Renovo: A Sensor-Based Therapeutic System for Brachial Monoplegia
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Abstract

Introduction: Patients with Brachial Monoplegia, paralysis of upper limb following various neurological disorders, require therapeutic interventions with proper assessment for rehabilitation. State-of-the-art assessment protocols, the majority of which are qualitative, often cause biased assessment. Very few therapeutic systems aim to assist the physiotherapists in this regard. Methods: We designed a sensor-based therapeutic system for assisting the physiotherapists with real-time visualization of performance metrics and a reliable quantitative assessment. 5 healthy subjects (\textit{Mean}=24.41±2.4 years, 80\% Male), 16 patients with Brachial Monoplegia (\textit{Mean}=39.56±16.4 years, 76.92\% Male), and 5 physiotherapists volunteered with informed consent. Each patient was evaluated by both the system and the physiotherapists in 3 sessions. Results: Insignificant difference between the mean (t(15)=1.39, p=.184) and the variance (F(1, 15)=1.05, p=.460) of system evaluation (\textit{Mean}=6.19, 95\% CI, [4.52, 7.86]) and that of the physiotherapists (\textit{Mean}=6.38, 95\% CI, [4.75, 8.01]) having a strong, positive correlation, \( r=.9885 \) was observed. The system showed good reliability from the Cronbach’s Alpha test with \( \alpha=.8499 \). Conclusions: To ensure effective rehabilitation, proper assessment is obligatory. Sensor-based measurement of performance metrics ensures reliability, reducing the chances of human error. Real-time visualization informs about patients’ progress. Automated quantitative assessment reduces the possibility of bias, allowing optimization of rehabilitation scheme.

Keywords: assistive technology; effective interventions; inertial sensors; neurological disorders; quantitative assessment protocol; real-time visualization; reliable measurement.

List of Abbreviations:
- ARS – Automated Rehabilitation System
- ATs – Assistive Technologies
- BM – Brachial Monoplegia
- CA – Cronbach’s Alpha
- ED – Euclidean Distance
- FES – Functional Electrical Stimulation
- FMA – Fugl Meyer Assessment
- GoEs – Goal-oriented Exercises
- HCI – Human Computer Interaction
- IMU – Inertial Measurement Units
- PCFF – Patient Consent and Feedback Form
- PMs – Performance Metrics
- PMV – Performance Metrics Vector
- POM – Progress Outcome Matrix
- RoM – Range of Motion
- RPMV – Reference Performance Metrics Vector
- SED – Session Euclidean Distance
- SUEF – System Usability Evaluation Form
- UI – User Interface

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1 INTRODUCTION

Hemiplegia is a neurological condition that causes impairments on one side of the body. This occurs mostly due to stroke, spinal-cord injury, brain tumors and infections. Brachial Monoplegia (BM) is a sub-category of Hemiplegia that causes impairments in any particular upper limb of the human body. About half of the stroke survivors are left with permanent impairments [1,2]. Patients with these impairments require appropriate therapeutic interventions for their rehabilitation. The aim of rehabilitation is to re-acclimate patients to the lost motor capabilities of their upper limb. However, it is difficult to determine the proper intervention for a particular impairment [3,4]. There are two reasons behind this. First, with gradual recovery, the nature of impairment changes and may require customized rehabilitation approach [5,6]. Second, there can be multiple impairments simultaneously [7]. Proper assessment and feedback on patients’ progress is obligatory for ensuring an effective intervention. Physiotherapists have adopted many state-of-the-art assessment methodologies [8-10], the majority of which are qualitative. One of the drawbacks of qualitative assessment is that it depends on the knowledge and experience of the physiotherapists. Very few methods [11,12] provide a quantitative scale of assessment. For example, the popular Fugl Meyer Assessment (FMA) [11] scale provides three levels of scoring (0-only few degrees, 1-decreased, 2-normal) for evaluating patients’ progress. Although quantitative, the assessment is completely dependent on how the physiotherapists interpret patients’ muscle spasticity. Therefore, there is a possibility of biased assessment of patients’ progress. Studies [13,14] have shown quantitative assessment ensures a more reliable evaluation than the qualitative counterpart. In practice, physiotherapists evaluate patients with BM based on their performance in Goal-oriented Exercises (GoEs). Problems with this approach are manifold. First, physiotherapists lack adequate information on patient’s motor functionalities a priori. Second, there is no provision for visualizing and tracking key Performance Metrics (PMs) such as Range of Motion (RoM), repetitions, min-max angular displacement, and so on in real-time. Third, inappropriate interventions may induce unwanted joint pains reducing effectiveness of therapy. Finally, patient’s progress might be unsatisfactory if interventions are not administered carefully. These GoEs are merely different combinations of basic motions of the upper limb. Therefore, to overcome these problems, reacclimatizing patients to the motor functionalities of their upper limb followed by advanced GoEs might be a better alternative approach.

In the conventional mode of therapy, physiotherapists cannot visualize the key PMs of any intervention in real-time. They measure RoM manually with the help of a goniometer [15,16] while patients hold their arms steady either voluntarily or with assistance from the physiotherapists. This makes recording RoM difficult for them and increases the probability of erroneous measurements. Keeping track of min-max angular displacement between sessions manually is also a tedious task for them. Physiotherapists manually count the repetitions of a particular therapy with no track of session time. They cannot fully ensure an unbiased evaluation of patients’ performance. Furthermore, there is a lack of an automated patient management system. Rehabilitation in this manner is both inefficient and difficult for the physiotherapists. There are potential factors that may lead to inaccurate measurement of PMs. Some of these are but not limited to – 1) Inability of the patients with BM to keep their arms steady until RoM is measured. 2) Need for assistance from another physiotherapist while taking measurements. 3) Lastly, the unavoidable human error. This inaccuracy may give a false interpretation of patients’ progress. Apart from these issues, the patients may also be faced with health issues such as unwanted joint pain, increased muscle spasticity, numbness and many more.

Over the years, researchers have developed numerous Assistive Technologies (ATs) for improving the quality of rehabilitation for patients with BM. Some of these include VR-based rehabilitation games [17-21], kinematic analysis of upper limb motion using wearable Inertial Measurement Units (IMUs) [22,23], robotic exoskeleton for quantifying motor functionality in object reaching and manipulating tasks [24-26], robot-assisted therapeutic intervention systems [27-30], and Functional Electrical Stimulation (FES) [31]. Researchers have also developed new standards for quantifying upper limb impairment based on kinematic analysis of upper limb motion using Microsoft Kinect [32] in different GoEs. However, few ATs such as the Automated Rehabilitation System (ARS) [33] have been developed that will not only assist physiotherapists with unbiased patient evaluation but also improve the quality and effectiveness of rehabilitation. In ARS, the authors have focused on the rehabilitation of 5 distinct movements of lower extremity after hip-knee replacement surgery. Using wireless IMUs, they have visualized the real-time motion of patients’ lower extremity with a 3D model applying forward kinematics [34-36]. The system provides guidelines to the patient for a certain therapy both visually and theoretically. It also provides visualization of the key PMs and an automated quantitative assessment of the patients.

Therefore, to assist physiotherapists in the rehabilitation of BM, there is a scope of developing a therapeutic system for real-time visualization of therapeutic interventions and quantification of the key PMs concomitant with an automated
quantitative assessment of patients’ progress. Some of the major challenges of developing such a system are to ensure its usability and acceptability [37] along with the reliability of the system-generated assessment scores. With regard to the research scope and challenges, we have developed Renovo, a wearable sensor-based therapeutic system for BM following HCI paradigms. In our study, we have featured 16 basic motions of both left and right upper limbs such as, Wrist Flexion-Extension, Radial-Ulnar Deviation, Forearm Pronation-Supination, Elbow Flexion, Shoulder Flexion-Extension, Adduction (Horizontal), Abduction (Horizontal and Vertical), and External-Internal Rotation (Horizontal and Vertical). Finger joint movements are out of the scope of this study and will be considered in a future analysis. We have explored the alternative approach (Fig. 1) to the rehabilitation of patients with BM, where, rather than initiating rehabilitation with GoEs, the patients were first acclimatized to their upper limb motor functionalities through basic arm movements. It is to be noted that the system is not capable of deciding on patients’ fitness for GoEs. Rather, based on the system generated scores, the physiotherapists decide whether a patient should be prescribed with GoEs. This research was conducted following the STROBE [38] checklist.

Figure 1: Overview of the alternative approach to the rehabilitation of patients with Brachial Monoplegia (BM). The patients are first reacclimatized to the motor functionalities of the upper limb using the proposed system. If their progress is satisfactory, the conventional approach of administering Goal-oriented Exercises (GoE) may be considered.

2 METHODS

2.1 Renovo

Renovo is an AT for assisting physiotherapists with real-time visualization and quantitative evaluation of patients in the rehabilitation of BM. It consists of a wearable device and a processing software. The wearable device contains two IMUs for real-time motion tracking, one on the upper arm (IMU1) and the other on the forearm (IMU2).

The User Interface (UI) of the processing software (Fig. 2) facilitates real-time 3D visualization of arm motion along with the key PMs. It also features patient management, therapy-session management, and therapy-data storage. Physiotherapists can enrol a new patient or administer therapy to an existing patient, where each patient is assigned a unique system-generated ID. In a particular session, physiotherapists can select only one intervention from a list of therapies provided in the UI. Our system also allows them to choose either Passive or Active mode of intervention for either left or right upper limb. In the Passive mode, they instruct and train the patients in a particular therapy. On the other hand, in the Active mode, the patients perform voluntarily under observation of the physiotherapists. The UI also provides static illustration on how a particular therapy needs to be performed for a particular limb, total number of sessions conducted so far, patient details along with that of the current therapy. There is an adjustable session timer with a maximum session duration of 30 minutes. A particular session starts after a 10 second countdown period upon selecting the “Start” button. This acts as a psychological preparation period for both the physiotherapists and the patients. A session can end in two ways, either voluntarily by selecting the “Stop” button or with the expiration of the session timer. At the end of every session, the physiotherapists are given the option to save or discard the corresponding motion data for further reference. In this way, recording of erroneous data can be averted.
The sensor data are processed on the host PC using the following steps (Fig. 3) for real-time visualization: 1) Prior to starting a session, the patients have to align their arm with the base posture of the corresponding therapy and hold for 8-10 seconds to allow for device calibration. 2) Raw motion data from the IMUs are then wirelessly transmitted to the host PC for further processing upon device connection. 3) After a session has been started, an orientation filter [39,40] is applied on this data for generating 3D orientation angles (yaw, pitch and roll). 4) These angles are then processed further for generating joint coordinates of upper limb for 3D visualization applying forward kinematics [34-36] and Denavit-Hartenberg convention [41,42]. 5) The key PMs of a patient during therapy are also generated from these angles. 6) All the processed information is then visualized in real-time in the system UI. The Real-time data processing favours seamless visualization of relevant information. Furthermore, wireless data transmission favours system portability and the patient is not required to be in closer proximity to the host PC.
Figure 3: Workflow diagram of the real-time visualization of relevant information using Renovo. 1) Equip patients with the wearable device followed by device calibration, 2) Transmit raw motion data wirelessly to the host PC, 3) Generate yaw, pitch, and roll angles applying an orientation filter on this data, 4) Generate the coordinates of 3D motion of the arm applying Forward Kinematics (FK) and Denavit-Hartenberg convention, 5) Generate performance metrics from the 3D orientation angles, 6) Visualize the information real-time on the system User Interface (UI).

2.2 Participants

5 healthy subjects (Mean=24.4±2.4 years, 80% Male), 16 patients with BM (Mean=39.56±16.4 years, 76.92% Male, 62.5% with paralyzed left arm), and 5 physiotherapists voluntarily took part in this study with informed consent. The healthy subjects were recruited from among the acquaintances of the authors for collecting reference motion data. The physiotherapists were from two government recognized rehabilitation centers. Only the patients approved by the physiotherapists and under their direct supervision suffering from BM due to any neurological disorders were included in this study. More patients could not be recruited due to the ongoing COVID-19 pandemic. Detailed demographics of the healthy subjects and the patients are provided in Table-1.

Table 1: Demographic details of the patients (p1-p16) and the healthy subjects (h1-h5).

| Patients | | | | Healthy Subjects | | | |
|---|---|---|---|---|---|---|---|
| | IDs | Age (Years) | Gender | Duration of BM (months) | Affected Limb | | IDs | Age (Years) | Gender | Dominant Limb |
| | p1 | 25 | F | 16 | Right | | h1 | 20 | F | Left |
| | p2 | 71 | F | 30 | Left | | h2 | 26 | M | Right |
| | p3 | 42 | F | 14 | Right | | h3 | 25 | M | Left |
| | p4 | 40 | M | 10 | Left | | h4 | 25 | M | Left |
| | p5 | 50 | M | 4 | Right | | h5 | 26 | M | Right |
| | p6 | 65 | M | 3 | Left | | | | | |
| | p7 | 70 | M | 12 | Left | | | | | |
| | p8 | 20 | M | 12 | Left | | | | | |
| | p9 | 35 | M | 1 | Left | | | | | |
| | p10 | 40 | M | 14 | Left | | | | | |
| | p11 | 40 | M | 12 | Left | | | | | |
| | p12 | 40 | M | 12 | Left | | | | | |
| | p13 | 25 | M | 2 | Right | | | | | |
| | p14 | 26 | M | 2 | Right | | | | | |
| | p15 | 22 | M | 12 | Left | | | | | |
| | p16 | 22 | M | 12 | Right | | | | | |
| Mean (M) | 39.56 | 10.5 | 24.4 | | | | | | |
| SD | 16.4 | 6.99 | 2.24 | | | | | | |
| Proportions | F (23.08%) | Left (62.5%) | F (20.0%) | Left (60.0%) | | | | | |
2.3 Experimental Procedure
At the beginning of any therapeutic intervention, the participants were equipped with the wearable device (Fig.3-Step 1). Before any patients were recruited, motion data from the healthy subjects were collected for all the motions featured in this study. Their data were later used as a reference for generating patient assessment scores through comparative analysis. In the case of the patients, selective motions were administered at the discretion of the physiotherapists. They advised on administering the rest gradually depending on the patients’ progress. For a particular motion, the physiotherapists first guided them in the Passive mode of intervention of Renovo. Subsequently, the patients performed the same in the Active mode and their motion data were collected. For any particular intervention, all the participants participated in at least 3 sessions. Duration of each session with the patients was at the discretion of the physiotherapists. After each session, the participants were allowed to rest for a while to reduce the possibility of any fatigue or injury. The patients were simultaneously evaluated by the physiotherapists using the quantitative portion of the FMA scale apart from the system assessment.

2.4 Performance Metrics Vector (PMV)
During therapy, the different motions of the upper limb are administered in a periodic fashion. In order to quantify the quality of these motions, feature vectors need to be derived from the corresponding motion data. These vectors summarize the statistical measures of the data. However, due to the periodic nature of these motions, different wave-related measures can also be derived from the data. In the literature, these feature vectors have been generated using measures that are either only statistical [23,43] or only wave-related [33] or both [18]. In our study, we have utilized both measures for generating PMs from the corresponding 3D orientation angles. The statistical metrics include, Standard Deviation (SD), Mean (M), Repetition Rate (C), and Median of amplitudes(peak) above 80% of max RoM (PA8). The wave related metrics include, RMS value (R), Wave Period (P), Velocity (V), and Amplitude (A). Combining all these metrics, for any particular intervention, a Performance Metrics Vector (PMV) (Eq. 1) was formed for each participant per session. These PMVs were stored as motion data only in the Active mode of intervention and later used in the comparative analysis for generating patient assessment scores.

\[
PMV = [SD, M, C, PA8, R, P, V, A]
\]  

(1)

2.5 System Assessment Score Generation
The following steps (Fig. 4a) were followed for generating patient assessment scores in any particular therapy: 1) Patient PMVs for each session were vector normalized. 2) PMVs of all sessions of all the healthy subjects were combined, their metric-wise mean was calculated followed by vector normalization to form a corresponding Reference PMV (RPMV). 3) For each session, the Euclidean Distance (ED) between the patient’s PMV and the corresponding RPMV was then calculated. This distance is a measure of a patient’s motor capability compared to that of a healthy person in that session for that therapy. However, it provides no information on the patient’s progress in subsequent sessions. 4) Therefore, for all possible pairs of subsequent Sessions, we stored the difference between their EDs (SEDs) in a Progress Outcome Matrix (POM). It is a lower triangular matrix with dimensions equal to the total number of therapy sessions. For any element in POM with value less than or equal to or greater than zero, the corresponding Progress Outcome (PO) was defined as negative or neutral or positive, respectively. Similar to the FMA scale, these outcomes were then mapped to three numeric values (0-negative, 1-neutral, and 2-positive) each having a unique definition and interpretation (Fig. 4b). 5) The Probabilities (P) of these outcomes were then calculated from the corresponding counts of negative \((n_0)\), neutral \((n_a)\), and positive \((n_p)\) outcomes from the \(N\) elements of POM (Eq. 2). 6) Finally, the assessment score was generated by calculating the corresponding expected value of progress in that therapy (Eq. 3).
Figure 4: (a) Workflow diagram of generating patient assessment score using Renovo. 1) Generate normalized Performance Metrics Vector (PMV), 2) Generate Reference PMV (RPMV) for the corresponding therapy with data from healthy subjects, 3) Compute Euclidean Distance (ED) between the session-wise PMV and the RPMV, 4) Generate the Progress Outcome Matrix (POM) from the difference of the EDs of all pairs of subsequent Sessions (SEDs), 5) Define Progress Outcomes (POs) and calculate their probabilities, 6) Calculate Expected Value of outcomes as the final assessment score of a patient after n sessions of a particular therapy. (b) Mapping of Progress Outcomes to numerical values and their corresponding Interpretation.

- \[ P(\text{Outcome}) = \begin{cases} P_N & \text{probability of Negative outcomes} \\ P_N & \text{probability of Neutral outcomes} \\ P_P & \text{probability of Positive outcomes} \end{cases} \]

- \[ \text{Assessment Score} = \sum_{i=1}^{n} \text{Numerical value of Outcome}_i \times P(\text{Outcome}_i) \]

A key point to be noted here is that the assessment score is the expected value of PO. As a result, the PO of a session is quantitatively related to the patient’s performance in a preceding session. Therefore, this score is cumulative and represents overall progress. Thus, in this regard, it is imperative to conduct at least 2 sessions for generating patient assessment scores using our proposed method. Furthermore, the maximum score of any session in our assessment protocol can be 2. Hence, the maximum cumulative score that a patient can obtain using our assessment method is twice the number of therapies administered.

### 2.6 Statistical Analysis

To ensure reliability of the assessment scores by the system, it is necessary to verify that their mean and variance do not differ significantly from that by the physiotherapists. To test for any significant difference in the mean and variance of the scores, we conducted paired two-tailed t-test for means and F-test, respectively. A significance level of \( \alpha = 0.05 \) was considered for all the above tests. Furthermore, Pearson’s correlation test was also conducted on these scores.

We collected feedback from both the physiotherapists and the patients using the System Usability Evaluation Form (SUEF) (Appendix – A) and the Patient Consent and Feedback Form (PCFF) (Appendix – B), respectively. The questionnaires were designed with elements combined from standard sets such as the USEQ (User Satisfaction Evaluation Questionnaire) [44] and QUIS (Questionnaire for User Interface Satisfaction) [45] and elements from feedback forms used in different studies [46, 47]. Based on these feedbacks, we conducted the Cronbach’s Alpha (a) (CA) test [48] for quantifying system reliability. In this test, systems with alpha value > 0.80 is considered to have good reliability.

### 3 RESULTS

The patient assessment scores by the system and average of the same by the physiotherapists after 3 sessions are summarized in Table-2a and Table-2b, respectively. The therapies that were not administered are shown by a ‘-‘.
| Therapy                  | \( P_1 \) | \( P_2 \) | \( P_3 \) | \( P_4 \) | \( P_5 \) | \( P_6 \) | \( P_7 \) | \( P_8 \) | \( P_9 \) | \( P_{10} \) | \( P_{11} \) | \( P_{12} \) | \( P_{13} \) | \( P_{14} \) | \( P_{15} \) | \( P_{16} \) |
|-------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Elbow Flexion           | 1.67      | 2         | 1         | 0         | 1         | -         | 1.33      | 1.33      | -         | -         | -         | 2         | -         | -         | -         | -         |
| Forearm Pronation       | -         | -         | 2         | 2         | -         | 1.67      | 0.33      | -         | 1.33      | 2         | 0.67      | -         | 1.33      | 0.67      | -         | -         |
| Forearm Supination      | -         | -         | 2         | 2         | -         | 0.67      | 0.33      | -         | 1.67      | -         | 1         | 0         | -         | 1         | 1         | -         |
| Shoulder Abduction      | -         | 0         | 2         | 2         | -         | 1.67      | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Extension      | -         | 0         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder External Rotation | -       | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | 0         | -         | 1.67      | -         | -         |
| Shoulder Flexion        | 1         | 0         | -         | 2         | -         | 0.67      | 1         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Horizontal Abduction | -       | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | 0.67      | -         | -         | -         | -         |
| Shoulder Horizontal Adduction | -       | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Internal Rotation | -       | 2         | 1         | -         | -         | 0         | -         | 2         | -         | 1.67      | -         | -         | -         | -         | -         | -         |
| Wrist Extension         | 1.33      | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | 1         | 0         | 1.67      | 1         | 1         |
| Wrist Flexion           | 1.67      | -         | 1         | 0         | 1         | 1.33      | 1.67      | -         | 0.33      | -         | 0         | 1.67      | 1.67      | 1.33      | -         | -         |
| Wrist Radial Deviation  | 1         | -         | -         | -         | 2         | -         | 0.67      | 1.33      | -         | 1         | 1         | -         | -         | -         | 2         | 2         |
| Wrist Ulnar Deviation   | 1.67      | -         | -         | -         | -         | -         | 0.67      | 1         | -         | 2         | 0.33      | -         | -         | -         | 0.67      | -         |

Table 2a: System generated assessment scores of the patients in different therapeutic interventions.

| Therapy                  | \( P_1 \) | \( P_2 \) | \( P_3 \) | \( P_4 \) | \( P_5 \) | \( P_6 \) | \( P_7 \) | \( P_8 \) | \( P_9 \) | \( P_{10} \) | \( P_{11} \) | \( P_{12} \) | \( P_{13} \) | \( P_{14} \) | \( P_{15} \) | \( P_{16} \) |
|-------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Elbow Flexion           | 1.2       | 1.8       | 1         | 0.8       | 0.8       | -         | 1.2       | 1         | -         | -         | -         | -         | 2         | -         | -         | -         |
| Forearm Pronation       | -         | -         | 1.8       | 2         | -         | 1.4       | 0.2       | -         | 1         | -         | 2         | 1         | -         | 1.6       | 0.8       |
| Forearm Supination      | -         | -         | 1.6       | 2         | -         | 1.2       | 0.2       | -         | 2         | -         | 1         | 0.2       | -         | 1         | 1         |
| Shoulder Abduction      | -         | 0.6       | 2         | 1.8       | -         | 1.8       | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Extension      | -         | 0.6       | -         | -         | -         | -         | 1         | 2         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder External Rotation | -       | -         | -         | -         | -         | -         | 1         | 1.2       | -         | 1.2       | -         | -         | 0         | -         | -         |
| Shoulder Flexion        | 1         | 0.6       | -         | 1.8       | -         | 1         | 1         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Horizontal Abduction | -       | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Horizontal Adduction | -       | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Shoulder Internal Rotation | -       | 1.2       | 1.4       | -         | 0.2       | -         | 1.8       | -         | 1         | -         | -         | -         | -         | -         | -         |
| Wrist Extension         | 1.6       | -         | -         | -         | -         | 0.4       | 1         | -         | 1.2       | -         | 1         | 1.2       | -         | 1         | 1         |
| Wrist Flexion           | 1.8       | -         | 1.4       | 0.2       | 0.8       | 1         | 1.8       | -         | 1         | 1.2       | -         | 0.2       | 1.2       | 1.6       | 1.4       |
| Wrist Radial Deviation  | 1         | -         | -         | 1.8       | -         | 1         | 1         | -         | 1         | -         | -         | -         | -         | 1.6       | 1.8       |
| Wrist Ulnar Deviation   | 1.6       | -         | -         | -         | 1         | 1         | -         | 2         | 0.8       | -         | -         | -         | 0.6       | -         | -         |

Table 2b: Mean of assessment scores of the patients by the Physiotherapists (PTs) in different therapeutic interventions.

Obtained Score: 8.34, 2, 3, 8, 11, 1, 9.67, 11.33, 2.67, 9.67, 4, 5, 4, 2.34, 9, 8
Max Obtainable Score: 12, 6, 6, 12, 14, 2, 22, 20, 4, 18, 10, 10, 4, 14, 12

Difference between the mean of system evaluation (Mean=6.19, 95% CI [4.52, 7.86]) and that of the physiotherapists (Mean=6.38, 95% CI [4.75, 8.01]) was statistically insignificant, t(15)=1.39, p=.184, α=.05. Their variances did not differ significantly as well, F(1, 15)=1.05, p=.460, α=.05. We also observed a strong, positive correlation between the two assessments, r=.9885. The summary of the results can be visualized from a scatterplot (Fig. 5a) and a boxplot (Fig. 5b) of these scores.
Figure 5: (a) Scatterplot of the patient assessment scores by the system (Mean = 6.19, 95% CI, [4.52, 7.86]) and mean of the same by the Physiotherapists (Mean = 6.38, 95% CI, [4.75, 8.01]) showing a strong positive correlation. (b) Boxplot of the assessment scores by the system and the PTs showing insignificant differences in mean (t(15)=1.39, p=.184) and variance (F(1, 15)=1.05, p=.460) of the scores at a significance level of α=.05.

From the summary of feedbacks of the patients and the physiotherapists (Fig. 6) according to the PCFF and SUEF forms, respectively, it was observed that about 43.75% of the patients did not feel the need for any assistance from the physiotherapists for rehabilitation using Renovo. About 68.75% of them were satisfied with our proposed method of interventions and 93.75% felt that the therapy was effective. All the patients found the system to be informative and they were able to visualize their performance with our system. The physiotherapists have verified that the device was harmless and do not have any long and short-term side effects. They have agreed upon the feasibility of our approach in motivating patients with BM towards rehabilitation. They also felt that the real-time visualization and automated patient assessment made it easier for them to conduct therapeutic sessions. Furthermore, the physiotherapists were convinced that, the system will allow them to have follow-up sessions with patients and guide them through optimized rehabilitation schemes. Considering both feedbacks, an average alpha value of $\bar{\alpha} = 0.8499$ was found from the CA test which is a measure of good system reliability [48]. Results of this test on system reliability from both the physiotherapists’ and the patients’ perspectives are summarized in Table-3.
Figure 6: Summary of the feedbacks on – (a) Patients’ satisfaction with the approach of therapy, (b) Patients’ evaluation of the system User Interface (UI), (c) Patients’ Interpretation of Renovo, (d) Physiotherapists’ (PTs’) satisfaction with the approach of therapy, (e) Physiotherapists’ (PTs’) evaluation of the system User Interface (UI).

Table 3: Results of Cronbach’s Alpha(\(\alpha\)) Test on system reliability from the perspectives of both the Physiotherapists (PTs) and the patients compared to the reference values.

| Respondent | Evaluation Criteria | Cronbach’s Alpha(\(\alpha\)) Test Results | Cronbach’s Alpha(\(\alpha\)) Reference |
|------------|---------------------|------------------------------------------|---------------------------------------|
| Patients   | USEQ Evaluation     | 0.7430, Acceptable                      | \(\alpha \geq 0.9\), Excellent       |
|            | Interface Evaluation| 0.8397, Good                            | \(0.8 \leq \alpha < 0.9\), Good       |
| Patients   | USEQ Evaluation     | 0.8739, Good                            | \(0.7 \leq \alpha < 0.8\), Acceptable |
| PTs        | QUIS Evaluation     | 0.9166, Excellent                      | \(0.6 \leq \alpha < 0.7\), Questionable|
| PTs        | Interface Evaluation| 0.8763, Good                            | \(0.5 \leq \alpha < 0.6\), Poor       |
| Average    | Reliability         | 0.8499, Good                            | \(\alpha < 0.5\), Unacceptable       |

4 DISCUSSION

Successful rehabilitation of BM depends on effective therapy and patient cooperation. Effectiveness can be ensured with accurate, real-time measurement of PMs and unbiased patient evaluation. Furthermore, feedback on the patients’ progress will motivate them towards regular therapy. We have demonstrated the feasibility and impact of a sensor-based AT, Renovo, for assisting physiotherapists in the rehabilitation of BM. Compared to the conventional mode of therapy, with this system, they can visualize key PMs efficiently in real-time with lesser human error without causing any injury to the patients. They can also keep a track record of the patients’ progress using the patient management feature. We have developed a quantitative assessment protocol for ensuring unbiased patients evaluation. We have shown this system-generated assessment to be statistically reliable.

We have developed Renovo by conducting recurring requirement analysis sessions with the physiotherapists. Their primary requirement was that any AT targeted towards the rehabilitation domain should not be unsupervised. In other words, the physiotherapists should be aware of patients’ progress so that proper therapies can be prescribed. The proposed system does not possess the ability to make any decision regarding patients’ fitness for GoEs. Rather, the system generated scores serve as a reliable metric for the physiotherapists to make this decision which meets their primary requirement. The physiotherapists had also mentioned that the patients should not feel that they no longer need guidance from the physiotherapists for their
rehabilitation. From our analysis of the patients’ feedback we have seen that this requirement has also been met by a very reasonable margin.

4.1 Limitations
There are few limitations of Renovo – 1) All the therapies need to be started from a corresponding base arm posture. If this posture is not maintained during device calibration, the system will give erroneous results. This is due to the way we have designed the 3D model of upper limb considering only two IMUs. However, if more IMUs were incorporated, this could be overcome at the cost of a complex wearable setup and device usability. Due to this limitation, we could explore interventions in sitting position only. 2) During the device calibration period, patients require assistance from the physiotherapists for holding their upper limb in the appropriate position which might be uncomfortable to some.

4.2 Future Works
We did not implement any tele-rehabilitation feature in this study. Therapies related to finger movements were not explored as well. However, we intend to explore these in a future analysis of our work. We also intend to overcome the limitations of the proposed system and come up with a more versatile solution.

4.3 Conclusion
To conclude, real-time measurement and visualization of PMs make conducting therapy sessions easier for the physiotherapists. Automated quantitative evaluation minimizes the chance of bias in patient’s progress assessment and helps physiotherapists in customizing rehabilitation schemes. Allowing patients to visualize their performance and providing regular feedback on their progress can motivate them towards rehabilitation.

DECLARATIONS

Conflict of Interest
The authors declare no conflict of interests that directly or indirectly affects the outcome of this study. All of them have approved this version of the manuscript for submission.

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Guarantor
MRK

CRediT Author Contribution Statement
MRK: Conceptualization, Methodology, Software, Validation, Formal Analysis, Investigation, Resources, Data Curation, Writing – Original Draft, Visualization, Project Administration. ME: Conceptualization, Methodology, Software, Investigation, Resources, Writing – Review & Editing. HM: Supervision, Methodology, Investigation, Resources, Writing – Review & Editing. MKH: Supervision, Methodology, Investigation, Resources, Writing – Review & Editing, Acquisition of Funding.

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APPENDICES

Appendix A: Patient Consent and Feedback Form (PCFF)

**Patient’s Consent**

Date: __________________

Patient’s Name: _____________________________________________________________

Patient’s ID: _______________  Age: _______________  Sex: ☐ Male  ☐ Female

Cause of Hemiplegia: _______________________________________________________

Affected Limb: ☐ Left Upper  ☐ Right Upper  ☐ Both

Duration of rehabilitation: ___________________________________________________

Name of physiotherapist: ____________________________________________________

Name of rehabilitation center: ________________________________________________

I agree to participate voluntarily in the experimental study of the research titled, “Renovo: A Sensor-Based Therapeutic System for Brachial Monoplegia” under the supervision of the aforementioned physiotherapist. I have been informed in details about the trial and have no objection about the methodologies and instruments used. I give my full consent in using my clinical trial data for research development. I also agree to answer the following questions without any manipulation.

Signature of patient  Signature of physiotherapist

**System Feedback Questionnaires**

Proceed only if you have agreed to participate in the previous section. Please read the questions carefully and answer accordingly.

A. Answer the following with a tick mark. The options indicate the following measures.

1. Very Poor / Strongly Disagree
2. Poor / Disagree
3. Moderate / Neutral
4. Good / Agree
5. Excellent / Strongly Agree

| Category                  | Questionnaire                                                                 | Choice |
|---------------------------|------------------------------------------------------------------------------|--------|
| USEQ (User Satisfaction  | a. How satisfied were you with the system?                                  | 1      |
| Evaluation Questionnaire) | b. How confusing was the system to you?                                     | 2      |
|                           | c. How clear was the information provided by the system?                    | 3      |
|                           | d. How relevant were the information displayed on screen?                   | 4      |
|                           | e. How comfortable were the wearable devices?                               | 5      |
|                           | f. Would you like to use this system again in your next session?            |        |
|                           | g. How much could you track your progress with this system?                |        |
|                           | h. How motivating was this system for you towards rehabilitation?          |        |
|                           | i. How safe did you feel while using the system?                            |        |
| Aesthetics                | a. I liked the way the system looked.                                       |        |
|                           | b. The 3D model of my arm was understandable.                               |        |
|                           | c. I liked the way the interface was organized.                             |        |
| Interface                 | a. It is useful to keep track of time elapsed.                              |        |
|                           | b. It is useful to keep track of the number of motions during therapy.     |        |
|                           | c. It is useful to keep track of the number of sessions encountered.        |        |
|                           | d. It is useful to keep track of my range of motion between two consecutive sessions. |        |
| Visual Cues               | a. The image displayed on screen for performing a therapy helped me perform the exercises. |        |
### Interface

**Visual Cues**
- b. It is useful to get real-time feedback of angular orientation of my movement. - 
- c. The 10s countdown timer at the start of each session mentally prepared me for the therapy.

**System Alert**
- a. System prompt for saving the session file was helpful. - 
- b. System prompt for device connectivity was helpful. -

### Before using this system, how did you feel about your performance in traditional therapy sessions? (Please tick all that applied during trial)

- I felt hopeless about my progress.  
- I felt hopeful about my progress.  
- I had little confidence in myself.  
- I was pretty confident in myself.  
- I was disappointed in myself.  
- I was blind about my performance.  
- I was well aware of my performance.  
- Therapy sessions were monotonous.  
- Therapy sessions were interesting.

### Answer in True or False.

| Statement                                                                 | T | F |
|---------------------------------------------------------------------------|---|---|
| a. I have got basic information to keep me updated about my performance.  |   |   |
| b. By using this system, I will not require any aid from the physiotherapist. |   |   |
| c. I am satisfied with the traditional therapeutic interventions.          |   |   |
| d. I felt the therapy was effective by using this system than my previous sessions without it. |   |   |

### What are some of the drawbacks of the system according to you? (If any)


Appendix B: System Usability and Feedback Form (SUEF)

Physiotherapist's Consent

Date: ____________________

I, ___________________________________, currently working at __________________ as a _______________________________, agree to participate in the following questionnaire session for usability feedback of the assistive tool “Renovo” based on the research titled, “Renovo: A Sensor-Based Therapeutic System for Brachial Monoplegia” after having used the system first hand.

_______________________

Signature of physiotherapist

System Feedback Questionnaires

Proceed only if you have agreed to participate in the previous section. Please read the questions carefully and answer accordingly.

A. Answer the following with a tick mark. The options indicate the following measures.

| Category                     | Questionnaire                                                                 | Choice |
|------------------------------|-------------------------------------------------------------------------------|--------|
| USEQ (User Satisfaction Evaluation Questionnaire) | a. How enjoying was your experience with the system? | 1 2 3 4 5 |
|                              | b. How successful were you in using the system?                              | 1 2 3 4 5 |
|                              | c. How capable were you in controlling the system?                           | 1 2 3 4 5 |
|                              | d. How clear is the information provided by the system?                      | 1 2 3 4 5 |
|                              | e. How comfortable were you with the system?                                 | 1 2 3 4 5 |
|                              | f. How helpful do you think this system will be for your rehabilitation?    | 1 2 3 4 5 |

B. Do you think that the wearable device is harmful for hemiplegic patients? Why? Why not?

____________________________________________________

____________________________________________________

C. Do you think that the proposed approach of therapy is feasible? Why? Why not?

__________________________________________________________________________

__________________________________________________________________________


D. Do you think that the proposed approach will increase patient’s performance and motivation? Why? Why not?
______________________________________________________________________________________________

E. How different did you feel from the traditional therapeutic interventions and by using this system?
______________________________________________________________________________________________

F. Do you think the patient will become dependent on the system? Why? Why not?
______________________________________________________________________________________________

G. What are some of the drawbacks of the system according to you? (If any)
______________________________________________________________________________________________