

Clinical Data Summary

Buick A, Kowalczewski J, Carson RG, and Prochazka Tele-Supervised FES-Assisted Exercise Hemiplegic Upper Limb. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 24: 79- 87, 2016.

Summary:

A ReJoyce workstation and a precursor of the ReGrasp hand FES stimulator were deployed in the homes of chronic stroke survivors to enable FES-assisted exercise therapy (FES-ET) in the guise of computer games. Eleven participants performed 6 weeks of 1 h/day, 5 d/wk, tele-supervised FES-ET. Significant improvements were seen in the Action Research Arm Test (ARAT) and the ReJoyce Arm and Hand Function Test (RAHFT). Participants with intermediate ARAT and RAHFT scores at baseline derived the greatest benefit.

Conclusion:

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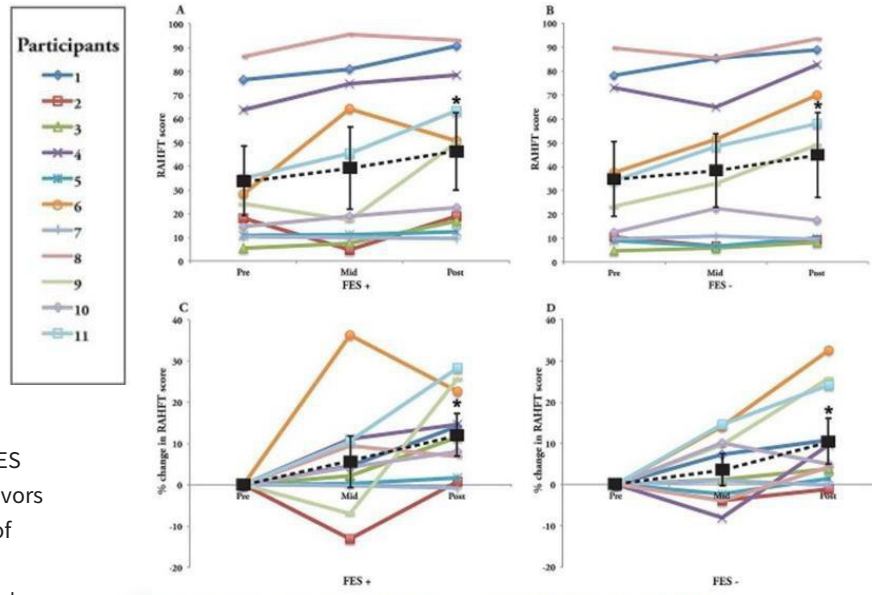


Fig. 1. Upper limb function pre-, mid-, and post-intervention, as measured by the RAHFT. Individual scores are plotted, with the group mean (error bars representing 1 SD) superimposed in black. Instances of a statistically reliable difference pre-post intervention are indicated by the symbol. (A) Mean RAHFT scores, pre, mid-, and post-treatment, tested with FES assistance. (B) Mean RAHFT scores, pre, mid-, and post-treatment, tested without FES assistance. (C) and (D) Mean percentage changes in RAHFT scores in (A) and (B).

Prochazka A, and Kowalczewski J. A fully automated, quantitative test of upper limb function. *Journal of Motor Behavior* 47: 19-28, 2015.

Summary:

The RAHFT was compared to the Action Research Arm Test (ARAT) and the Fugl-Meyer Assessment (FMA) in 13 tetraplegic individuals. Concurrent and criterion validities of the RAHFT were supported by a high level of correlation with the ARAT. The mean test-retest difference in RAHFT scores was not statistically significant, supporting the reliability of the test. The RAHFT showed less ceiling effect than either ARAT or FMA. These data help validate the RAHFT as a quantitative, automated alternative to the ARAT and FMA.

Conclusion:

The RAHFT is the first comprehensive test of arm and dexterous hand function that does not depend on human judgment. It offers a standardized, quantitative outcome evaluation.

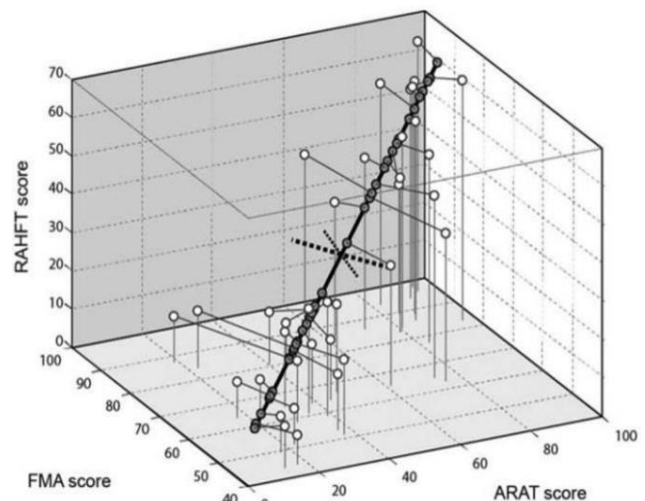


Fig. 2. Three-dimensional plot of Action Research Arm Test (ARAT), Fugl-Meyer Assessment (FMA), and ReJoyce Automated Hand Function Test (RAHFT) scores from 34 test sessions. Each open circle shows the normalized scores of the three tests in a given participant in a given test session. The solid line is the first principal component (PC1) of the data points, and the dashed lines are PC2 and PC3. The grey circles are the nearest points on PC1 to each data point.

Summary:

This article reviews emerging technology for upper extremity rehabilitation. People living with hemiplegia due to stroke and tetraplegia due to SCI find it difficult or impossible to perform many activities of daily life. Intensive exercise therapy supplemented with functional electrical stimulation (FES), can improve upper extremity function, but delivering the treatment can be costly after recipients leave rehabilitation facilities.

Conclusions:

Exercise therapy combined with FES, supervised over the Internet, will soon be adopted worldwide so it is crucial to understand the technical barriers, the anticipated motor improvements and the process of optimizing the tele-therapy protocols to maximize the benefits of the emerging technology.

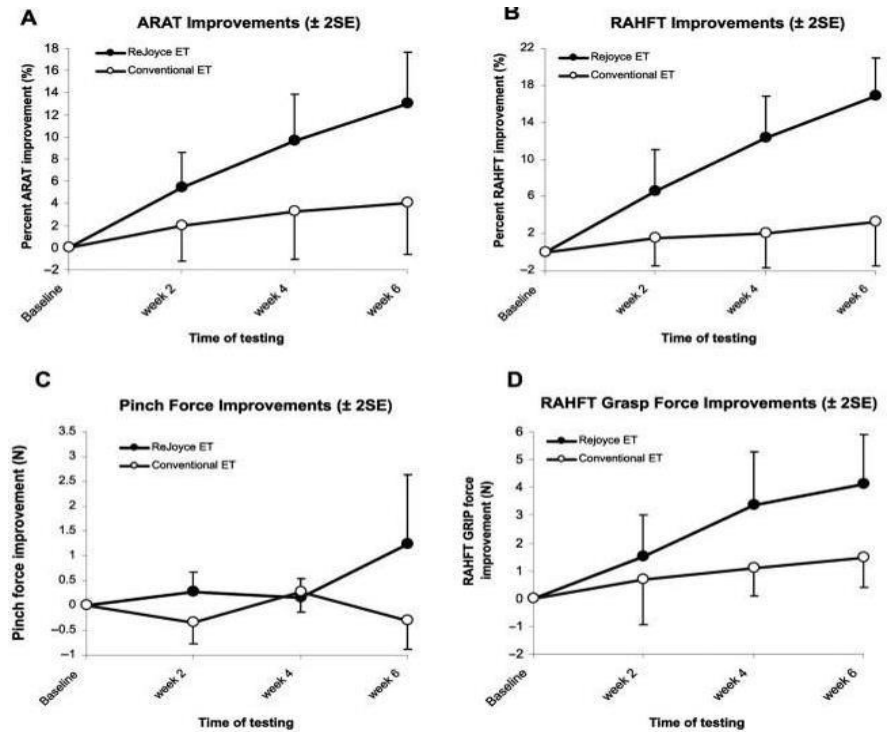


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Kowalczewski J, Chong SL, Galea M, and Prochazka A. In-home tele-rehabilitation improves tetraplegic hand function. *Neurorehabilitation and Neural Repair* 25: 412-422, 2011.

Summary:

This was a randomized, controlled trial on tetraplegic people in which FES-assisted exercise therapy (ET) was compared with conventional therapy, both being tele-supervised 1 hour/day, 5 days/week for 6 weeks. FES-ET was performed on a ReJoyce workstation. A forerunner of the ReGrasp was used by the FES-ET group. This was a fingerless glove with an inbuilt stimulator and electrodes. The stimulator was controlled by a wireless earpiece which detected voluntary toothclicks. The FES-ET group showed statistically larger improvements in hand function than the conventional therapy group.

Conclusion:

In participants with tetraplegia, FES-ET on a ReJoyce workstation led to larger improvements in hand function than conventional therapy. The improvements exceeded the Minimal Clinically Important Difference (MCID), which is often used as a criterion to introduce a treatment into best practice.

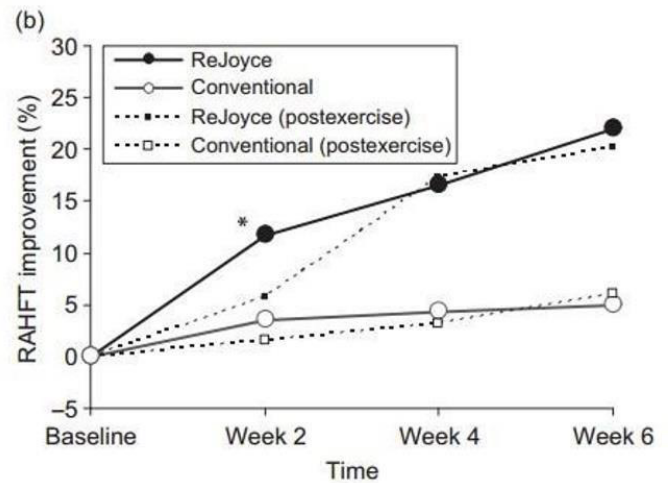
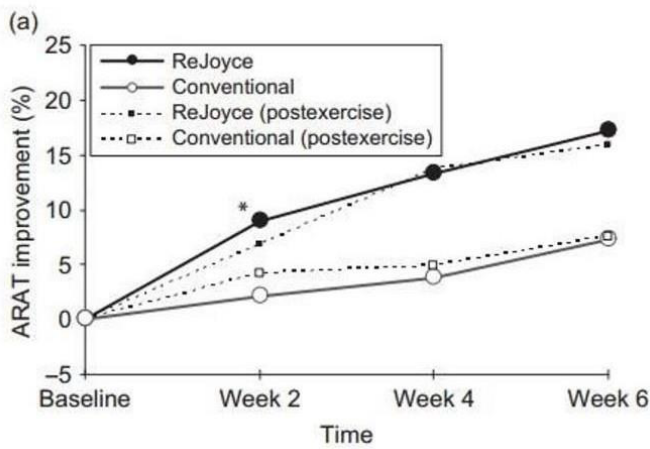


Fig. 4. Hand function tests performed during biweekly laboratory visits by participants taking part in the IHT study (Kowalczewski et al., 2011). (a) Mean improvements over baseline in the Action Research Arm Test (ARAT). Solid and dashed lines: scores before and after 1-h of FES-ET performed in the laboratory. Notice that at 2 weeks, there was a significant difference (asterisk) between the pre-ET and post-ET scores, which we attribute to muscle fatigue. This was not seen in subsequent sessions at 4 and 6 weeks. (b) Mean improvements in the ReJoyce automated hand function test (RAHFT), showing a similar difference in pre- and post-ET scores at 2 weeks.

Kowalczewski J, Gritsenko V, Ashworth N, Ellaway P, and Prochazka A. Upper-extremity functional electric stimulation-assisted exercises on a workstation in the subacute phase of stroke recovery. *Archives of Physical Medicine and Rehabilitation* 88: 833-839, 2007.

Summary:

This was a double-blind, randomized, controlled trial of FES-assisted exercise therapy (FES-ET) in 19 sub-acute stroke patients (less than 3 months post-stroke). Participants performed exercises on a prototype ReJoyce workstation. A modified Bionic Glove was used to assist hand opening and grasp. Participants either did FES-ET 1 h/day on 15- 20 consecutive workdays or they received 15min of passive electrical stimulation 4 d/week and 1 hr of FES-ET on the 5th day. Both groups showed improvements in clinical tests of upper extremity function, the higher-intensity exercise group improving significantly more than the control group.

Conclusion:

FES-ET initiated in the sub-acute stage of recovery after a stroke has beneficial and long-lasting effects on upper limb function.

Combined Kinematic Scores

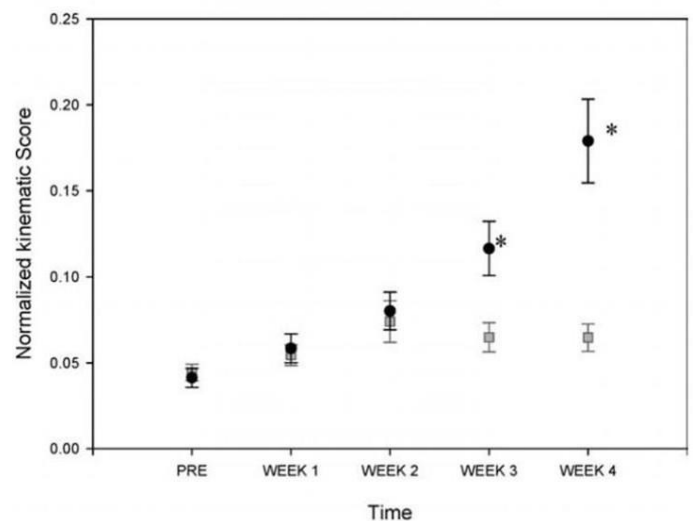


Fig. 5. Mean CKS standard error computed from the workstation data over the 4-week duration of treatment. The pretreatment values are those obtained during a single workstation session during the assessment stage. Each group was tested at the end of each week. Legend: black symbols, high- intensity FES-ET group; gray symbols, low-intensity FES-ET group. *Significant difference with post hoc Tukey HSD ($P < .05$).

Summary:

This report concerns a clinical trial with the fore-runner of the ReJoyce workstation, a rotatable circular table with attachments representing activities of daily life. Six hemiplegic subjects performed a set of tasks with their affected hand 1 hour/day for 12 days. A modified Bionic glove stimulator was used to assist hand opening. Two out of three clinical tests showed improvement in hand function.

Conclusion:

Hand function can be improved in people with hemiplegia whose motor impairment excludes them from conventional constraint-induced movement therapy.

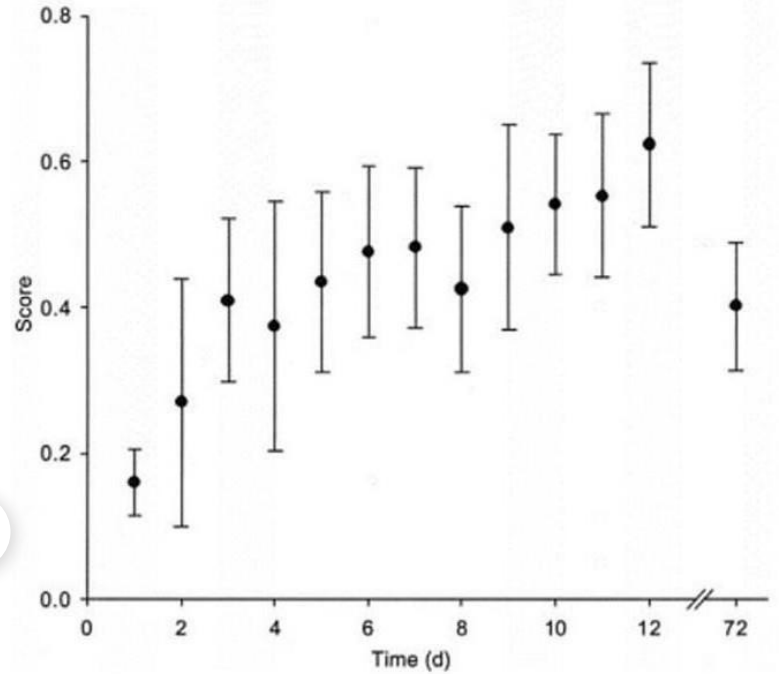


Fig. 6. Mean final performance scores averaged over all subjects +/- SD.