Feasibility of Using the RAPAEL Smart Glove in Upper Limb Physical Therapy for Patients after Stroke: A Randomized Controlled Trial

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Abstract—We aim to assess the feasibility of using the RAPAEL Smart Glove as an assistive tool for therapists in clinical rehabilitation therapy settings and to investigate if it can be used to improve the motor recovery rate of stroke survivors. Our randomized controlled study involved 13 post-stroke inpatients. An experimental treatment consisted of one 30-minute game-assisted therapy and one 30-minute conventional therapy per day while the control treatment consisted of two 30-minute conventional therapies. Each therapy block consisted of 15 days over a period of 3 weeks. The measured outcomes were the scores on the Wolf Motor Function Test and the active range of motion for the forearm and the wrist. The mean Wolf Motor Function Test score for the group that received game therapies as well as conventional therapies was significantly higher than that for the group who received only conventional therapies. The results suggest that the motor recovery rate of the clinical rehabilitation therapies can be improved when wearable sensors and therapeutic games are used by therapists in their routine therapy practice.

I. INTRODUCTION

Strokes are a major cause of mortality and permanent disability for adults worldwide [1]. To achieve motor recovery, patients who experience strokes need to undergo rehabilitation therapies. The repetitive nature of therapeutic exercise tasks, however, often deters the patient from engagement and timely recovery. Addressing this, the feasibility of using video games in stroke rehabilitation is gaining increasing attention by academic and clinical communities. By embedding exercise tasks in entertaining games, it is predicted to increase the engagement of the patient and subsequently lead to greater motor recovery [2]. More specifically, many are interested in utilizing commercially available gaming consoles and video games, such as Nintendo Wii [3]–[7] and Sony PlayStation [8], [9]. Their games are originally designed to entertain normally functioning people, and they may therefore not induce the focused therapeutic exercise movements of the paretic limbs. In previous studies, the use of such games has often been studied for home therapy or an alternative to conventional recreational therapy while therapists are not or minimally involved.

We employ the RAPAEL Smart Glove (NEOFECT Rehabilitation Solutions, S. Korea [10]), which are commercially available wearable sensors that can sense wrist and finger movements, and its accompanying video games, which are designed to induce the targeted movements of paretic wrists and fingers. We investigated the feasibility of using the RAPAEL as an assistive tool for therapists in routine clinical settings and to determine if its use can improve the motor recovery rate in the same given time when compared to conventional therapy without using it. To answer these questions, we conduct a randomized controlled study with 13 stroke inpatients. Our empirical results suggest that rehabilitation therapies may induce higher motor recovery rate when wearable sensors and therapy games are used.

II. RAPAEL SMART GLOVE

The RAPAEL Smart Glove is a wearable sensory solution (Fig. 1(a)). It contains a single 9-axis movement and position...
sensor with 3 acceleration channels, 3 angular rate channels and 3 magnetic field channels that measures wrist movements and 5 bending sensors that measure finger movements. It is accompanied by video games that are designed to induce targeted wrist and finger movements, that include forearm supination/pronation, wrist flexion/extension, wrist radial/ulnar deviation, and finger flexion/extension. For instance, a table wiping game is designed to induce wrist radial/ulnar deviation movements (Fig. 1(b)).

### III. METHODS

#### A. Study Population

We recruited cognitively competent (≥ 24 Mini-Mental State Examination [11]) inpatients from Heeyeon Rehabilitation Hospital (Changwon, S. Korea) who were above 18 years of age and had long-term motor impairment of an upper limb from a stroke. Such impairment was defined as 30% to 90% on active range of motion in forearm supination/pronation and wrist flexion/extension. The patient should be able to execute but cannot complete forearm and wrist movements to the full extent by themselves. To avoid the confounding effect of spontaneous improvement, patients with a stroke that had occurred at least 4 months before enrolment were considered for participation.

#### B. Study Interventions

Using the computer-generated random numbers, patients were evenly assigned to group A and to group B. The therapists of the patients that were assigned to group A were introduced to the RAPAEL and its games. Before the beginning of the study, they were given three days to try the game therapy with patients who were not included in the designed study. For the study, all the therapies were performed by the therapists who were originally assigned to the participating patients by the hospital before the deployment of the RAPAEL.

1) Conventional Therapy: For the upper-limb therapy, the patients in the control group (Control 1 and Control 2 in Fig. 3) received two 30-minute sessions every day, 5 days of therapies a week for 3 weeks.

2) Game-Mediated Therapy: The patients in the experiment group received all the conventional therapies of the hospital except that one 30-minute upper-limb therapy session was conducted using the RAPAEL (Fig. 3). To maintain the engagement of the patients during the study period, therapists were permitted to use a combination of different video games. Their choices were, however, limited to the games for forearm and wrist movements.

#### C. Outcome Measures

A single therapist who was unaware of study group assignments assessed all the patients 15 sessions after randomization. The therapist assessed the patients from group A one more time after 30 sessions. Outcomes were changes in the
Wolf Motor Function Test score\textsuperscript{1} \cite{12} and the active range of motion\textsuperscript{2} of the forearm and wrist movements \cite{13}. First, changes of group A after 15 sessions from the study onset were measured. Changes of group B for 15 sessions were measured and compared (between-groups). Since the RAPAEL was used as an assistive tool for therapists, the different levels of the therapists' competency and the unmodeled patients’ characteristics may have affected motor recovery. Hence, measured changes of the group A for the first 15 sessions were compared with those of the same group after another 15 sessions (within-group in Fig. 3).

\textbf{D. Statistical Analysis}

The between-group analyses were performed using a Mann-Whitney U-test (A in Fig. 3). The within-group measures were analyzed using a Wilcoxon signed-rank test (B in Fig. 3). For both cases, null hypotheses were tested at the 5\% significance level. MATLAB R2012a was used for the statistical analyses. Analyses were considered statistically significant when $p < 0.05$.

\textbf{IV. RESULTS}

\textbf{A. Study Participation}

We screened 110 inpatients, of whom 14 underwent randomization evenly to the group A and the group B (Fig. 2). The most common reason for exclusion of patients from the study was active range of motion outside the required range of 30\% to 90\%. A total of 13 patients (93\%) completed the study. All 7 patients in group A attended the first 15 sessions and the last 15 sessions. Six participants in group B attended the 15 sessions.

\textbf{B. Baseline Characteristics of the Participants}

The two-sample Kolmogorov-Smirnov test showed the baseline characteristics of the two groups to be similar in all the measures. The mean age was 73.0 ± 7.6 years; 93\% of the participants were women; and all were Asian. The average time from the stroke onset until study entry was 13 months (range, 4 to 23 months). At the baseline, the mean Wolf Motor Function Test score was 52.2 ± 15.1. The average active range of motion was 79.2 ± 8.9, 84.2 ± 5.3, 66.2 ± 19.5, 52.3 ± 13.2 degrees for forearm supination, pronation, wrist flexion, and wrist extension respectively.

All 13 patients were receiving routine rehabilitation therapy at the baseline and at any time point during the study. Two sessions targeted upper-limb function every weekday. Each therapy was approximately 30 minutes long.

\begin{table}[h]
\centering
\caption{Baseline Characteristics of the Participated Patients}
\begin{tabular}{|c|c|c|}
\hline
Characteristic & Group A (N=7) & Group B (N=6) \\
\hline
\multicolumn{3}{|c|}{\textbf{Age–yr}} \\
Mean & 75 ± 9 & 71 ± 6 \\
Range & 59–80 & 60–79 \\
\hline
\multicolumn{3}{|c|}{\textbf{Sex–no.(\%)}} \\
Male & 0 (0) & 1 (14) \\
Female & 7 (100) & 5 (86) \\
\hline
\multicolumn{3}{|c|}{\textbf{Affected side–no.(\%)}} \\
Left & 4 (57) & 3 (50) \\
Right & 3 (43) & 3 (50) \\
\hline
\multicolumn{3}{|c|}{\textbf{Time from stroke to randomization–mo.}} \\
Mean & 14 ± 7 & 11 ± 7 \\
Range & 6–23 & 4–23 \\
\hline
\multicolumn{3}{|c|}{\textbf{Measurement of function}} \\
Score on Wolf Motor Function Test & 54.1 ± 15.0 & 50.0 ± 16.3 \\
Degree on active range of motion & & \\
Forearm Supination & 81.4 ± 7.5 & 76.7 ± 10.3 \\
Forearm Pronation & 82.9 ± 5.7 & 85.8 ± 4.9 \\
Wrist Flexion & 72.9 ± 11.1 & 58.3 ± 25.0 \\
Wrist Extension & 52.1 ± 13.1 & 52.5 ± 14.1 \\
\hline
\end{tabular}
\end{table}

\begin{table}[h]
\centering
\caption{Changes in Outcomes at Posttest 1: Group A vs. Group B}
\begin{tabular}{|c|c|c|c|}
\hline
Outcome & Group A & Group B & $P$ Value \\
\hline
Wolf Motor Function Test & 6.00±2.77 & 2.00±1.67 & 0.02 \\
\hline
Active range of motion & & & \\
Forearm Supination & 5.71±7.32 & 1.67±2.58 & 0.40 \\
Forearm Pronation & 3.57±4.76 & 0.00±0.00 & 0.24 \\
Wrist Flexion & 2.86±5.67 & 0.83±4.92 & 0.66 \\
Wrist Extension & 5.71±6.07 & -0.83±4.92 & 0.11 \\
\hline
\end{tabular}
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\begin{table}[h]
\centering
\caption{Changes in Outcomes of Group A at Posttest 1 vs. Posttest 2}
\begin{tabular}{|c|c|c|c|}
\hline
Outcome & Posttest 1 & Posttest 2 & $P$ Value \\
\hline
Wolf Motor Function Test & 6.00±2.77 & 0.00±2.89 & 0.046 \\
\hline
Active range of motion & & & \\
Forearm Supination & 5.71±7.32 & 2.14±2.58 & 0.63 \\
Forearm Pronation & 3.57±4.76 & -2.14±5.67 & 0.25 \\
Wrist Flexion & 2.86±5.67 & -2.14±4.88 & 0.31 \\
Wrist Extension & 5.71±6.07 & 0.71±5.35 & 0.31 \\
\hline
\end{tabular}
\end{table}

\textbf{C. Effectiveness}

1) Primary Outcome: At 15 sessions, the mean change in the Wolf Motor Function score for group A was greater than that for group B (between-groups). The mean change in the Wolf Motor Function score for group A for the first 15 sessions was 2.86 ± 5.8, which is greater than the mean change for group B (2.00 ± 1.67), with a $P$ value of 0.02 (Table II).

\begin{table}[h]
\centering
\caption{Changes in Outcomes of Group A at Posttest 1 vs. Posttest 2}
\begin{tabular}{|c|c|c|c|}
\hline
Outcome & Posttest 1 & Posttest 2 & $P$ Value \\
\hline
Wolf Motor Function Test & 6.00±2.77 & 0.00±2.89 & 0.046 \\
\hline
Active range of motion & & & \\
Forearm Supination & 5.71±7.32 & 2.14±2.58 & 0.63 \\
Forearm Pronation & 3.57±4.76 & -2.14±5.67 & 0.25 \\
Wrist Flexion & 2.86±5.67 & -2.14±4.88 & 0.31 \\
Wrist Extension & 5.71±6.07 & 0.71±5.35 & 0.31 \\
\hline
\end{tabular}
\end{table}
sessions was better than that for the following 15 sessions (within-group). Both results were statistically significant.

2) Secondary Outcome: The patients receiving mixed therapies, compared with those receiving only the conventional therapies of the hospital, had greater improvement in active range of motion. The same patients had greater improvement when receiving mixed therapies than receiving only the conventional therapies of the hospital. None of these differences were statistically significant.

V. DISCUSSION

In this study of rehabilitation strategies for inpatients with upper-limb impairment 4 months or more after a stroke, we found significant benefit of the combination of the game-assisted therapy and the conventional therapy over the conventional therapy alone. After the first 15 sessions, there was a significant difference in the primary outcome with mixed therapies when compared with conventional therapies only. Difference in secondary outcomes were not statistically significant. The same patients showed significant difference in primary outcome when receiving mixed therapies compared with receiving conventional therapies only. Difference in secondary outcomes were not statistically significant. No serious treatment-related adverse events were observed or reported.

Unlike previous studies of game-assisted therapy, which employed the commercially available game devices to entertain normally functioning population, this study used a wearable sensor to measure the wrist and finger joint movements and video games that are designed to induce the movements in those joints that could be selected for by the therapist. Furthermore, most previous studies evaluated the game therapy for its feasibility as an alternative to recreational therapy at the absence or the limited presence of the therapist. In this study, the sensor and games were used to assist the routine therapy sessions administered by the therapist in clinical settings.

There is no universally accepted protocol for upper-limb rehabilitation after a stroke, and treatment programs vary in the duration, intensity, and frequency of rehabilitative care by hospitals and therapists. A major advantage of this study was that the study was conducted in a single site and the clinical effects of the experimental treatment of the patients was compared against the control treatment of the same patients as well as others in the same study site. Hence, the treatment programs that could be varied by hospitals and therapists were eliminated.

Limitations of this study include a preponderance of women (93%) and the small number of patients. There was no break between the first 15 sessions and the second 15 sessions for the group A. Hence, there could be carryover effects of the initial mixed therapy to the subsequent conventional therapy. Potentially, no mean change in the Wolf Motor Function Test and negative changes in forearm pronation and wrist flexion might imply the negative effect of removing the experienced visual stimuli and feedback (TABLE. III). Also, the 15 sessions of the mixed therapy were always followed by the conventional therapy only, and the counterbalancing was not considered in this study design.

VI. CONCLUSION

We found that there were trends toward greater improvement for post-stroke patients with upper-limb impairment for at least 4 months when game-assisted therapy is provided along with conventional therapy for 15 sessions, compared to when they received conventional therapies only. The study provides evidence of the potential benefits of wearable sensors, such as the RAPALE!, and video games that help train selective joint movements. When used as assistive tools for the therapist, they may improve the motor recovery rate of the patient in the same given time.

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REFERENCES