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Corresponding Author:	Nam-Jong Paik Seoul National University Bundang Hospital Seongnam, Gyeonggi KOREA, REPUBLIC OF
Corresponding Author's Institution:	Seoul National University Bundang Hospital
Corresponding Author E-Mail:	njpaik@snu.ac.kr
Order of Authors:	Minki Sin
	Won-Seok Kim
	Kyujin Cho
	Nam-Jong Paik
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TITLE:

Isokinetic Robotic Device to Improve Test-Retest and Inter-Rater Reliability for Stretch Reflex Measurements in Stroke Patients with Spasticity

AUTHORS & AFFILIATIONS:

Minki Sin[1]*, Won-Seok Kim[2]*, Kyujin Cho[3], Nam-Jong Paik[2]

[1]Department of Medical Assistant Robot, Daegu Research Center, Korea Institute of Machinery & Materials, Daegu, Republic of Korea
[2]Department of Rehabilitation Medicine, Seoul National University College of Medicine and Seoul National University Bundang Hospital, Seongnam, Republic of Korea
[3]School of Mechanical and Aerospace Engineering, Seoul National University/IAMD, Seoul, Republic of Korea

*These authors equally contributed to this study and preparation of the manuscript.

Corresponding Author:

Nam-Jong Paik (njpaik@snu.ac.kr)
Tel: 82-31-787-7731

E-mail Addresses of Co-authors:

Minki Sin (mksin@kimm.re.kr)
Won-Seok Kim (wondol77@gmail.com)
Kyujin Cho (kjcho@snu.ac.kr)
Nam-Jong Paik (njpaik@snu.ac.kr)

KEYWORDS:

stroke, muscle spasticity, stretch reflex, isokinetic, reliability, quantification, electromyography, torque

SUMMARY:

Using a robotic isokinetic device with electromyography (EMG) measurements, this protocol illustrates that isokinetic motion itself can improve inter-rater reliability for the angle of catch measurements in stroke patients with mild elbow flexor spasticity.

ABSTRACT:

Measuring spasticity is important in treatment planning and determining efficacy after treatment. However, the current tool used in clinical settings has been shown to be limited in inter-rater reliability. One factor in this poor inter-rater reliability is the variability of passive motion while measuring the angle of catch (AoC) measurements. Therefore, an isokinetic device has been proposed to standardize the manual joint motion; however, the benefits of isokinetic motion for AoC measurements has not been tested in a standardized manner. This protocol investigates whether isokinetic motion itself can improve inter-rater reliability for AoC measurements. For this purpose, a robotic isokinetic device was developed that is combined

with surface electromyography (EMG). Two conditions, manual and isokinetic motions, are compared with the standardized method to measure the angle and subjective feeling of catch. It is shown that in 17 stroke patients with mild elbow flexor spasticity, isokinetic motion improved the intraclass correlation coefficient (ICC) for inter-rater reliability of AoC measurements to 0.890 [95% confidence interval (CI): 0.685–0.961] by the EMG criteria, and 0.931 (95% CI: 0.791–0.978) by the torque criteria, from 0.788 (95% CI: 0.493–0.920) by manual motion. In conclusion, isokinetic motion itself can improve inter-rater reliability of AoC measurements in stroke patients with mild spasticity. Given that this system may provide greater standardized angle measurements and catch of feeling, it may be a good option for the evaluation of spasticity in a clinical setting.

INTRODUCTION:

Spasticity after stroke is common and has been shown to induce complications, including pain and contractures, resulting in reduced quality of life[1-3]. Measurement of spasticity is important to properly plan the course of treatment and determine the efficacy of treatment. Commonly used tools in the clinical setting are the Modified Ashworth scale (MAS)[4], which is a nominal measurement system for resistance to passive movement, and the modified Tardieu scale (MTS), which measures the angle of catch (AoC), representing the velocity-dependent characteristic of spasticity[5]. However, these measurement tools have been shown to have limited inter-rater reliability[6,7], requiring the same rater to perform these tests to maintain satisfactory reliability[8].

Three factors have been shown induce variability in AoC during MTS measurement, including (1) errors from angle measurements by a goniometry; (2) variability of manually moved joint motion profile between raters; and (3) variability in sensing the catch between raters[9]. A novel isokinetic robotic device with torque sensors is presented in this protocol. This device is applied to stroke patients with mild elbow flexor spasticity using surface electromyography (EMG) measurements[10]. It was hypothesized that the standardization of elbow joint motion will improve inter-rater reliability for AoC measurements elicited by the elbow flexor stretch reflex. To prove this, the reliability for AoC as measured by surface EMG was calculated and compared between the isokinetic passive and manual fast elbow extension, using this developed robotic device and EMG. **Figure 1** shows an overview of the entire experimental procedure. In detail, the MTS measurement stage was conducted by two raters, and the order of experiments (manual vs. isokinetic motion) and order of raters were randomly determined, which required about 50 min for each subject (**Figure 1**).

PROTOCOL:

1. Experimental set-up

1.1. Patient recruitment

NOTE: All procedures were reviewed and approved by the Seoul National University Bundang

Hospital Institutional Review Board. These subjects were inpatients or outpatients with stroke diagnoses from four rehabilitation hospitals in the region.

1.1.1. Perform the screening process using the following inclusion criteria: (1) upper extremity hemiparesis due to stroke; (2) over the age of 20 years; (3) mild elbow joint spasticity of MAS 1-2; (4) no previous disease affecting function of the hemiparetic arm, except for stroke; (5) free from hemodynamic instability; (6) no severe elbow contracture; (7) possibility for the shoulder to be abducted 90° and forearm to be in the neutral position without any joint pain; and (8) normal cognitive, language, visuospatial, or attention ability to follow experimental procedures.

NOTE: The criteria are designed to screen patients who are able to participate in the experiment and regulate factors affecting the results.

1.1.2. Recruit subjects who are provided with a detailed explanation of the entire study and expected clinical issues. Consent must be obtained prior to inclusion.

1.1.3. Demographics and baseline characteristics of the recruited subjects are shown in **Table 1**.

1.2. Experimental system

NOTE: A customized robotic device is used to produce standardized motion and measure the quantitative data simultaneously. The robotic system consists of a robotic part, control system, and measurement units. The overall configuration is shown in **Figure 2**.

1.2.1. Robotic part

1.2.1.1. For the robotic part, use a one-degree-of-freedom planar robot consisting of a motor and a forearm manipulandum, with three other components for adjusting the robot height and installing the device to various desks. The overall composition is shown in **Figure 2A**.

1.2.1.2. For the forearm manipulandum, use an elbow joint connected to the motor, a linear slider with a fixation block to adjust the overall length and two cuff units for fixating the forearm and hand (as shown in **Figure 3**). The elbow joint has a rotating plate and a thrust bearing to prevent chafing during the experiment, and the cuff units were curved similar to that of a human forearm and were made using a 3D printer. The handle unit is designed to accommodate both left and right handed individuals, making it available to any subjects.

1.2.1.3. Use a motor with a low gear ratio of 51:1, which should have back-drivable characteristics and the ability to produce a nominal speed of 315°/s and a continuous torque of 42.33 Nm.

1.2.1.4. Use a lab jack unit that is attached to the bottom of the motor to adjust the height of the motor unit. The height of the robot will be able to be adjusted to the sitting height of various subjects.

1.2.1.5. Place a fixation arm for mounting the device to the desk on the front part of the robot. The fixation arm will be movable up and down through a linear shaft and has clamps for securing to the desk.

1.2.1.6. Place casters with stopper on the bottom of the robot, making the robot movable and grounded during the experiment.

1.2.2. Control system

1.2.2.1. Use a personal computer (PC), real-time processor, and motor driver for the central control system. The detailed control architecture block diagram is shown in **Figure 4**.

1.2.2.2. Use a graphic user interface (GUI) to control the experiment mode (maximum ROM measurement, Isokinetic MTS, and manual MTS measurement modes) and store robot motion data. It contains a control panel and a monitoring panel (**Figure 5**). Details on the GUI configuration are included in the appendix.

1.2.2.3. Implement the robot control algorithm using a real-time processor. The control algorithm consists of three control loops. The first loop is a data input/output loop that runs at 1 MHz from the FPGA module of the sbRIO. The second is a robot motion control loop that runs at 1 kHz from the real-time VI level. The last is a data communication loop that runs at 250 Hz. This loop transmits robot data (time, angle, torque and trigger signal for matching with EMG data).

NOTE: The real-time processor has two communication modules: NI-9237 and NI-9853. The NI-9237 is an analog input device for receiving torque sensor data, and the NI-9853 is a CAN communication module for communicating with the motor driver.

1.2.3. Measurement units

1.2.3.1. Mount a torque sensor between the manipulandum and the motor to measure the reaction force. The torque data is transferred to the real-time processor via NI-9237. The NI-9237 has its own passband, stopband, and alias-free bandwidth filter. The filtered data enters the FPGA module and is processed again at 100 Hz with a low-pass filter to remove noises.

1.2.3.2. Measure the joint angle by an encoder (HEDL 9140, Maxon, Switzerland) attached to the motor. The angle data is transferred to the real-time processor via the motor driver.

1.2.3.3. Measure muscle activity with an eight-channel surface EMG device. The EMG data was collected at a sampling rate of 1024 Hz, and initially processed with a bandpass filter (20–450 Hz) and a notch filter (60 Hz). The measured EMG data is transferred to the PC directly.

2. Experimental set-up

NOTE: Two raters should participate in this experiment. In our case, the first rater was a physiatrist with more than 6 years of experience in rehabilitation, and the second rater was an occupational therapist with more than 3 years of experience in stroke rehabilitation.

2.1. Initial posture setting

2.1.1. Place the patient in a chair with his/her back in a straight posture.

2.1.2. Secure both sides of the shoulder and abdomen with seatbelts to keep the shoulder position stable throughout the experiment.

2.1.3. Place the subject's hemiparetic arm lightly on the robot manipulandum without fastening the strap.

2.1.4. Unfasten the fixation block of the linear slider so that the cuff can be moved freely on the slider and allow the subject's hemiparetic arm to be placed on the robot manipulandum without fastening the straps.

2.1.5. Adjust the height of the robot using the lab jack until the patient's shoulder is abducted 90°. Confirm the abduction angle using a goniometer.

2.1.6. Instruct the subject to hold the handle and fasten the hand to the handle with straps. Align the rotation axis of the robot and anatomical axis of the elbow joint.

2.1.7. Flex and extend the elbow joint so that the position of the cuff can be readjusted naturally in an optimal position without generating resistance during the elbow movement. Then, fasten the fixation block to fix the position of the cuff and fasten the straps of the forearm cuff.

2.1.8. Attach the surface EMG electrodes on the biceps brachii muscle in the hemiparetic arm.

2.2. Passive ROM measurement

NOTE: Passive ROM is used as a boundary ROM in the following experiments to prevent problems caused by movement outside the patient's operation range.

2.2.1. Input the patient's hemiparetic side information into the program GUI (right or left).

2.2.2. Set the elbow 90° flexed using a goniometer. Press the **90 deg set** button on the GUI panel. This process matches the angle recognized by the robot with the actual human joint angle.

2.2.3. Press the **Finish set** button on the GUI to switch the robot to the actuating state.

2.2.4. Click the buttons on the **Motor run** panel on the left side of the GUI in order from top to bottom.

2.2.5. Set the speed to 1°/s, then click the **run** button. The robot will extend the elbow slowly at 1°/s from a 90° flexed posture until the reaction torque reaches a certain threshold level or extends by 170°.

NOTE: In this experiment, the torque threshold was set to 0.6 Nm. This value is determined experimentally via a pilot study.

2.2.6. The maximum extended angle is automatically stored as the maximum ROM.

2.2.7. Change the speed to -1°/s and click the **run** button again. The robot flexes the elbow slowly until the reaction torque reaches the threshold level.

2.2.8. The maximum flexed angle is automatically stored as the minimum ROM.

3. MTS measurement

NOTE: The time required for each step is shown in **Figure 1**. The total time taken by one subject to perform all the experiment is about 50 min (including the experiment set-up step), but most of the time should be spent resting to maintain consistency of fatigue.

3.1. Inertia effect compensation

NOTE: Theoretically, there should be no inertia effect during the isokinetic motion. However, there may be an inertia effect at the beginning of the motion. The inertial force should be compensated to measure only the reaction force generated by a stretch reflex. Since the magnitude of the inertial force is different for each subject, a preliminary test for the inertial force compensation should be performed before the actual MTS measurement. An example result is shown in **Figure 6**.

3.1.1. Click the **Back** button on the control panel. The robot will flex the elbow to minimum angle posture (maximally flexed posture).

3.1.2. Set the speed to 150°/s and turn on the **Inertia test** button then the **Run** button. The robot will apply a short perturbation of 5° to the patient at a rate of 150°/s. The peak torque and period value of each trial are automatically stacked and displayed on the GUI panel.

3.1.3. Repeat steps 3.1.2–3.1.3 two more times. Determine a proper peak torque value and period value from the measured data and enter the value on the program GUI. The compensation torque profile (τ_{comp}) is automatically generated based on **Equation 1** below, where: a represents the determined amplitude and λ represents the period.

$$\tau_{comp} = \begin{cases} \frac{a}{2} \cdot \left(1 - \cos\left(\frac{2\pi \cdot t}{\lambda}\right)\right) & (t \leq \lambda) \\ -0.15 \cdot \frac{a}{2} \cdot \left(1 - \cos\left(\frac{2\pi \cdot t}{\lambda}\right)\right) & (\lambda < t \leq 2\lambda) \\ 0 & (t > 2\lambda) \end{cases}$$

NOTE: The shape of the inertial torque is modeled as a raised cosine shape to reduce the calculation load. The compensation torque, which is designed for two periods due to the inertia effect, almost disappears after the second period. The amplitude of the second period is designed to be 15% of the first period.

3.2. Familiarization step

3.2.1. Prior to the actual experiment, perform three training operations to familiarize the patient with sudden movements.

3.2.2. Click the **Back** button on the panel. The robot will flex the elbow to the minimum angle posture.

3.2.3. Click the **Run** button after informing the subject. The robot will extend the patient's elbow at a rate of 150°/s, until the angle reaches to a maximum angle or the reaction torque reaches the threshold level.

3.2.4. Repeat steps 3.2.2–3.2.3 two more times and take a 5 min rest before starting the test.

3.3. Isokinetic MTS measurement

NOTE: The isokinetic MTS measurement is designed to implement an ideal MTS measurement condition. The robot produces accurate constant velocity motion at a predetermined speed (150˚/s) until reaching the maximum ROM or until reaching a certain threshold of the reaction torque. The maximum ROM value is determined in step 2.2, and the torque threshold value is determined as 0.6 via previous pilot studies, which is sufficient for detecting stretch reflexes.

3.3.1. Click the **Back** button to flex the elbow to the minimum angle posture.

3.3.2. Click the **Run** button without informing the subject. The robot will extend the patient's elbow at a rate of 150°/s until the angle reaches the maximum angle or the reaction torque reaches a certain threshold level. Time, angle, reaction torque, and trigger signal data are stored during the test.

3.3.3. Take a 2 min break between sets and repeat steps 3.3.1–3.3.3 two more times.

3.3.4. Take a 5 min rest after performing three sets.

3.4. Manual MTS measurement

NOTE: The manual MTS measurement is designed to simulate the MTS measurement normally performed at actual medical sites. To compare the results of isokinetic MTS, the robotic device is used only as a quantitative measuring tool that removes the measurement error, and actual measurement operation is performed by a human rater. For this purpose, the robot only compensates the friction of the robot itself. Details of the friction removal is in the appendix.

3.4.1. Click the **Back** button to flex the elbow to the minimum angle posture.

3.4.2. Click the **Free run** button, and the robot operation will change to manual operation mode.

3.4.3. Hold the handle of the manipulandum and stretch the subject's arm. During operation, the rater should generate a constant speed of 150°/s.

3.4.4. Turn off the **Free run** mode and take a 2 min break.

3.4.5. Repeat steps 3.4.1–3.4.4 two more times.

3.5. Repeat MTS measurement

3.5.1. Take a 10 min rest after finishing the whole experiment with the first rater.

3.5.2. Change the rater (to the second rater) and repeat steps 3.3–3.4.

4. Quantifying the AoC

NOTE: AoC is determined based on two data: EMG and torque. AoC is determined by manual analysis due to the noisy characteristics of the EMG data and variability of individual characteristics. The AoC selection is carried out by a third rater, who is blind to the order of raters.

4.1. Isokinetic MTS experiment data analysis

4.1.1. AoC evaluation using EMG data

NOTE: Generally, AoC is determined as the angle at which the maximum peak value of the EMG occurs. However, a stretch reflex duration is different for each patient; thus, using the EMG maximum peak point as an AoC is expected to have low reliability. The time difference may not be large; however, the AoC error can be significant due to the fast assessment speed of the MTS method. Therefore, the angle at the start of EMG upsurge point is selected as the AoC.

4.1.1.1. Process the raw EMG data using the root mean square (RMS) to smooth the data and

amplify it 50x.

4.1.1.2. Synchronize the EMG data and robot angle data using the trigger signals of each data set.

NOTE: In this system, the EMG data is measured by an independent device, unlike other data; therefore, the reference time may be different. The EMG device has a trigger interrupt marking function, which obtains the trigger signal from a real-time processor at the onset of MTS assessment.

4.1.1.3. Determine the AoC manually as the starting point of the RMS EMG upsurge. The example is shown in **Figure 7**.

NOTE: The RMS EMG of <0.1 is ignored here because it appears frequently even without the stretch reflex. Thus, a clear upsurge point at the start of the peak is selected as the AoC.

4.1.2. AoC evaluation using the torque data

NOTE: Muscles have passive mechanical characteristics that acts like a spring-damper system. Even if the muscle does not exert any force, the reaction force can increase as the muscles stretch. Because the intensity of the passive mechanical property and stretch reflex varies from patient to patient, it is difficult to identify the catch using only the absolute value of the reaction force. Instead, in this study, the catch is determined by changing the passive property due to spasticity rather than the absolute value of the reaction force. The change of the passive property is manually determined by the change in the slope of the regression line of the reaction torque.

4.1.2.1. Draw one regression line from the point where the trigger signal goes up and draw another regression line from the point where the trigger signal goes down.

4.1.2.2. Compare the slopes of the two regression lines. If the gradients of two regression lines show a significant difference, AoC can be determined at the intersection of two regression lines. The example is shown in **Figure 8**.

4.2. Manual MTS experiment data analysis

NOTE: In the case of manual MTS, it is difficult to separate the force exerted by the subject and that applied by the rater using only one torque sensor. Therefore, in the case of manual MTS, only an AoC analysis using EMG data is performed without performing AoC analysis using the torque data.

4.2.1. AoC evaluation using EMG data

NOTE: The method to determining AoC evaluation using EMG is basically the same as for the

isokinetic MTS case.

4.2.1.1. Process the raw EMG data using the RMS method to smooth the data and amplify it 50x.

4.2.1.2. Synchronize the EMG data and the robot angle data using the trigger signals of each data set.

4.2.1.3. Determine the AoC manually as the starting point of the RMS EMG upsurge. An example is shown in **Figure 9**.

5. Data analysis

5.1. Normalized assessment motion index (NAMI)

NOTE: The AoC of MTS can be affected by various motion factors, such as assessment speed, acceleration, etc. Therefore, the assessment motion should be as isokinetic as possible. The NAMI is proposed to evaluate the ideality of the assessment motion. The proposed index is a non-dimensional index that can be used to evaluate the consistency of the assessment motion assigned to the subjects in each trial.

5.1.1. Calculate the ROM, maximum velocity and assessment time from each assessment trial.

NOTE: The angle is measured by the encoder; thus, the calculated velocity is noisy. Therefore, the maximum velocity is determined as the maximum velocity of the trend line, not the peak point.

5.1.2. Calculate the NAMI value for each trial during the whole experiment using **Equation 3**:

$$NAMI = \frac{\theta_{max} - \theta_{min}}{\omega_{max} \cdot \Delta t} \rightarrow \frac{deg}{deg/s \cdot s}$$

Where: θ_{max} and θ_{min} represent maximum and minimum angles, respectively, measured during the experiment; ω_{max} is the maximum assessment speed; and Δt is the total time spent for one assessment. **Figure 10** shows an example of each variable.

NOTE: The proposed index gives a score close to 1 if the assessment motion is close to completely isokinetic and a score close to 0 if the velocity of the motion is inconsistent.

5.2. Statistical analysis

NOTE: All statistical analyses are performed using the PASW statistical package (SPSS version 18.0). The intraclass correlation coefficient (ICC) method is used to identify the test-retest reliability and inter-rater reliability. Only results from the second and third tests are used to

calculate the ICC.

5.2.1. To verify test-retest reliability, calculate the ICC from the measured AoC data and NAMI result.

5.2.2. To verify inter-rater reliability, calculate the ICC from the average of AoC and NAMI data.

5.2.3. Calculate the p-value of the AoC results using paired sample t-tests to evaluate the differences between each rater or each assessment trial.

NOTE: P-values of <0.05 are considered statistically significant.

5.2.4. Calculate the Pearson correlation coefficient between AoC based on EMG criteria and torque criteria to verify a correlation between the two methods.

REPRESENTATIVE RESULTS:

The reliability is divided into four grades according to the ICC value: extremely excellent (>0.90), excellent ($0.75 < ICC \leq 0.90$), fair to good ($0.40 < ICC \leq 0.75$), and poor (<0.40). The standard error of measurements (SEM) was calculated to determine the error component of the variance. The smallest detectable difference (SDD) was calculated from the SEM of test-retest data.

Normalized assessment motion index (NAMI): the NAMI score during an isokinetic motion was always 1, which means that the isokinetic device always generated a uniform constant input velocity. However, the test-retest reliability of the NAMI during a manual motion was poor for both rater 1 (ICC [95% CI] = -0.035 [-0.495–0.441]) and rater 2 (ICC [95%CI] = 0.438 [-0.038–0.752]). Moreover, the inter-rater reliability of the NAMI during manual motion was also poor (ICC [95% CI] = 0.148 [-0.344–0.576]). Conversely, the results of the two human raters showed almost equal averaged NAMI values (0.68 and 0.67 for each rater). The consistency error of the two human raters was larger than that of the isokinetic device, showing a large difference between the two raters. These results indicate that an assessment motion by a human rater is lacking in the isokinetic characteristics and that motion is inconsistent depending on the subject.

Test-retest reliability: **Table 2** shows test-retest reliability for the AoC results in three conditions (isokinetic-EMG, isokinetic-torque, manual-EMG). The test-retest reliability for manual MTS was excellent (ICC = 0.804 and 0.840). However, the isokinetic MTS measurement improved test-retest reliability to the extremely excellent grade on both the EMG and torque criteria (**Table 2**)

Inter-rater reliability: **Table 3** shows inter-rater reliability for the AoC measurement performance in three conditions. The ICC of the inter-rater reliability of the manual MTS was 0.788, which was near the lower limit of the excellent grade. The isokinetic MTS improved inter-

rater reliability to the ICC of 0.890 based on EMG data and to the ICC of 0.931 based on torque data.

Correlations and consistency of timing of AoC between the EMG and torque criteria: the two AoC results calculated from the EMG data and torque data during the isokinetic MTS show a significantly high correlation in both rater 1 (Pearson correlation coefficient = 0.937, $p < 0.001$) and rater 2 (Pearson correlation coefficient = 0.957, $p < 0.001$). Moreover, the timing of AoC between the two results was highly consistent with an ICC of 1 ($p < 0.001$).

FIGURE AND TABLE LEGENDS:

Figure 1: Experiment flow chart. This figure is modified from Sin et al.[10].

Figure 2: Isokinetic MTS test robot. (**A**) Configuration of the isokinetic robot device. (**B**) Inside configuration of the device. The control system includes a real-time processor and motor driver. (B) was previously published by Sin et al.[10].

Figure 3: Composition of the manipulandum. Two cuffs for the wrist and forearm are connected to the linear slider through a fixation block, making the position of the cuff adjustable. A handle and hand strap are switchable from left-to-right.

Figure 4: Control system Configuration. The right three blocks show the hierarchy of the control system and arrows show the data flow between each unit.

Figure 5: Graphic user interface (GUI). The left side is the controller panel, which contains the various buttons or numeric controls required for robot control. The right side is a monitoring panel that shows the angle, interaction torque, and trigger signal in real-time.

Figure 6: Example of inertia effect compensation. The green line indicates the raw torque; the blue dotted line indicates the inertial force model; and the red line indicates the inertial torque compensation result. This figure was previously published by Sin et al.[10].

Figure 7: Example of AoC evaluation using EMG data (isokinetic MTS case). An RMS EMG value of less than 0.1 is regarded as normal. Selection of the starting point of the clear EMG upsurge point is performed, and the angle value at that time is determined as AoC. This figure was previously published by Sin et al.[10].

Figure 8: Example of AoC evaluation using torque data (isokinetic MTS case). Evaluation involves the following steps: draw two lines connecting the torque of the assessment starting point and the end point with an arbitrary torque data, respectively; find the point where the two lines become the regression line of the torque data before and after the selected point; if there is a significant difference between the gradient of two regression line, it is judged that a stretch reflex occurs at this point. This figure was previously published by Sin et al.[10].

Figure 9: Example of AoC evaluation using EMG data (manual MTS case). As done in the isokinetic case (**Figure 7**), the AoC is determined as the angle when a clear upsurge of the EMG occurs. This figure was previously published by Sin et al.[10].

Figure 10: Variables for the normalized assessment motion index (NAMI). Intuitively, the NAMI value is the ratio of the area under the velocity graph to the area of the gray box. More isokinetic movements show values closer to 1. This figure is previously published by Sin et al.[10].

Table 1: Subjects demographics and baseline characteristics.

Table 2: Test-retest reliability results for the angle of catch measured with isokinetic robotic devices and robotic devices with manual motion. This table was published by Sin et al.[10] (p-values are calculated by paired sample t-test). SEM: standard error of measurement, SDD: smallest detectable difference, ICC: intraclass correlation coefficient, EMG: electromyography.

Table 3: Inter-rater reliability results for the angle of catch measured with isokinetic robotic devices and robotic devices with manual motion. This table was published by Sin et al.[10] (p-values are calculated by paired sample t-test). SEM: standard error of measurement, ICC: intraclass correlation coefficient, EMG: electromyography.

DISCUSSION:

This study attempted to standardize the MTS measurement using a robotic isokinetic device. It was investigated how the consistency of assessment motion affects the results of MTS measurement.

The NAMI value was proposed to represent the degree of variability in assessment motion. As expected, unlike the isokinetic motion method with no variability, the manual method showed variability between tests and between raters, resulting in poor reliability, which is consistent with results from previous studies[7,8]. The results on reliability for AoC measurement show that isokinetic motion itself can increase interrater reliability, compared to manual motion. Although, there have been concerns regarding the less stretch reflex provocation by the isokinetic motion[11,12], subjects in this study with mild elbow flexor spasticity (MAS 1, 1+, 2) showed consistent stretch reflexes measured by surface EMG during isokinetic motion. This demonstrates that an isokinetic device can be used to measure AoC reliably, even in patients with mild elbow spasticity. AoC was also calculated by the torque criteria in this study. Interestingly, AoC measured by using both the EMG and torque criteria showed a high correlation, while the torque criteria alone showed a higher inter-rater reliability, which is consistent with the results provided by Lynn et al.[13]. Therefore, spasticity evaluation using the torque criteria is expected to be a better method with respect to reliability and convenience.

This new approach for quantifying the MTS measurement has some issues and limitations. First, the posture during AoC measurements in this study was different from conventional MTS measurements[14]. The conventional MTS was performed in the absence of shoulder abduction;

in contrast, in this study, measurements were performed with the shoulder abducted 90 degrees. However, the purpose of this study was to verify the effects of consistency of the assessment motion on the AoC reliability. The posture used in this experiment makes it easy to measure AoC using the torque data by eliminating the influence of forearm weight, which is difficult to measure separately. Therefore, this experiment provides a perspective on how the assessment motion affects the reliability of AoC measurements.

Second, the AoC measurement using both the torque and EMG criteria was performed subjectively. However, this was conducted by a third rater who was blind to the subject information and order of raters to minimize potential bias. Third, the increase of the reaction torque due to passive mechanical properties was unexpected when designing the experiment initially. It was expected that the reaction torque is mainly caused by stretch reflex; however, in patients with mild spasticity, many cases showed that the reaction torque caused by passive stiffness was dominant. Therefore, AoC was obtained through post-experimental data analysis rather than real-time identification. Finally, there was relaxation of the elbow flexor during repetitive passive stretching. The experiment was designed to incorporate sufficient resting time to prevent fatigue throughout the experiment, and no subjects complained of fatigue. However, it is hard to prevent relaxation of the muscle due to repetitive passive stretching. To reduce this impact, the experiment was designed to randomize the order of raters, and the results showed no significant relaxation phenomenon between the two raters.

The goal of this study was to improve evaluation methods that rely on the subjective sense of the rater and hold them to more objective and quantitative standards. The results show the possibility of increasing assessment reliability using a robotic device. However, the method performed in this study is only half-automated, because the AoC evaluation is done by a human. It is expected that the further studies will enable real-time spasticity evaluation with high reliability and objectivity.

ACKNOWLEDGMENTS:
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DISCLOSURES:
All authors declare no conflict of interest.

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Figure 1

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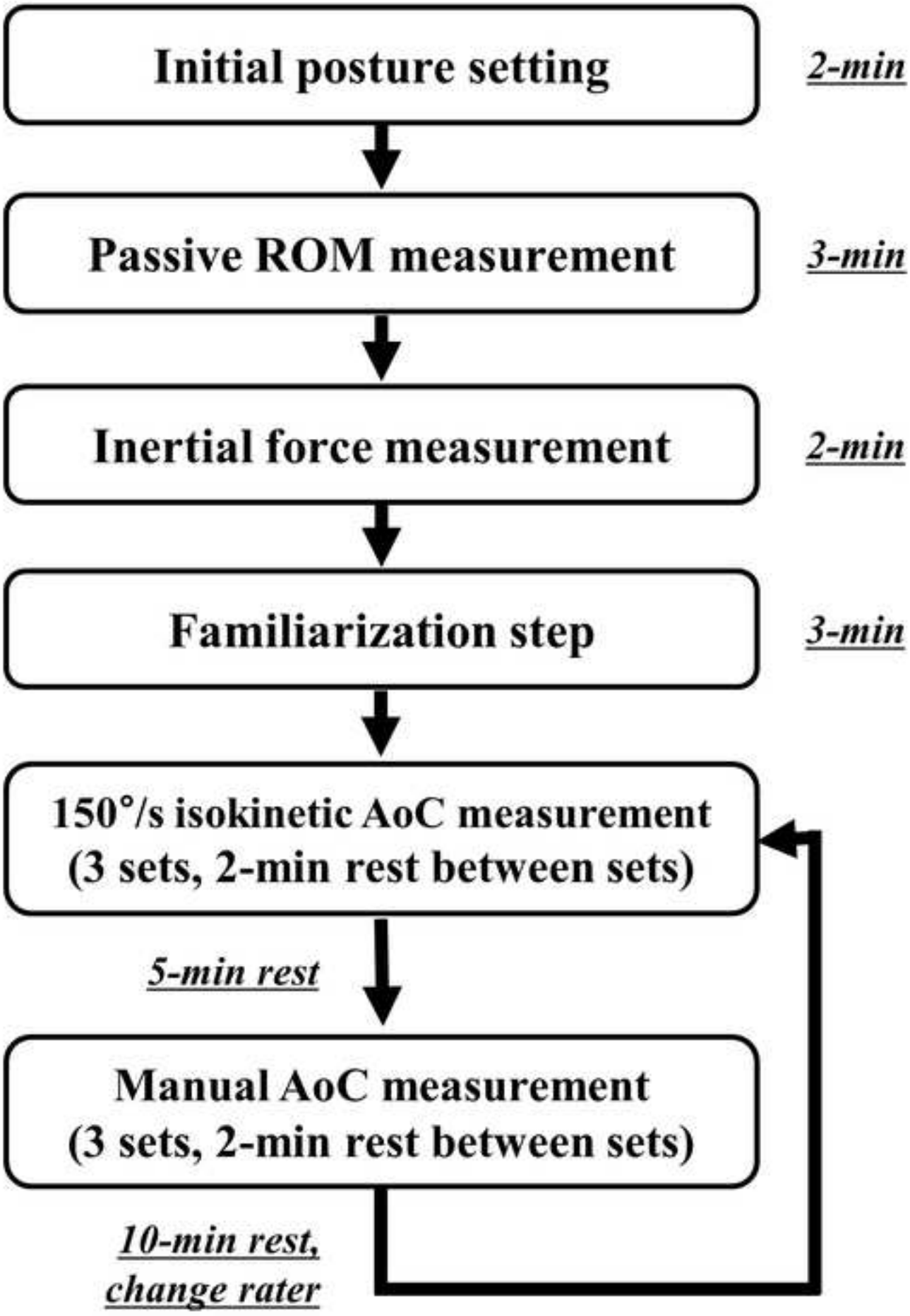

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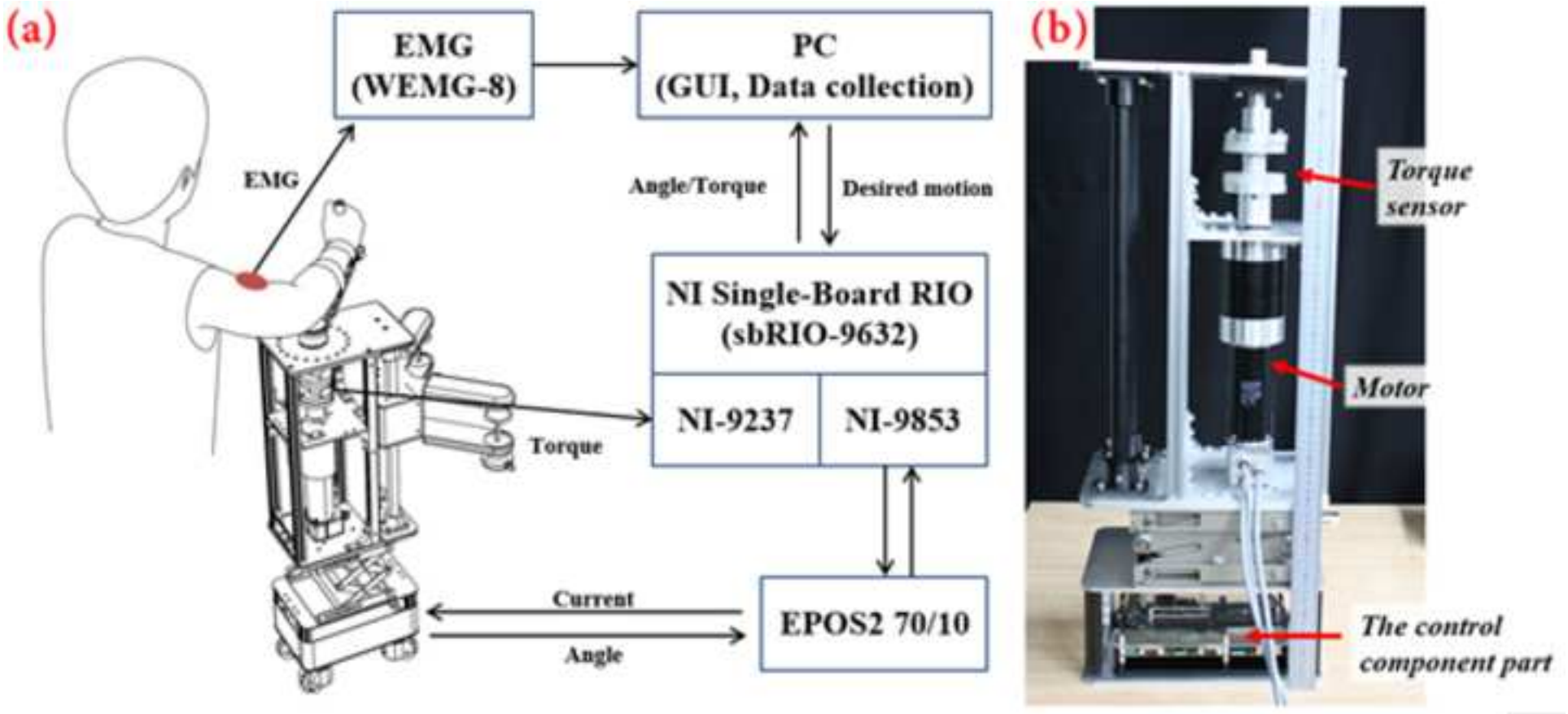

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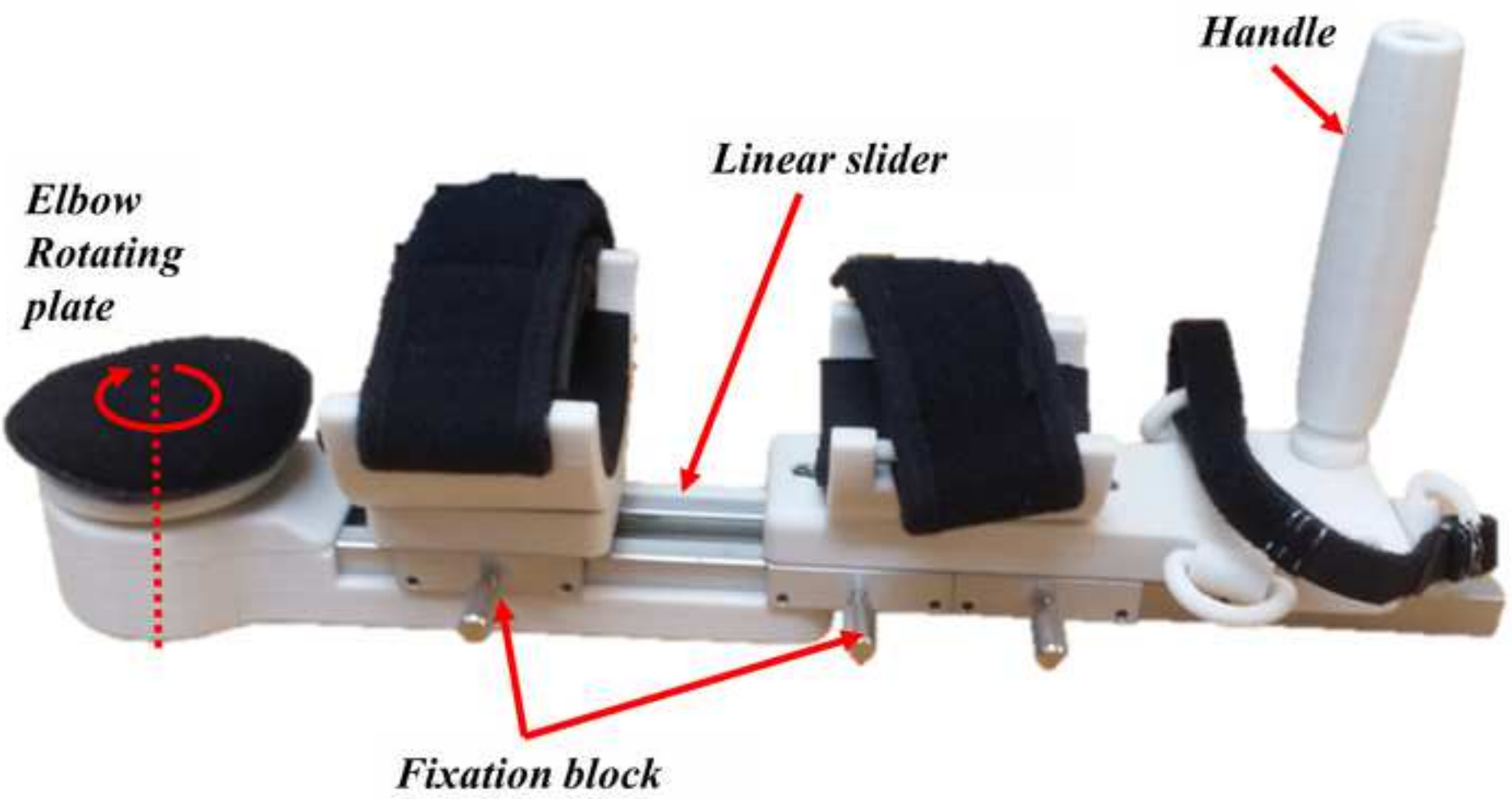

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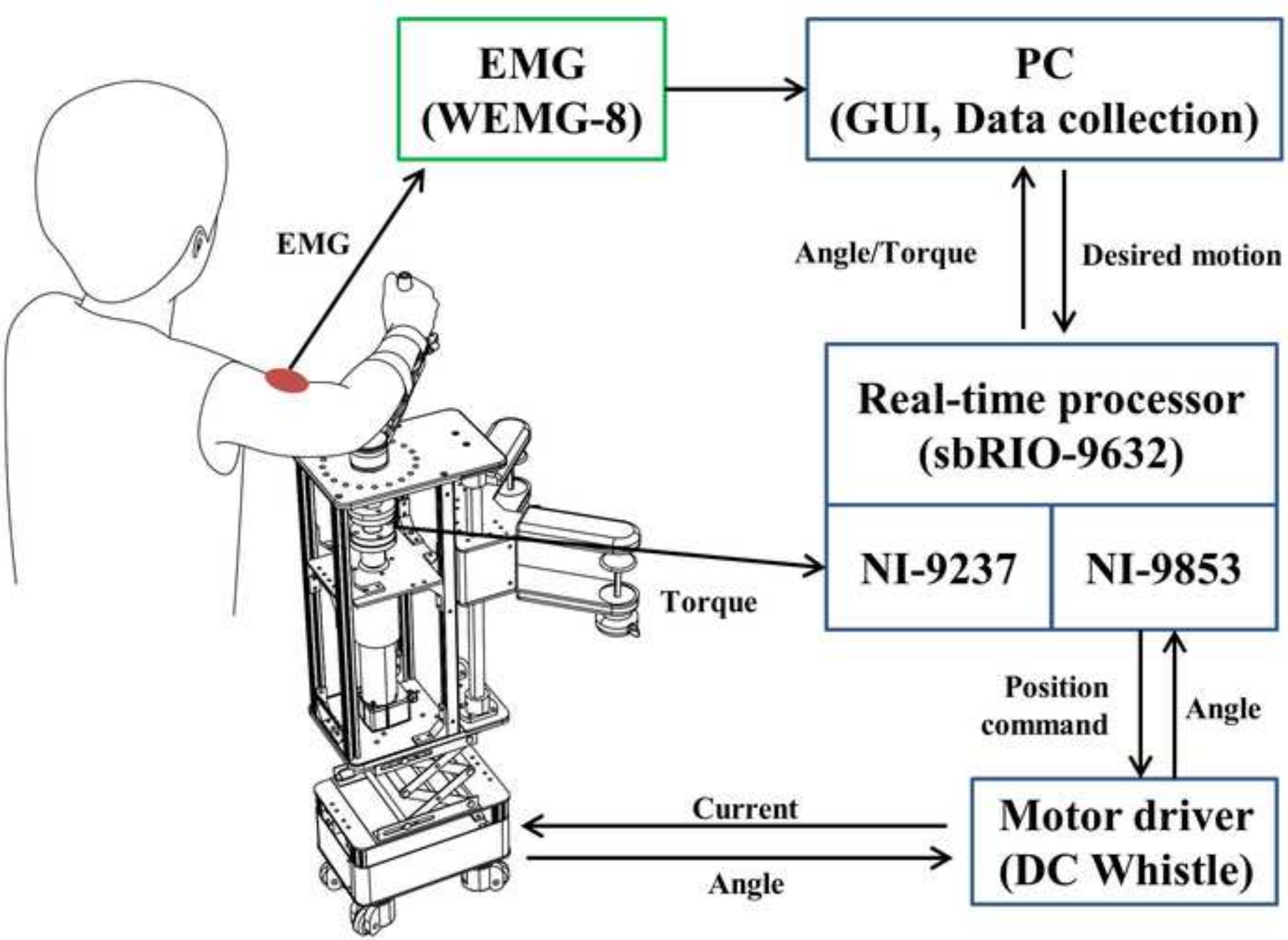

Figure 5

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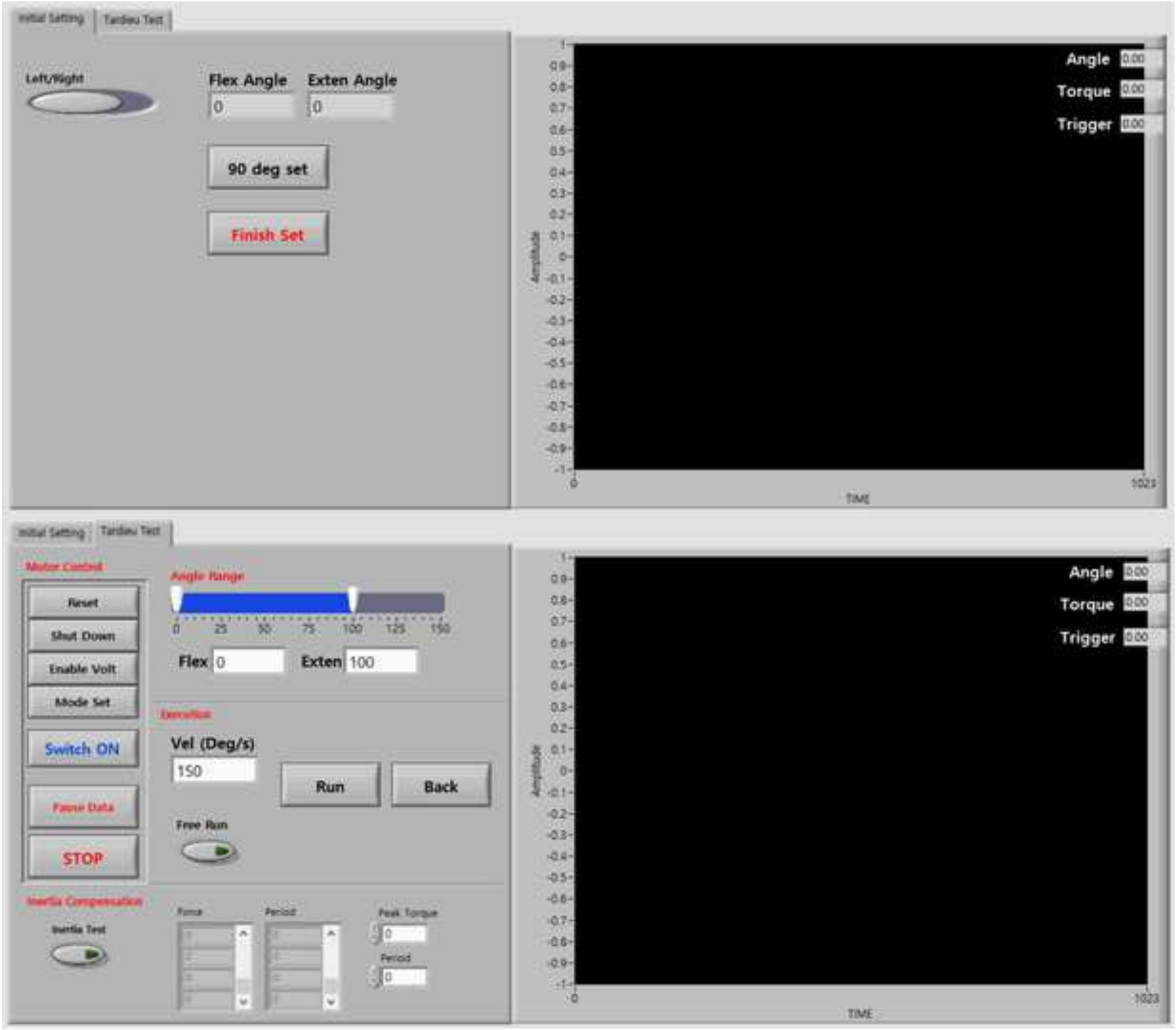
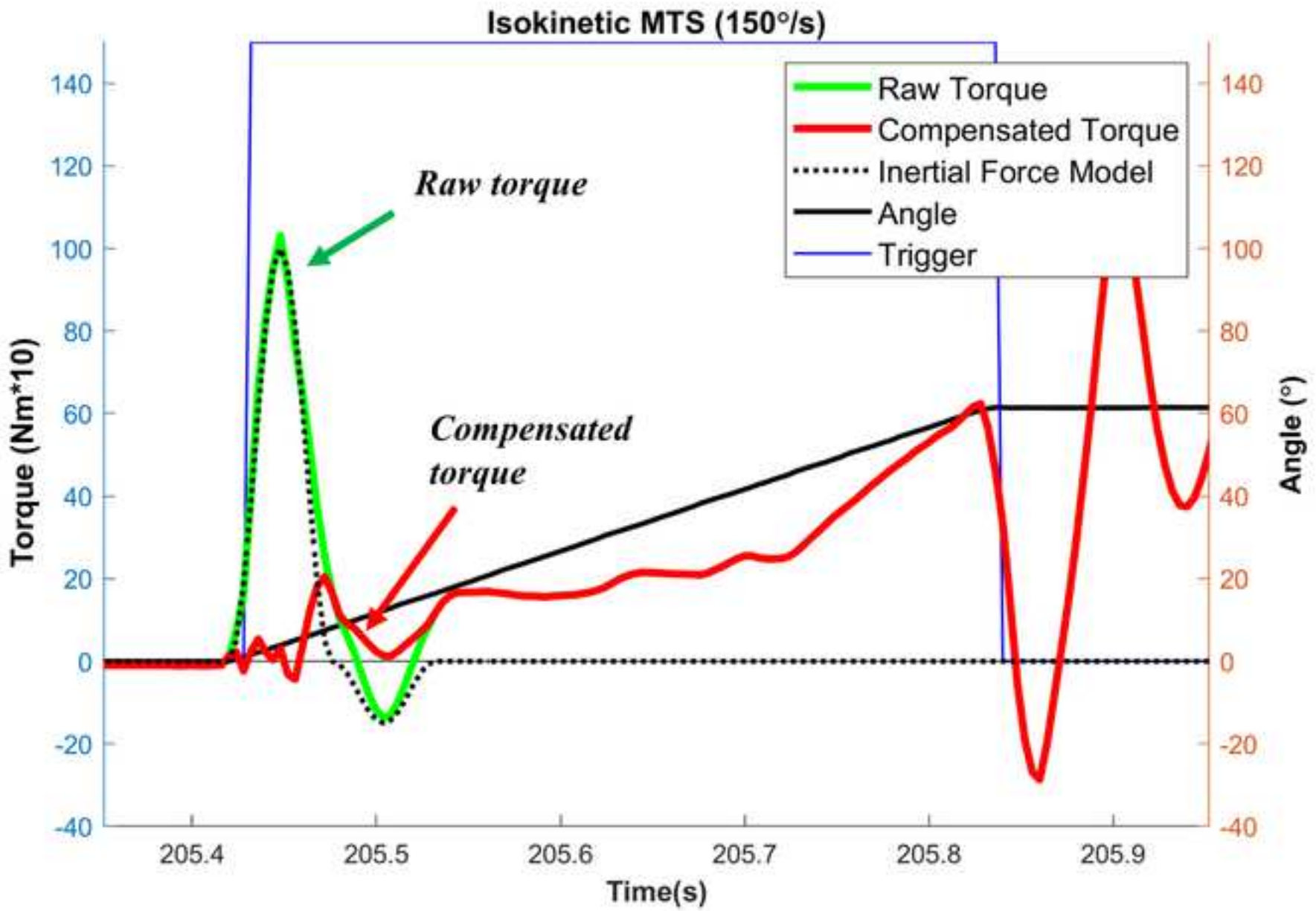


Figure 6



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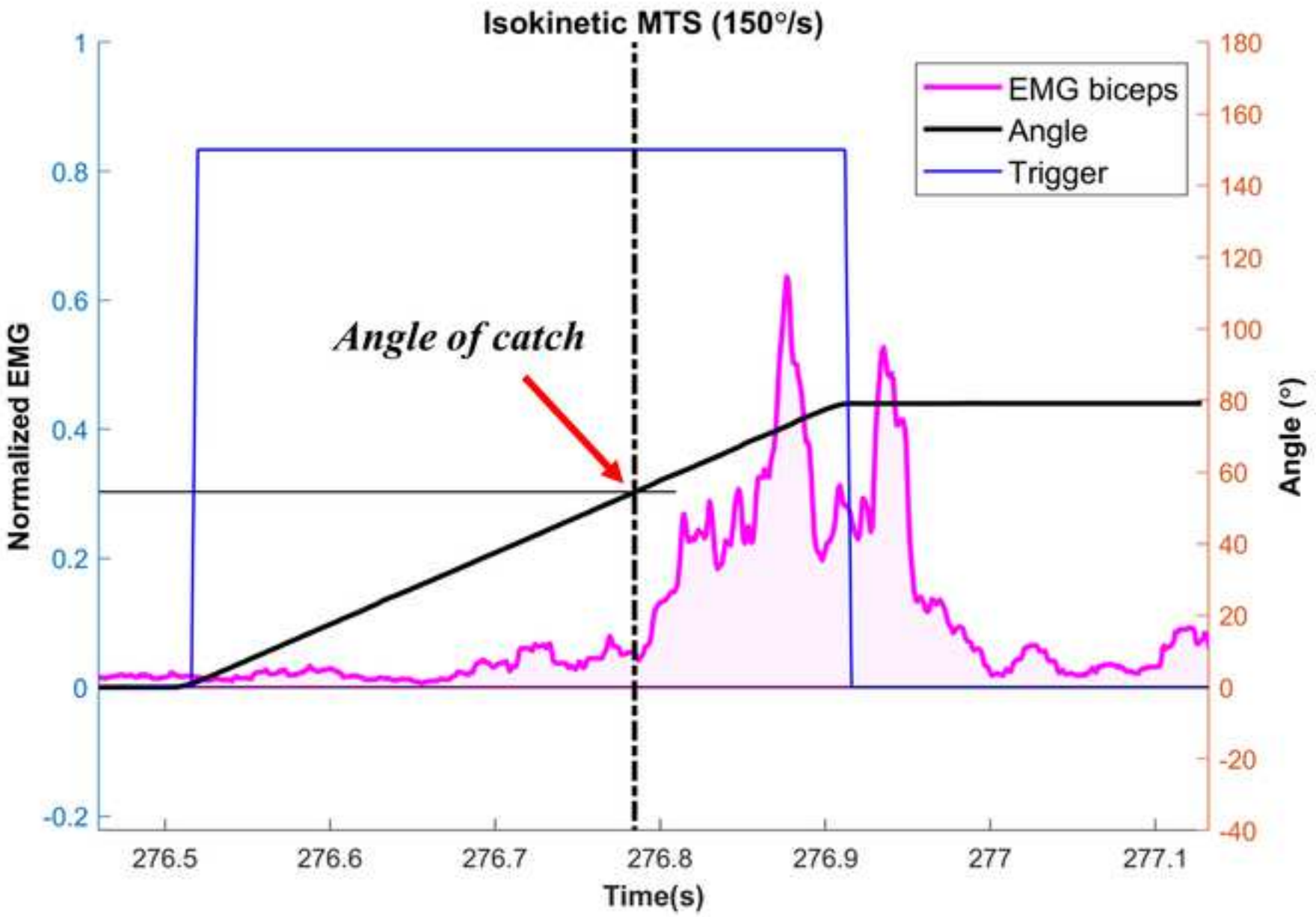

Figure 8

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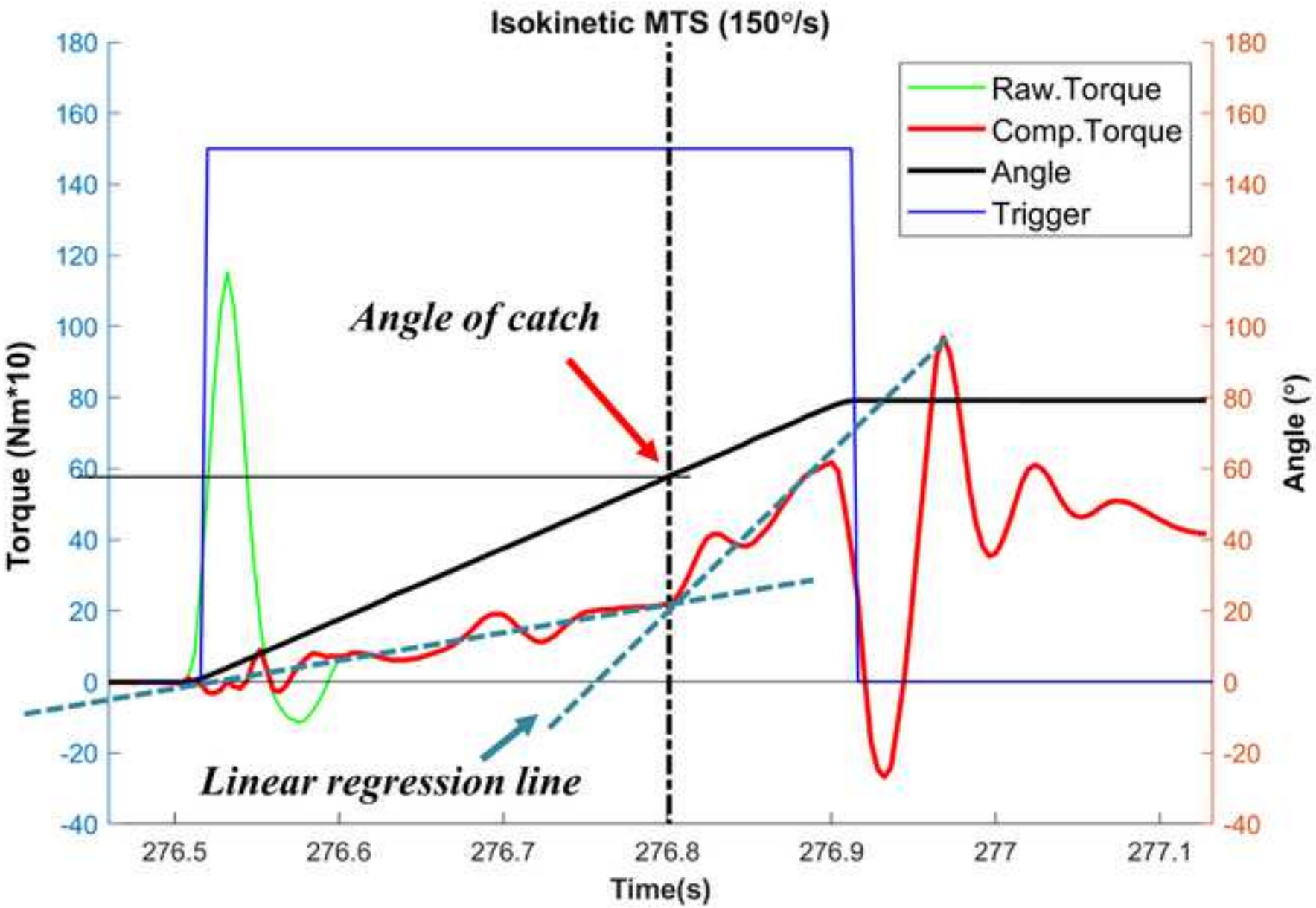

Figure 9

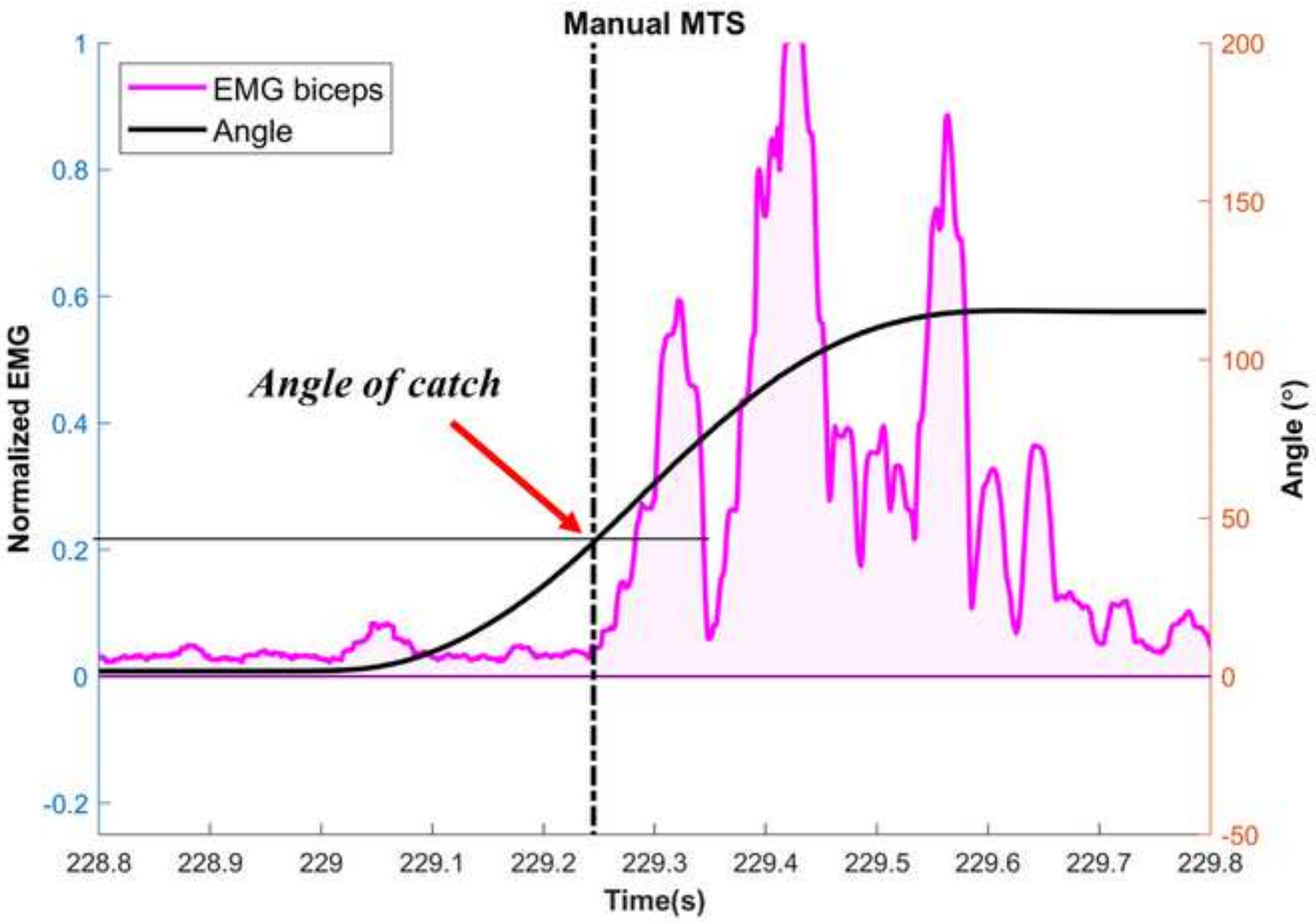

Figure 10

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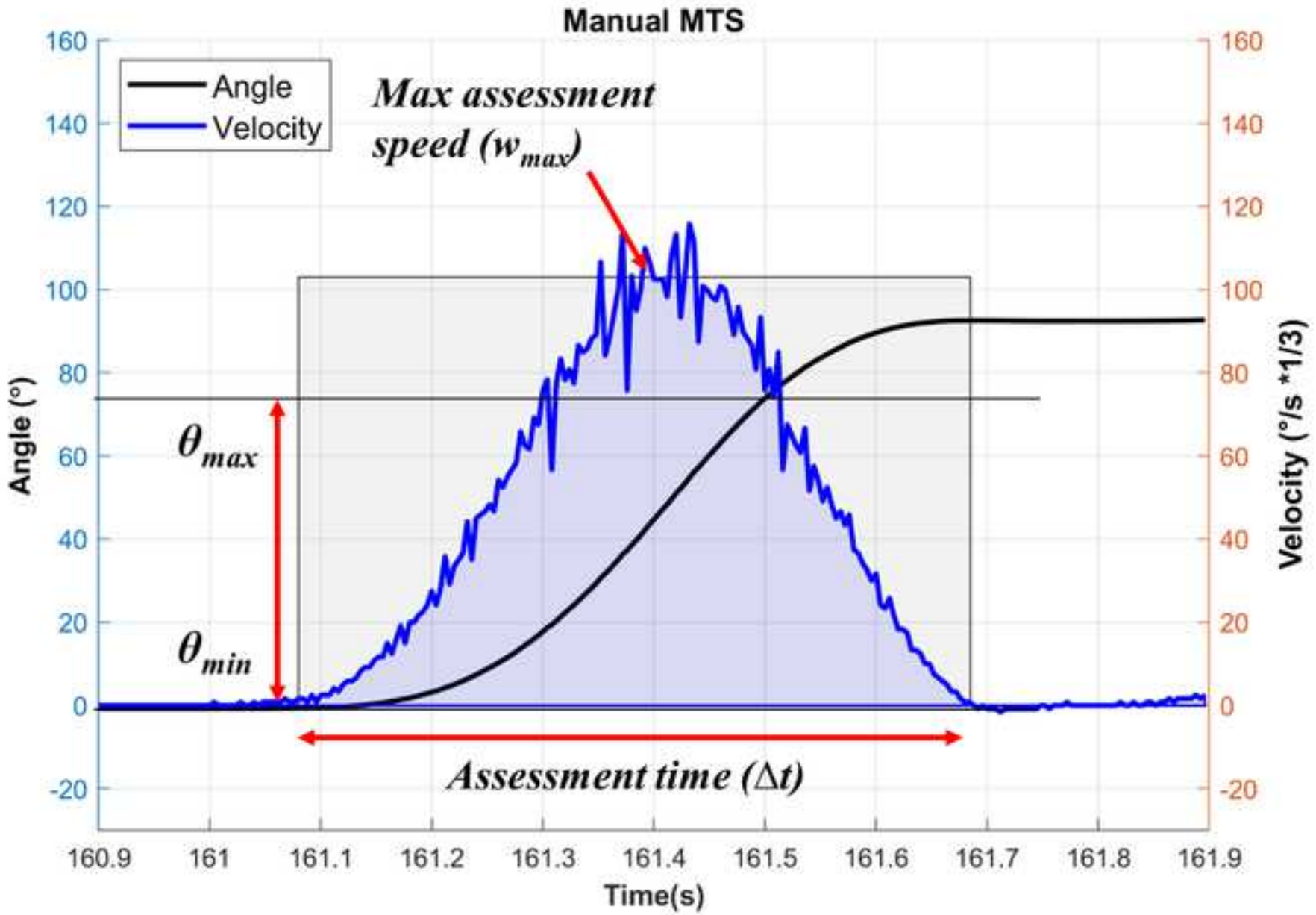

Table 1

Variable	Result
Age, years, mean (SD)	54.6 (12.2)
Gender, n (%)	
Men	14 (82.4)
Women	3 (17.6))
Days from stroke onset, median (IQR)	722 (1226)
Hemiplegic side, n (%)	
Right	10 (58.8)
Left	7 (41.2)
Stroke type, n (%)	
Ischemic	11 (64.7)
Hemorrhagic	6 (35.3)
Stroke lesion, n (%)	
Cortical	4 (23.5)
Subcortical	13 (76.5)
Brunnstrom stage, median (IQR)	
Arm	4 (1)
Hand	3 (1)
Leg	4 (1)
Muscle Power, median (IQR)	
Elbow flexor	4 (1)
Elbow extensor	4 (1)
MAS, elbow flexor, n (%)	
1	7 (41.2)
1+	5 (29.4)
2	5 (29.4)

Table 2

	Test Mean (SD)	Retest Mean (SD)	*p*	SEM	SDD
Rater 1					
Isokinetic (150°/s) motion with EMG	93.74 (28.35)	90.93 (25.44)	0.216	12.12	33.59
Isokinetic (150°/s) motion with torque	90.30 (27.93)	89.61 (27.25)	0.201	3.02	8.37
Manual motion with EMG	82.67 (19.11)	82.03 (21.73)	0.838	17.21	47.7
Rater 2					
Isokinetic (150°/s) motion with EMG	90.77 (28.69)	88.14 (28.34)	0.123	15.1	41.86
Isokinetic (150°/s) motion with torque	97.06 (23.47)	94.37 (25.86)	0.192	9.9	27.44
Manual motion with EMG	80.96 (21.30)	80.46 (22.81)	0.875	16.94	46.96

ICC (2,1) (95% CI)
0.948 (0.857-0.981)
0.997 (0.992-0.996)
0.804 (0.538-0924)
0.929 (0.929-0.991)
0.959 (0.873-0.987)
0.840 (0.601-0.941)

Table 3

	Rater 1 Mean (SD)	Rater 2 Mean (SD)	*p*	SEM
Isokinetic (150°/s) motion with EMG	88.16 (28.24)	89.46 (28.33)	0.973	17.81
Isokinetic (150°/s) motion with torque	94.32 (240.13)	95.71 (24.44)	0.775	12.54
Manual motion with EMG	80.81 (18.98)	80.71 (21.17)	0.586	17.5

ICC (2,1) (95% CI)
0.890 (0.685-0.961)
0.931 (0.791-0.978)
0.788 (0.493-0.920)

Name of Material/ Equipment	Company	Catalog Number	Comments/Description
3D printer	Lokit	3Dison+	FDA type 3D printer
Ball sprine shaft	Misumi	LBF15	
Bridge Analog Input module	National Instruments	NI 9237	
CAN communication module	National Instruments	NI 9853	
Caster	Misumi	AC-50F	
Electromyography (EMG) device	Laxtha	WEMG-8	
EMG electrode	Bioprotech		1.8x1.2 mm Ag–AgCl
Encoder	Maxon	HEDL 9140	500 CPT
Gearbox	Maxon	GP 81	51:1 ratio
Lab jack	Misumi	99-1620-20	
Linear slider	Misumi	KSRLC16	
Motor	Maxon	EC-60	brushless EC motor
Motor driver	Elmo	DC Whistle	
PLA	Lokit		3D printer material
Real-time processor	National Instruments	sbRIO-9632	
Torque sensor	Transducer Techniques	TRS-1K	

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Name:	Nam-Jong Paik
Department:	Department of Rehabilitation Medicine
Institution:	Seoul National University Bundang Hospital
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Comment 1: 1. If the main point is not the construction of the device; could you possibly condense 1.2 and move it to the introduction? Section 2 may be best in the introduction as well.

Response 1:

The construction of the robotic device is not the main topic in this paper. However, in order to fully understand the whole experiment, detailed information about the equipment may be needed to clarify the protocol part. Moreover, it was difficult to put all the necessary information in the introduction part, because there was a word limitation in the introduction part.

We agreed to move the section 2 to the last part of the introduction. We moved section 2 to the introduction as a one paragraph. Some contents of the section 2 were not appropriate for the introduction part, so these were moved to protocol part as 'Note'.

Comment 2: 1.2.1: Figure 2 does not have panels, but 2a and 2b are mentioned here. Please clarify.

Response 2:

Thank you for your comment. We corrected the wrong numbering in the original manuscript. (Fig. 2(a) is still Fig. 2(a) and the Fig. 2(b) is modified to Fig. 3). The figure files were also uploaded with correct numbers.

Comment 3: Figure 1a looks to be largely the same as Figure 3-are both necessary?

Response 3:

Although both figures contain similar components, we think that both figures are necessary to understand the protocol. Fig. 1(a) is needed to understand section 1.2.1 and Fig. 3 is necessary to understand section 1.2.2. For instance, although Fig. 3 contains an illustration of the device, the control system configuration and data flow are key points of this figure. It would be possible to merge two figures into one, the merged figure becomes too complicated and it will be difficult for the reader to understand this figure.

Comment 4: Figures 6-8: Please use ‘150°/s’)

Response 4:

We change the title from 'deg/s' to '°/s' for the figure 6 to 8.

Comment 5: Figures 6-10: The use of, apparently, one y-axis for 3 different units is still confusing-can these be spread out into multiple graphs per figure?

Response 5:

In this experiment, it was important to show how EMG, torque, and motion are related when the catch occurs. Therefore, our first intention for the current figure was showing all the information in one figure. The current figures show the EMG data as additional information, even when the torque-based analysis was performed. Similarly, the torque data was shown in the figure for the EMG-based analysis.

However, we agree that the y-axis of those figures may be confusing. Therefore, we modified the figures to be more simple, by removing unessential data. Moreover, the important data in each picture is located on the left side of the y-axis, and the other data is displayed on the right side of the y-axis.

Comment 6: Table 2: What statistical test was used to produce p-values? Please explain in the legend.

Response 6: We added the statistical test for p-values in tables 2 and 3.

.

1. Graphic User Interface (GUI) of the controller

Note: This part is a detailed description of the control GUI used in this experiment. The GUI was made using LabVIEW. This section provides detailed information to supplement the outlined steps s3 to 4.

1.1. The GUI consists of two panels: the control panel on the left side and the monitoring panel on the right side.

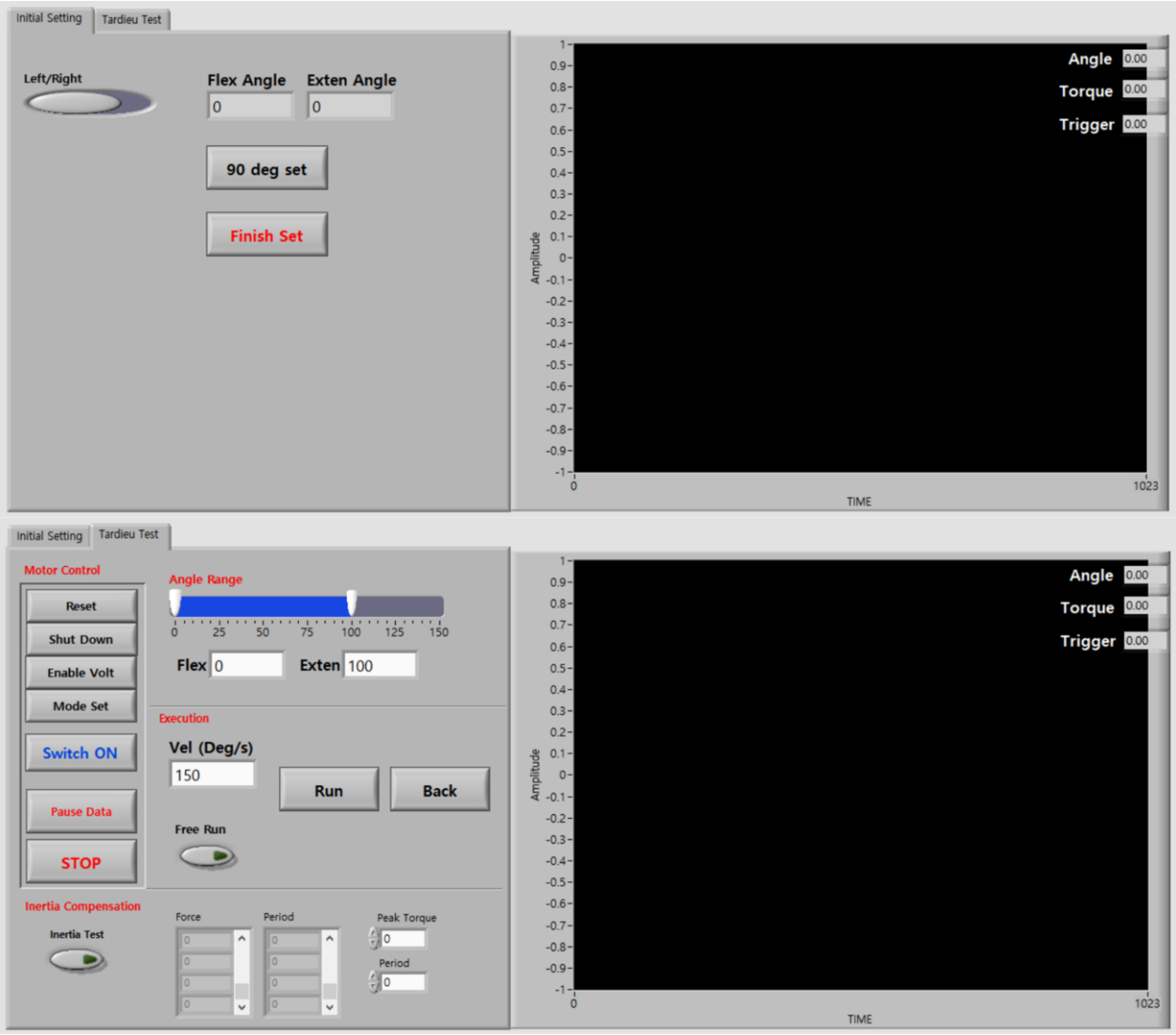

Figure a.1. GUI used in the experiment. GUI for the Initial setting step (Top) and GUI for the Tardieu test step (Bottom)

1.2. The control panel provides an interface for posture setting and robot control, and consists of two layers. The first layer is the 'Initial Setting' panel and second is the 'Tardieu Test' panel.

1.2.1. The ‘Initial Setting’ panel has three buttons. The first is the ‘Left/Right’ toggle button, which is used to enter the subject’s hemiparetic side information. The second button is the ’90 deg set’ button, which is used to match the robot angle with the human anatomic angle in elbow 90 degree flexed posture. The third button is the ‘Finish set’ button to complete this step and proceed to the next layer, the ‘Tardieu Test’ panel. If you push the ‘Finish set’ button, the control panel will change to the ‘Tardieu Test’ panel.

1.2.2. The ‘Tardieu Test’ panel has four sections. The ‘Motor control’ section; ‘Angle Range’ section; ‘Execution’ section; and ‘Inertia compensation’ section.

1.2.3. The ‘motor control’ section has a total of seven buttons. The top four buttons with black letters are used to initialize the motor, and the ‘Switch ON’ button is used to turn on and off the motor. The ‘Data stop’ button is used to end the data communication between the real-time controller and PC. The ‘Stop’ button is used to completely stop the motor.

1.2.4. The ‘Angle Range’ section shows the minimum and maximum range of the angle. The robot can only be operable in the blue region.

1.2.5. The ‘Execution’ section has one number panel, one toggle button, and two buttons. The number panel is the velocity setting panel. The possible range is -1 to 200. The ‘Run’ button will actuate the motor at the given velocity. The velocity of the positive value is in the extension direction. Additionally, the ‘Back’ button is used to return the motor to the minimum angle with 5 deg/s velocity. The toggle button is the ‘Free Run’ button, which is used to change to motor control mode for manual MTS experiment.

1.2.6. The ‘Inertia compensation’ section has one toggle button, two tables and two number input panels. If the toggle button is on, the robot will only move a range of 5 degrees to perturb the user to measure the inertia force. The table shows the resultant inertia force and period, as well as the two number panel is input panel for determined a peak torque value and a period value for inertia effect compensation.

1.2.7. When the toggle button is on, the motor will only momentarily perturb the user if stays within the 5-degree range.

1.3. The monitoring panel shows the state data of the robot (motor angle, interaction torque and trigger signal) in real time.

Friction removal

Note: During the manual MTS measurement, the robotic device was used only as a measurement tool. Therefore, the robot should be as transparent as possible without affecting the experiment. For this purpose, the friction of the robot should be compensated to make the

robot back-drivable.

1.4. The robotic device used in this experiment was a simple 1-DoF device, most of the resistance is caused from the gearbox of the motor.

1.5. The friction of the gearbox can be modeled as a coulomb plus viscous friction. The figure below shows the typical form of the coulomb plus viscous friction.

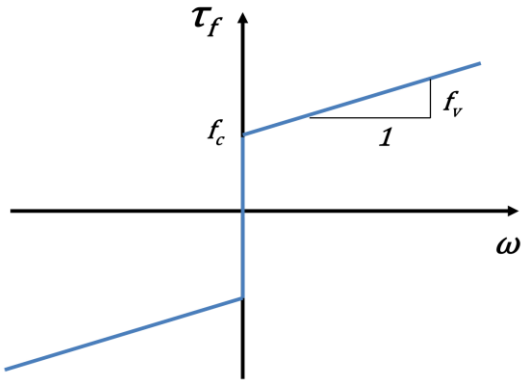

Figure a.2. General form of the coulomb plus viscous friction

1.6. The coulomb plus viscous friction can be expressed in the following equation:

$$\tau_f = \text{sign}(\omega) \cdot (T_v \cdot \text{abs}(\omega) + T_c)$$

1.7. Where τ_f is the total friction force generated by the motor, T_v and T_c are the viscous friction coefficient and Coulomb friction coefficient, respectively. And ω represents angular velocity.

1.8. The viscous friction coefficient (T_v) and the coulomb friction coefficient (T_c) were determined experimentally to minimize the motor resistive torque.

1.8.1. First, gradually increase the T_c value from 0, and find the value at which the manipulandum starts to move with a small force. Find the highest T_c value where there is no occurrence of motor movement without external force.

1.8.2. Move the manipulandum and measure the torque and velocity. Plot the torque-velocity graph. Repeat it with increasing T_v value and select the T_v value that minimize the slope of the graph.

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