>
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<tr>
<td>0.67 ± 0.77</td>
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<tr>
<td>Elbow</td>
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<td>Mean ± Std Dev.</td>
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<td>1.67 ± 0.91</td>
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<tr>
<td>Wrist</td>
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<td>Mean ± Std Dev.</td>
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<td>Median</td>
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<td>Min; Max</td>
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<tr>
<td>0.89 ± 1.02</td>
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<tr>
<td>1.0</td>
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<tr>
<td>0.4</td>
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<tr>
<td>T-1 (N = 19)</td>
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<tr>
<td>Mean ± Std Dev.</td>
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<td>Min; Max</td>
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<tr>
<td>31.21 ± 16.92</td>
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<td>33.7</td>
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<td>7;55</td>
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<td>0.37 ± 0.6</td>
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<td>1.79 ± 0.98</td>
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<td>T0(N = 10)</td>
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<td>Mean ± Std Dev.</td>
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<td>Min; Max</td>
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<tr>
<td>40.37 ± 18.57</td>
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<td>49.3</td>
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<td>9;62</td>
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<tr>
<td>0.25 ± 0.77</td>
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<tr>
<td>1.44 ± 1.03</td>
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<td>T1 (N = 19)</td>
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<tr>
<td>41.75 ± 18.95</td>
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</tr>
</tbody>
</table>
Results:

- FM: Significant improvement in upper limb:
  - Baseline: 33
  - 4 weeks: 49
  - One month of follow up: 49.5

- All subjects showed excellent compliance and remarkable satisfaction

- No dropouts associated to intolerance to treatment

- Motor learning maintained 1 month after, indicated that patients were not in a spontaneous recovery stage
In this presentation:

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  - Germany: sub acute stroke
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  - Japan: sub acute stroke
- New article
- General conclusions
- Ongoing studies
Clinical Trial of ReoGo for the Rehabilitation of Post-Stroke Hemiplegia - exploratory study


Japan

Objective:

- To examine whether robotic therapy in addition to standard UE training improves UE function more than self-training in addition to standard training.

- To examine which severity level of hemiplegia could benefit from the robotic therapy.
Design:

- Prospective, single-blinded, randomized, multicenter
- 6 rehabilitation facilities
- 60 patients (41 men, 19 women; mean age, 64.8 ±10.8 years)
- Sub-acute post-stroke Hemiplegia (UE Brunnstrom stage III to IV) experienced stroke in the previous 4 to 8 weeks
Treatment protocol:

- In addition to daily therapy sessions
- 40 min of ReoGo therapy or self-training (control group).
- 6 weeks (7 days a week)

2010, Japan
Results:

- Robotic therapy group, as compared to control group

  - Significant improvement in the FM Flexor Synergy score (score change $2.1 \pm 2.7$ vs. $0.1 \pm 2.4$; $p<.01$)

![Effect on UE Synergy Movement](image-url)
Results:

- Robotic therapy group, as compared to control group

  - Shoulder/Elbow/Forearm score
  - (score change $4.8 \pm 5.0$ vs $1.9 \pm 5.5$; $p<.05$).
Participants were divided with baseline FM total score into: higher (>30) or lower (<30) function cohort.

- In the higher function cohort, no significant difference between two groups.

- In the lower function cohort, RoGo therapy significantly improved FM Shoulder/Elbow/Forearm score compared with control group (score change $6.6 \pm 5.1$ vs $2.2 \pm 6.2$; $p<.05$)
Baseline UE Function and FMA Improvement

Higher Class
Baseline FMA total score ≥ 30

Lower Class
Baseline FMA total score < 30

Robotic therapy group
Control group

Change in score on FMA

Pre  Post

n.s.  p<0.05

n.s.  p<0.001

n.s.  p<0.05
Conclusions:

- People with moderately severe hemiplegia benefit from the ReoGo, robotic therapy

- ReoGo treatment benefits include:
  - Repetitive movement
  - Correct movement pattern
  - Constant amount of assistance

2010, Japan
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Development and Validation of the First Robotic Scale for the Clinical Assessment of Upper Extremity Motor Impairments in Stroke Patients

Omer Einav, Diklah Geva, Doron Yoeli, Marina Kerzhner, Karl-Heinz Mauritz

Topics in Stroke Rehabilitation, November 2011
Objective

➢ To develop and validate the first robotic-based procedure for assessing upper extremity motor impairments in stroke patients, and to test its discriminative power.
100 Stroke patients were evaluated before starting treatment by:

- ReoGo scale (9 tasks)
- Fugl-Meyer (FM) motor test
- Wolf Motor Function Test (WMFT)
- Action Research Arm Test (ARAT).
Results

- The total ReoGo score correlated closely with the upper extremity scores of the FM, WMFT and ARAT ($r = 0.95$, $0.93$ and $0.90$, respectively).

- The ReoGo score was able to discriminate between low, moderate, and high functioning patients (86% agreement $K = 0.79$, with FM).
Conclusions

- The validity of the Reo Scale Assessment is comparable with that of the FM, WMFT, and ARAT.

- The objective measuring and scoring of the ReoGo make it an efficient tool for assessing motor function of stroke patients in clinical and research settings.
In this presentation:

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- New article
- General conclusions
- Ongoing studies
ReoGo treatment is safe with no side effects

ReoGo Therapy is appropriate for a wide range of post-stroke populations (sub-acute and chronic)

Significant functionality improvements maintained overtime

Patient compliance and satisfaction are excellent

Remarkable recovery of UE mobility in severe hemiplegia
In this presentation:

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  - Italy: chronic stroke
  - Japan: sub acute stroke
- New article
- General conclusions
- Case study & Ongoing studies
Use of Robotics in Spinal Cord Injury: A Case Report

Lori Sledziewski, Roseann C. Schaaf, Julie Mount


Objective

to examine the use of robotics to treat upper extremity (UE) dysfunction in tetraplegic patients with spinal cord injury (SCI).
Method.

A 51-yr-old man with an incomplete SCI received combined traditional occupational therapy with ReoGo, 28 days post injury.

The ReoGo treatment includes:

18 consecutive 1 hour sessions

3 sets of 10 repetitions for each of the following exercises:

(1) Forward reach, (2) Forward thrust, (3) Horizontal reach, (4) Hand to mouth
M.R. demonstrated improvements on all outcome measures.

1. Increase in AROM
2. Increased independence in self-care (FIM score)
3. Increase in strength (MMT score)
4. Increase in perceived right UE function (CUE score)

Conclusion:

The findings demonstrate the ReoGo’s utility in combination with traditional occupational therapy.
Changes in Right Upper Extremity Strength Using Manual Muscle Testing (MMT)

- **Admit**
- **Mid Point**
- **Discharge**

**Upper Extremity Motion**

<table>
<thead>
<tr>
<th>Motion</th>
<th>Admit</th>
<th>Mid Point</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoulder flex/ext</td>
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<tr>
<td>Shoulder ABD/ADD</td>
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<td>Shoulder IR</td>
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<td>Shoulder ER</td>
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<tr>
<td>Elbow flex/ext</td>
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<tr>
<td>Pronation</td>
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<td>Supination</td>
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<td>Wrist flex</td>
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<tr>
<td>Wrist ext</td>
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</tbody>
</table>
FIM Scores

Area of Self Care
On Going Studies

Germany, Neils Birbaumer

- Combined treatment of ReoGo and BCI - EEG
  - 21 stroke patients (40)
  - Daily training sessions of 45 min. for 4 weeks

- Results - Training effect was greatest with the ReoGo compared to the hand orthosis (control)
- ReoGo was very well accepted and tolerated by all patients.
Italy, 2011

- F. Bovolenta – article to be published
- Franco Molteni - ReoGo and EMG
  - One case study, chronic stroke patient
Using surface dynamic electromyography during Upper-extremity robotic training

F. MOLTENI, M. CAIMMI, A. CAZZANIGA, G. GASPERINI, E. GIANDOMENICO, C. GIOVANZANA

Europa Medicophysica, 2008
• 5 Sub acute stroke patients

• 2 weeks therapy – 10 sessions

• 30 min of ReoGo reaching exercises in the following modes:
  • Guided
  • Initiated
  • Step initiated

• The EMG pattern of the arm and shoulder muscles was recorded
Results

In general in this preliminary study the pattern of activity of the arm and shoulder muscles has improved.

Conclusion

The dynamic EMG could be useful for monitoring the patient’s muscular activity during robotic treatment.
Muscle activity patterns correlates with ReoGo treatment

After 1 month of treatment, the patient has improved the motion control (as presented in the table above); the on-off pattern is more similar to the normal one (there are clear activation and rest periods). The improvement is evident.
USA – at least 3 more studies

- Kessler Institute for Rehabilitation, USA
- NY Presbyterian Hospital, affiliated to Columbia University, USA
- National Institute of Neurological Disorders and Stroke, USA
New Clinical Study, 2011
New Clinical Study, 2011

Getting people back on their feet
Robot-Assisted Gait Training for Patients with Hemiparesis Due to Stroke

Stanley Fisher, Leah Lucas, T. Adam Thrasher

Topics in Stroke Rehabilitation, May-June 2011

USA, 2011
Objective
To compare the outcomes of robot-assisted gait training (RAGT) using ReoAmbulator with a traditional therapy program.

Design
- 20 Stroke patients (two groups of 10)
- Control group: 1-hour sessions of conventional therapy
- RAGT group: 30 min. of conventional therapy and 30 min. of ReoAmbulator
- 24 sessions
Outcome measures

- 8-meters walk test
- 3-minute walk test
- Tinetti balance assessment

Results

- Stroke patients improved walking function following ReoAmbulator therapy

- The functional gains of the robotic therapy were not significantly better than conventional physical therapy.
Conclusion

ReoAmbulator and conventional physical therapy, as applied in this study,* may produce similar clinical outcomes.

The added value of the ReoAmbulator treatment

- Physical therapy required significantly more therapist time (12 additional therapist-hours per patient) than the RAGT.

- ReoAmbulator therapy can provide a controlled, consistent level of therapy in many different settings.

*Please note that the duration of the robotic therapy in this study was only 30 min.
Thank You

www.motorika.com