Design and Development of Robotic Rehabilitation Device for Post Stroke Therapy

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***Abstract*—To help the neurological patients regain mobility to their impaired arms, a robotic rehabilitation device (called RSP-60) is developed for this purpose. This paper presents the development of a lightweight portable robotics elbow brace device that fits snugly onto Asian patients with weak upper-limb impairment for repetitive elbow flexion and extension rehabilitation without the presence of the therapists. The device is integrated with surface electromyogram (S-EMG) sensors for assistive & assessment purpose, LabVIEW based interface and built in signal processing module for interactive actuation of device. A secondary anthropometric data are mainly collected from Asian subjects with age ranges of 18 to 60 years & above and statistically analysed to use as a design guideline. Pilot clinical trial was carried out with post-stroke patients to access a safety aspect of using the device and evaluate the performance of the device in terms of a valuable therapist's time saving, usage of bio-feedback for active assistive & assessment, usability and users' perception towards using robotics device in rehabilitation. Both experimental condition data and qualitative results are presented and a pain numeric rating scale (NRS) is used for pain assessment tool.**

***Index Terms*—robotics rehabilitation, EMG, elbow brace, repetitive therapy, assessment, anthropometric, stroke**

I. Introduction

Stroke is the fourth prevalent cause of death in Singapore and responsible for 8.9% of death cases in 2013 [1]. Numbers of patients suffer from stroke rise every year which is a growing public health concern. Rehabilitation is still a key to recovery for patients with neurological-related injury and repeated practice of a particular movement appears to be crucial for motor recovery in hemiparesis patients [2], [3]. The use of robotic interventions for the rehabilitation has shown promising results for patients to improve their motor functions [4], [5]. The promising fact of robotics therapy is meaningful and motivating for patient which is a key driver towards recovery. A vast majority of existing market robotics rehabilitation devices for upper-limb are technologically advanced and designed for clinical setting [6]. The availability of these devices in clinical settings is limited and there is still a need to develop new devices to facilitate rehabilitation process through current findings and solutions [6].

In Singapore, a typical therapy session involving repetitive limb flexion and extension still require therapists to perform physically on patients, thus posing a challenge in healthcare industry due to manpower crunch. This paper presents a developed portable robotics device that fits snugly onto Asian patients with varied upper-limb impairment for continuous rehabilitation through the use of bio-feedback signals to assist therapists and patients to have more intensive exercise. This robotic intervention could leverage to reduce the therapists' time and physical strain. Portability allows the device to reach easily to patients and everywhere needs unlike those existing stationary upper-limb exercisers and is also a potential to use at home. Light weight is a most favourable concern with a portable and wearable device not to have strain on the paretic upper extremity. This fact fosters a favourable climate to develop a separate portable control system instead of on-board. The goal of the rehabilitation training is not only to maximize the number of repetition but to maximize the patient's attention and effort as well [7]. The sEMG is well accepted as biofeedback signals in assistive devices for interactive action of upper and lower limb therapies by driving the actuator from voluntary inputs from person after stroke [8]. The studies had shown that muscle coordination at the elbow joint improved only during EMG-driven robot-assisted training but not in the CPM treatment [9]. It also becomes a window to provide new way of impairment measure for the intensity of muscle activity generated during various exercises and functional activity [10]. LabVIEW based interface was developed in order that patient profile can be recorded and provide better tracking for assessment purpose rather than manually note down.

Clinical evidence of device efficacy and safety are required for a medical device to achieve clinical acceptance from hospital and successful practical

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implementation of the device. Pilot clinical study carried out at Kwong Wai Shiu Hospital on stroke patients allowed us to understand its potential towards real world applications. Overwhelming with positive perception from therapists and patients aligned the whole research to its objective perfectly. The urge for bringing the value of this technology to the people it needs most and rehabilitation technology to full time assistive technology, therefore, is propelling to find solution from different disciplines for coming out product and treatment outcome as a key element for a research and development.

II. Design Overview

The project aims to develop a portable light weight elbow brace robotics rehabilitation device for Asian patients to facilitate flexion and extension of the elbow joint with an aim for faster recovery by motivating through the use of bio-feedback signals together with progress logging facility to store and assess the patient performance. The device is relatively needed to be compact enough for its portability and light weight feature. Strength, low specific gravity and impact resistant factors, bio-comparability, therefore, become essential properties for a material selection and usage for design. Actuator is one of the main components of the device and also induced most of the weight. Both small and light weight yet produced high torque are the criteria needed for motor selection. Extensible design for varied physique of patients with maximum comfort and also usable for both left & right arm becomes a real challenge in design. Ensuring the suitable material with right amount of structural dimension in design is critical to favour minimum weight to strength ratio without compromising safety and performance as its intended. To make full use of biofeedback signals in assisting patients for interactive movement, the challenge is required to minimize noise level between sensing electrode and preamplifier. Besides, a Latrobe Fellowship research team, Edelstein Eve A et al., explored the value of a collaborative approach to evidence-based design through a pilot study of the effect of colour and lighting on patient well-being [11]. We have acknowledged its benefits and selected carefully based on the Latrobe Fellowship research team findings. This R&D work is, therefore, highlighted that it's not just about pleasant and fantastic appearance even for colour in the decision making of medical devices. The entire system consist of motorize elbow brace, surface EMG sensors, control box, and user interface.

A. Anthropometry and Its Use for Design

The physical characteristic of human body is so diverse that design often needs to reflect on range of anthropometric data to meet end user requirements. The call to action about anthropometry study for Asian subject was motivated to cater the design to fit snugly and comfortably on a wider range of target users.

The data present in this paper are statically analysed from the journal paper of M.Y. Rosnah, R.H. Mohd, and S.N. SAR [12], T. K. Chuan, M. Hartono, N. Kumar [13] to understand a various Asian physiques and theoretically computed with a method of C.E. Clauser, J.T. McConville, and J.W. Young [14], W.T. Dempster [15], R. Drillis, R. Contini, and M. Bluestein [16] for weight and center of mass of human body segments. The secondary anthropometry data are in total 580 male and 342 female subjects of Indonesian, Malaysian and Singaporean with the age range from 18 to 60 years and above. The analysed data (Table I) are used as an input to define design specifications and torque required for motor selection.

TABLE I. A Secondary Anthropometric Data of Asian Subjects

Description	5%ile	50%ile	95%ile	SD
Stature (cm)	139.5	161.5	183.5	14.1
Weight (kg)	37.3	57.8	85.2	18.7
Shoulder-elbow length (cm)	27.1	34.2	46.8	6.4
Elbow-fingertip length (cm)	37.9	43.9	52.3	4.7
Hand length (cm)	14.3	17	23.7	3.1
Hand breadth (cm)	5.9	7.9	10.1	1.3
Forearm length	23.3	27.4	29	1.9
CG of hand from wrist crease (cm)	5.6	7.7	12	2.4
CG of forearm-hand from fulcrum (cm)	14.5	23.4	35.4	9.3
Hand weight (kg)	0.22	0.38	0.59	0.15
Forearm-hand weight (kg)	0.82	1.33	2.04	0.49
Torque for hand (Nm)	0.13	0.27	0.64	0.2
Torque for forearm-hand (Nm)	1.27	3.04	6.21	2.13

B. Mechanical Design

Today design thinking extended to every field of activity to create new innovation, and not only new ways of solving problems but to solve new problems [17]. The RSP-60 (Recovery is So Possible-60) was developed by converting user needs to engineering such as; slide to size length adjustment to cater for different hand, forearm and shoulder length, flexible link to cater for different arm profile, Malleable aluminium cuffs support for different arm circumferences, able to set different range of elbow flexion and extension motion for various medical condition, suit for both left and right arm because of symmetry in design, maximize the synchronize movement by attaching from side of the arm with sufficient comfortable support, Incorporate with additional mechanical lock to maximize safety, exchangeable anti-slip padding to be more secure, stable and hygiene. Movements such as lateral flexion and lateral extension of the wrist are facilitated by an adjustable torque hinge for resistance bearing exercises, positioning and stretching tighter muscle.

Market awareness factors such as; functional, attractiveness, pleasure in use, usability, accessibility, performance, reliability, safety, environmental factor, usefulness, affordability, acceptability, simplicity, cost to benefit and ease of maintenance, could find within RSP-60. The weight of whole device including actuator is designed around 500g thereby not putting too much muscle strain on patients. The approach of modularity in the design is advantageous beyond flexibility and a light-weight portable design creates an opportunity for diverse physical properties with various medical conditions.

C. Electronic Hardware and Software Interface Design

The complete electronic control system comprised of electronic hardware interface and graphical user interface for user interaction and actuating the elbow brace. Electronic hardware interface consists of a microcontroller, surface EMG (S-EMG) module and an USB based Data Acquisition (DAQ) device interfaced to a computer. DAQ device is USB 6009, from National Instruments, USA. It has 8 single ended Analog channel with multiple Digital I/O. Digital I/O is configured to send control signal to the microcontroller for activation of the motor based on the mode selection.

S-EMG module consists of a surface EMG sensor from B&L engineering, USA to captures the electrical activity of the muscles caused due to the patient's intention to move the affected hand. EMG signal is further amplified and processed to decide the trigger signal level required to activate the motor for the patient to perform therapy. EMG signals are connected to the DAQ device interfaced to the LabVIEW based GUI developed for mastery control of the entire system. LabVIEW based GUI has been developed in-house for user friendly and simple for operation. EMG sensor is connected to an EMG amplifier designed for amplification and filtering of the raw EMG signal.

Microcontroller employed here is only to control the motor triggered through the DAQ device by the GUI running on a Windows-based computer. Microcontroller will call an appropriate function routine to run the motor either for left hand or right hand therapy based on the selection of a hardware control switch provided for the therapist to select. The entire elbow brace system integrated with the Electronic hardware is to self-initiate for faster recovery, Flexible mode for patient such as Passive or Active-assisted, Visual and Audio feedback, Progress logging with ability to store the patient performance data.

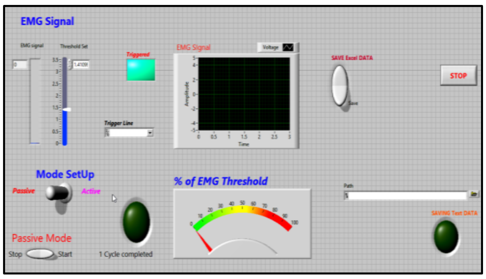

Figure 1. LabVIEW based UI.

The GUI is shown in Fig. 1 which has the features to enter patient information, to set threshold level to actuate the Elbow brace. Elbow brace mode can be set to passive or active mode by a soft button control. GUI will display the EMG signal while it is being captured in real time for monitoring. The GUI will store the EMG signals along with the patient's details in computers HDD, for assessment.

D. Experimental Design

Both mechanical and electronic components together with software was undergone a vagarious in-house laboratory testing to access the safety aspects such as reliability, functionality, and ergonomics. We have evaluated to understand the behaviour of robotics motor, its capability, limitation, & reliability. There is no device used robotics motor as an actuator over 120 devices summarized and compared by P. Maciejasz, J. Eschweiler, K. Gerlach-Hahn, A. Jansen-Troy and S. Leonhardt [6]. Where reliable data about evaluation with robotics motor for rehabilitation device could not be found widely, our results serve to guide the future R&D work and could learn the present boundary. It is also important to test before proceeding with designing and modelling to avoid design work failure.

1). Experimental Results

The motor (Model MX-106R) was able to rotate for flexion and extension smoothly during the lab test with simulated weight as shown in Fig. 2 which illustrates the experiment set up design.

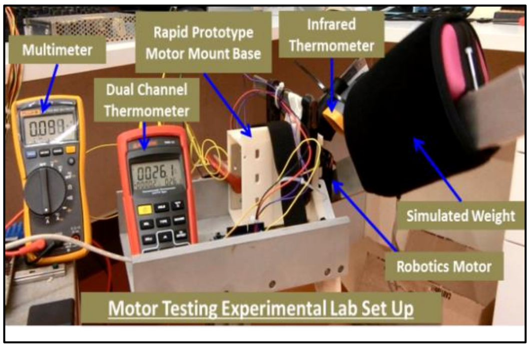

Figure 2. Experimental Lab Test to evaluate reliability and functionality

The motor could run 100k cycles continuously with relatively low heat generation as shown in Fig. 3 and negligible noise level. Hundred thousand cycle test had shown the reliability of the device especially at the rotation joint where the highest stress level lied. It was observed that entire mechanical structure was tolerated well during testing without any failure.

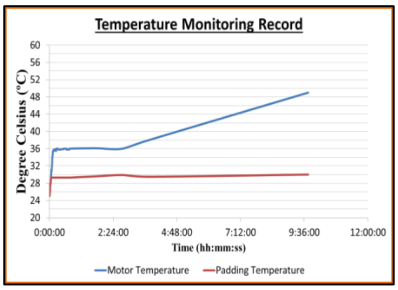

Figure 3. Temperature recorded with dual channel thermometer during in-house laboratory testing.

Fig. 4 is recording of motor withdrawal current of rotation angle between 0 ° and 120 ° with a set value of 1 rpm which allowed us to define the battery, power source, maximum device usable timeframe, recharging time requirements and many other aspects. Motor could perform accurately for temperature limit error, overload error and other functions with simulated condition which is to ensure user safety.

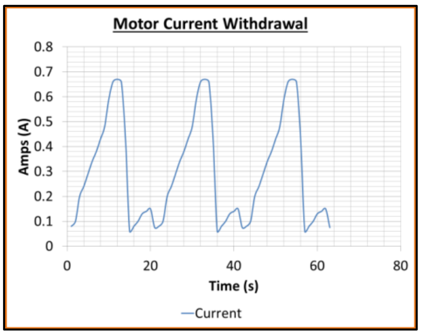

Figure 4. Motor Current recorded during in-house laboratory testing

Fig. 5 was captured during the test with healthy subject to ensure safety aspect, usability, and functionality. There were 10 healthy subjects volunteered for the test. Healthy subject test was completed safely and successfully with positive feedback from the participant and also provided the opportunity to identify room for improvement before proceed a pilot clinical trial with stroke patient.

Figure 5. Healthy subject test to ensure its safety, usability and ergonomics.

III. Pilot Clinical Trial

A clinical trial was conducted on post stroke patients (n=6; mean age 58.3 ± 20.1) to evaluate the performance of using the robotics elbow brace device on patients, the manpower saving by using the device for elbow flex/extension rehabilitation, and to evaluate the usage of Bio-feedback for active assistive therapy.

A. Subjects

Total 6 Subjects- 5 Males and 1 Female, Age range 35 – 90 years old, Post stroke within 2years, exhibiting chronic, moderate upper extremity impairment.

B. Intervention

The subjects were allocated into two groups at the baseline as group A for active and group B for passive. For the passive group, the patients were too weak for EMG signals to be detected, and the device would be used as passive for flexing and extending their elbow. Whereas for active-activated, the EMG signals would be detected from patients and the brace could be activated to perform rehabilitation through the use of bio-feedback signal. Both groups were received a usual regimen from therapists while the study would focus on their paretic upper extremities. Besides, both groups were received 15 minutes of an additional repetitive robotics upper-limb therapy session for 2 days per week and total 8 sessions needed to complete. The trial was conducted at Kwong Wai Shiu Hospital, Day Rehabilitation Centre.

C. Results

1). Evaluating performance of using the robotics elbow brace device on patients:

A pain numeric rating scale (NRS) has been implemented widely as a valid, reliable and appropriate for use in clinical practice [18]. NRS was used as an assessment scale with an 11-point pain intensity numerical rating scale where 0 = no pain and 10 = worst possible pain to evaluate the usage of device before, during and after each robotics therapy session. No subjects addressed any pain and zero score of NRS was recorded across all subjects. Questionnaire survey was constructed to understand users' experience and perception towards using the device. The result of the patient's feedback survey is presented in Fig. 6 and interpreted as described below.

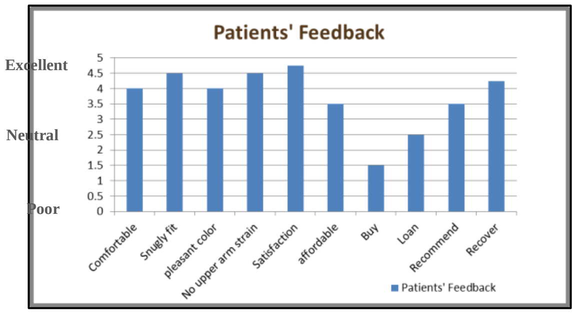

Figure 6. Patients' Feedback Survey Results shown in above graph reflected their satisfaction with using the device for repetitive upper arm rehabilitation therapy.

Patients experienced that using the device was comfortable and fit well to their paretic arm. They felt that device did not make any physical strain due to its light in weight nature. Patients like the lavender colour and artistic appearance of the device. Patient would like to see the device in red and blue colour as well while some felt that colour is not important and can accept any colour. Though patients felt that S$1000 for device price is still affordable, they prefer it to be in few hundreds price range. Majority of patient would like to loan the device instead of buying it if there is an option while some were keen to own it. One patient suggested to implement as soon as possible and also would like to have a hand grasping assisted facility on the device. Patients were willing to recommend the device to others who have the same medical condition as them. Last but not least, patients enjoy doing the robotics therapeutic session and believe that device could help them to recover faster.

2). Evaluating the manpower saving by using the device for elbow flex/extension rehabilitation:

It can be found that total therapists' time saving of 10 hours over a week by integrating 15 minutes robotics therapy for reaching repetitive task without the present of therapist. While therapeutic time needed for a patient is an hour per day for five days a week, two more additional patients could visit the rehabilitation centre for the same number of available therapists to receive treatment therapy which reflect the review of R. Riener, T. Nef, and G. Colombo [19] that the patients can train more intensively with robot-aided therapy, while releasing the therapist from manual movement therapy.

3). Evaluating the usage of Bio-Feedback for active assistive therapy:

Fig. 7 is representing the recording of biceps muscle activity used to trigger the flexion of elbow activity. It was also found that all subjects from group A was able to contract & extend the muscle and able to produce EMG amplitude always greater than the set threshold value and was successfully able to trigger the brace by their own EMG. It proves that our brace is able to provide interactive & active therapy mode and also use for assessment to measure the intensity of muscle activity generated during various exercises during the trial.

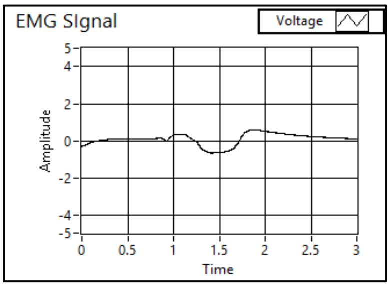

Figure 7. Rectified and smoothed EMG of Group A Subject' Biceps muscle data captured when the brace was triggered.

Fig. 8 is representing the recording of triceps muscle activity used to trigger the extension of elbow activity during the trial.

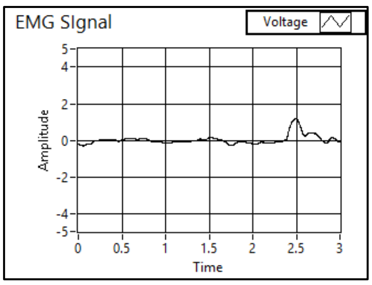

Figure 8. Rectified and smoothed EMG of Group A Subject' Triceps muscle data captured when the brace was triggered.

IV. Discussion

The clinical trial created an opportunity to elaborate more details about user experience and device was performed well on all the patients. The robotics device not only provides number of repetition but also draws patients' attention and effort with the help of bio-feedback effect. Positive results to its feasibility of using the device through pilot trial becomes a potential to further conduct a longer period of trial to obtain a clinically important data regard to patient's recovery and efficacy of the device. Recovery of body functions and activities are significant during first 6 months after Stroke though recovery is a dynamic process that cannot be encapsulated at one time point [20]. The period after stroke before admission, therefore, would be taken into consideration. Ageing is also an important factor to be taken into account for analysing recovery. A review of Peter Langhorne et al. stated that promising effects on motor recovery of the arm were seen in trials of EMG biofeedback & robotics and recommended to evaluate the effectiveness of intervention in a routine clinical setting for subsequent new trials [21]. The statement has been acknowledged for a follow-up trial and also observed that some functional specific task and goal setting can be integrated into the robotics therapeutic session by the assistant of elbow brace device through EMG biofeedback and the outcome could be measured with Fugl-Meyer [22] and Barthel Index [23] as a reliable assessment tool.

Spasticity defines as a motor disorder resulting from hyper excitability of the stretch reflex which is characterized by exaggerated tendon jerks and velocity-dependent increases in tonic stretch reflexes [24]. Since spasticity is velocity dependent, the device, RSP-60 has possibility to set the different rotational speed thus becoming an advantage to maintain the velocity low enough to avoid excessive activation of impaired stretch reflex mechanism. However, setting the right threshold becomes challenge due to the presence of EMG activity in the spastic muscle. Besides, H.S.K. Wimalaratna, and R. Capiledo described a case of an acute hemiplegic patient who was unable to voluntarily contract the muscles of the arm yet was observed to move the arm reflexively while yawning [25]. The device is, therefore, necessary to have capability to act the involuntary motor response triggered by the impaired stretch reflex mechanism and yawning appropriately. It would be beneficial to include interactive meaningful game related to functional tasks in robotics therapy environment in follow up trial [26], [27]. Focused visual input may be an important feature of training because Activity within the dorsal premotor cortex for the affected hand after stroke reveals its contribution as a substrate of functional gains for use of the hand, bolstered by connections to visuomotor regions [28]. However, more work has gone into proving plasticity after stroke without a specific rehabilitation intervention than into trying to extract the elements of training that induce plasticity in relation to behavioural gains [28]. Therefore, a careful implementation of evidence based intervention strategies and measuring impairment precisely is extremely important to extract the efficacy lead to functional recovery.

Therapists' time is extremely valuable as their expertise need to provide across a large number of patients at rehabilitation unit for patients' recovery. The study shows that administration of patient capacity can be increased by integrating the robotics therapy to usual regimen. Home is the highest quality of life setting with lowest cost of health care services. All the patients, therefore, to have the value of this technology at home, continuous effort towards cost effectiveness for portable and wearable robotics device is necessary [29].

V. Conclusion

The robotic rehabilitation device (RSP-60) has been developed and pilot clinical trial using the device was conducted successfully and safely. The S-EMG sensors with capability to measure surface EMG simultaneously from 2 different sites had been tested to its feasibility with different threshold levels setting for biceps brachii muscles and triceps brachii muscles. The adjustable and lightweight portable device fit snugly on to patients with various physiques. The device could be used for high intensity repetitive task without the presence of therapist which has potential to adopt a home-based therapy. The device could be integrated into the usual upper extremity therapy to save therapists' time. Both therapists and patients have positive perception on using robotics therapy which supports to bring the technology closer to the patients.

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