

CLINICALLY COMPLIANT SMART DIAGNOSIS SYSTEM
FOR UPPER LIMB SPASTICITY

YEE JINGYE

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*For my dear Lord Jesus Christ, my dearest family members,
all my previous and current life group members, spiritual family in Hope Batu Pahat,
and all my beloved friends.*



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ABSTRACT

Spasticity is a velocity dependent increase in muscle tone triggered by the increased excitability of the muscle stretch reflex, which could bring about huge physical and emotional impacts on the patients and the family members. The clinical management of spasticity is linked to the severity of the spasticity. Thus, an accurate and reliable assessment of severity is important. The Modified Ashworth Scale (MAS) is one commonly used clinical scale for spasticity assessment based on the resistance against passive movement about a joint with varying degrees of velocity. Due to the ambiguity of the qualitative description of the MAS, the spasticity assessment can be subjective and adequate training is required to ensure interrater reliability. The outcome of this research is a smart diagnosis system for upper limb spasticity based on MAS, which integrates mechatronics system and data-driven classification model. A 3C Framework is designed as the development blueprint for the medical computer-assisted diagnosis system, which includes the Conceptualisation, Creation, and Pre-Clinical Validation phases. In this work, a clinical database of upper limb spasticity for the Malaysian population is developed, and the collected clinical data is used for the development of the data-driven classification model. The classification model is supported by quantitative measurement data acquired with the data acquisition system from 50 recruited subjects. Important features as discussed with the physicians were extracted from the clinical data, and a Logical SVM-RF classifier is developed. This classifier combines the decision-making logic of the physicians and the prowess of different machine learning classifiers, achieving a 91% accuracy in diagnosing the subjects of 6 different MAS levels. This work digitalises the clinical assessment of spasticity as a first step towards the integration of artificial intelligence (AI) and data analytics into the Malaysian clinical setting.

ABSTRAK

Spastisiti merupakan fenomena peningkatan kekerasan otot yang berlaku akibat daripada peningkatan aktiviti refleks regangan otot yang bergantung pada kelajuan pergerakan, dan ia boleh membawa kepada kesan fizikal mahupun emosi kepada para pesakit dan ahli keluarga mereka. Pengurusan klinikal spastisiti berkait rapat dengan tahap keparahannya. Oleh itu, penilaian keparahan spastisiti yang tepat dan boleh dipercayai adalah penting. *Modified Ashworth Scale (MAS)* merupakan satu skala klinikal yang biasa digunakan untuk penilaian keparahan spastisiti berdasarkan tahap tentangan sesebuah sendi terhadap pergerakan pasif yang dikenakan padanya dengan kepelbagaian halaju. Skala MAS mempunyai deskripsi bersifat kualitatif yang mengaburkan. Oleh itu, penilaian keparahan spastisiti dengan MAS adalah amat subjektif dan memerlukan latihan yang mencukupi untuk memastikan kebolehpercayaan keputusan diagnosis antara penilai. Hasil penyelidikan ini adalah satu sistem diagnosis pintar untuk spastisiti bahagian atas anggota badan berdasarkan MAS, yang merupakan satu kacukan sistem mekatronik dan model klasifikasi berasaskan data. Rangka Kerja 3C telah direka sebagai rangka kerja pembangunan sistem diagnosis berbantuan komputer, yang merangkumi fasa Konseptualisasi, Penciptaan, dan Pengujian Praktikal. Dalam penyelidikan ini, pangkalan data klinikal untuk spastisiti anggota badan atas bagi populasi Malaysia telah dibangunkan, dan data tersebut digunakan untuk membangunkan model klasifikasi berasaskan data. Model klasifikasi tersebut berasaskan data kuantitatif yang diperoleh daripada 50 subjek dengan sistem pemerolehan data yang dibangunkan. Ciri-ciri penting seperti yang dibincangkan dengan pakar perubatan telah diekstrak daripada data berkenaan, dan model pengelas Logik SVM-RF telah dibentuk. Model ini menggabungkan logik membuat keputusan pakar perubatan dan kekuatan pelbagai pengklasifikasi, yang mencapai ketepatan 91% dalam mendiagnosis subjek daripada 6 tahap MAS berbeza. Penyelidikan ini mendigitalkan penilaian klinikal spastisiti sebagai permulaan ke arah penyepaduan kecerdasan buatan dan analisis data ke dalam amalan klinikal Malaysia.

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PERPUSTAKAAN TUNKU TUN AMINAH

LIST OF SYMBOLS AND ABBREVIATIONS

θ_{elbow}	-	Elbow angle
<i>AI</i>	-	Artificial Intelligence
<i>ANN</i>	-	Artificial Neural Network
<i>API</i>	-	Application Programming Interface
<i>AS</i>	-	Ashworth Scale
<i>CAD</i>	-	Computer-assisted diagnosis
<i>CART</i>	-	Classification and Regression Trees
<i>DLL</i>	-	Dynamic Link Library
<i>DT</i>	-	Decision Tree
<i>EMG</i>	-	Electromyography
<i>GUI</i>	-	Graphical user interface
<i>MAS</i>	-	Modified Ashworth Scale
<i>MMSE</i>	-	Mini-Mental State Examination
<i>MTS</i>	-	Modified Tardieu Scale
<i>NINDS</i>	-	National Institute of Neurological Disorders and Stroke
<i>PWD</i>	-	Person with disabilities
<i>RF</i>	-	Random Forest
<i>ROM</i>	-	Range of Motion
<i>SCI</i>	-	Spinal cord injury
<i>sEMG</i>	-	Surface electromyography
<i>SVM</i>	-	Support Vector Machine
<i>TS</i>	-	Tardieu Scale
<i>UiTM</i>	-	Universiti Teknologi MARA
<i>ULS</i>	-	Upper limb spasticity
<i>UPSC</i>	-	UiTM Private Specialist Centre
<i>USA</i>	-	United States of America
<i>WHO</i>	-	World Health Organization

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PT TA UTHM
PERPUSTAKAAN TUNKU TUN AMINAH

CHAPTER 1

INTRODUCTION

1.1 Background of study

Spasticity is a velocity dependent increase in muscle tone triggered by the increased excitability of the muscle stretch reflex. According to the National Institute of Neurological Disorders and Stroke (NINDS) of the United States of America (USA), spasticity is the condition of abnormal increment in muscle tone or stiffness that might induce pain or discomfort by interfering in the movement or speech of a normal human being [1]. Clinically, spasticity manifests as an increased resistance or muscle tone by muscles during passive stretching or lengthening [2]. Spasticity is common among patients with conditions such as brain injury, cerebral palsy, multiple sclerosis, spinal cord injury (SCI) and stroke.

Spasticity could cause huge physical and emotional impacts on the patients and the family members. Physically, spasticity could cause discomfort and stiffness, while spasms can be annoying and painful, and may disrupt motor function [3]. Besides the physical activities, the presence of spasticity and spasms could cause emotional impact on the patients. For instance, the localisation of spasticity in both legs or the right arm can produce a significant impact on “Need for Assistance/ Positioning” and “Social Embarrassment” [4].

The clinical management of spasticity is linked to the severity of the spasticity, and thus the reduction of personal and societal impact of a spasticity subject lies in the accurate assessment that precedes the rehabilitation intervention. However, an accurate and reliable assessment of severity is in itself a challenging area [3]. There are ongoing research activities into different assessment strategies, including gait

analysis and biomechanical, neurophysiological, and clinical measurements. The provision of rehabilitation services requires a multidisciplinary team led by a rehabilitation physician. The shortage of rehabilitation professionals and the limitation of rehabilitation facility is hindering optimal rehabilitation service provision in Malaysia. There are only 84 rehabilitation physicians in a country of 32 million. The welfare department recorded 453,258 registered persons with disabilities (PWD) in 2017 [5]. This number is clearly under reported of actual numbers. Thus, the patients in rural areas face issues in accessing rehabilitation facilities which are confined to the big cities. To tackle this urgency, there are growing appeals for the digitisation of rehabilitation services.

In the current clinical practice, the more commonly used assessment scales are the Ashworth Scale (AS) or Modified Ashworth Scale (MAS) [6], and MAS is also the most cited scale in the literature [7]. The MAS classify the severity level of spasticity based on the resistance against passive movement about a joint with varying degrees of velocity. The MAS grades range from 0 to 4, with six severity grades: 0, 1, 1+, 2, 3, and 4. The shortcoming of the mentioned assessment scale is its qualitative nature as opposed to quantified figures and numbers. The therapist will diagnose the severity level of the spasticity level based on one's interpretation of the stated definition and experience [8], and resulting in the interrater and intrarater variability as compiled in [9]. The key problem with this approach is the reliability on one's experience rather than universally accepted standard.

In Malaysian clinical practice, the occupational therapist or physiotherapist diagnoses the severity level of the spasticity based on experience and qualitative scale of MAS. The MAS assessment of the therapists are heavily influenced by subjective feeling instead of measurable and quantified value. Rehabilitation physicians and therapists diagnose the severity level of spasticity based on experience and interpretation of the stated definition of MAS, resulting in the lack of consistency and the interrater (more than one observer) and intrarater (within an individual observer) variability. Current clinical practice utilises a conventional goniometer to determine the range of motion (ROM) and the catch angle of the patients' spastic arm. Data are recorded manually on papers. Such data is often managed individually and not convenient to be shared among clinics.

In this course of digitisation, the advancement of the computing power and artificial intelligence can be leveraged to improve the diagnosis accuracy of a patient,

and the same can be done on a patient with spasticity. With the assistance of a mechatronics system consisting of corresponding sensors and artificial intelligence, the diagnosis of spasticity can be quantified, and its severity level based on clinical scales can be predicted by a computer model trained with real life clinical data.

1.2 Problem statement

Based on the available literatures, there are several data collection attempts for spasticity both within and outside Malaysia for the purpose of computer-assisted diagnosis. The parameters collected include the kinematic and kinetic aspects such as the joint angle, joint movement velocity, and joint torque in action. None of the studies mention about the inclusion of electromyography (EMG) in their attempts, even though EMG has been proven as highly correlated to AS and MAS clinical scales. Zooming into the rehabilitation scene in Malaysia, none of the clinical data collected has complete MAS clinical spectrum from MAS level 0 to level 4, and they are also not publicly accessible for the utilisation in improving the rehabilitation healthcare scene of Malaysia.

The spasticity severity level of the patients acts as a guideline for the prescription of medication and physical rehabilitation routine by the medical personnel. Hence, the precision and accuracy of spasticity severity level assessment is essential for the wellbeing of the patients and lowering the overall negative impact to the society. With the collected clinical data, the research teams attempt to utilise machine learning and deep learning in assisting the diagnosis of spasticity. However, the literatures show that none of the attempts are aiming to diagnose the full spectrum but only parts of the spasticity clinical scale. All the attempts of computer-assisted diagnosis based on MAS clinical scale have excluded at least one of the MAS levels in their studies. A data-driven assisted-diagnosis model which covers all the MAS levels is still a gap to be filled in if there is a serious attempt in digitalising the diagnosis of spasticity.

On top of that, the development of a mechatronics system requires a proper framework and guideline. This is especially true for a computer-assisted diagnosis (CAD) system, as it involves multiple stakeholders and users including the patients itself. There are various frameworks for the development of data analytics projects or mechatronic systems, yet there is not any properly drafted framework for the

development of a computer-assisted diagnosis system which is a mixture of both systems specially for the assisted medical diagnosis purpose.

1.3 Objectives

The main aim of this study is to develop a clinically compliant smart diagnosis system for upper limb spasticity. In short, this work aims to reduce the interrater and intrarater variability of spasticity assessment by the proper quantification of the qualitative description of MAS, and the training of computer system to identify and imitate the decision-making process of medical expert.

The aim of this work is broken down into clearer and more discrete objectives below:

- i. To establish a quantitative clinical database for upper limb spasticity of Malaysian patients containing kinematics, kinetics, and physiological data.
- ii. To develop data-driven machine learning model for severity level classification of upper limb spasticity.
- iii. To design a complete framework for the development of computer-assisted diagnosis system.

The first objective is to establish a quantitative clinical database for upper limb spasticity of Malaysian patients which contains kinematics, kinetics, and physiological data. This clinical database contains all the relevant information of the spasticity which includes elbow angle, elbow resisting force, and bicep surface electromyography (sEMG). There is no publicly available existing clinical database for Malaysian patients which contains all the vital information for the development of a data-driven machine learning classification model.

The second objective is the development of a data-driven machine learning model which can diagnose the upper limb spasticity severity level. This algorithm is a crucial part of the smart diagnosis system, and there is no available algorithm anywhere which covers the classification of upper limb spasticity for the whole MAS clinical scale spectrum.

The third objective is the design of a development framework for the creation of a computer-assisted diagnosis system. The development of a mechatronics system requires a proper and systematic guideline to prevent the uncoordinated and messy

development process. A proper development framework for computer-assisted diagnosis system could reduce the miscommunication and time-required during the development process.

1.4 Scope

To produce a specialised study on this topic, the scope of this work has been limited to the constraints listed below:

- i. The clinical compliance of the developed system lies in the usage of the clinical data and the MAS clinical scale in the system, and the usage of the system fits into the current clinical practice.
- ii. The smartness of the developed system lies in the automatic classification of the upper limb spasticity severity level provided by the developed data-driven machine learning classification algorithm.
- iii. The focus of the study will be spasticity occurs in the upper extremities, which is known as upper limb spasticity.
- iv. The main parameters for the diagnosis are the elbow angle, elbow force, and surface electromyography (sEMG) of bicep.
- v. The development of the data processing pipeline and the Machine Learning model is performed in the Python language.
- vi. The clinical assessment scale used for the assessment of upper limb spasticity severity level is Modified Ashworth Scale (MAS).
- vii. The severity levels for the classification are the MAS 0, MAS 1, MAS 1+, MAS 2, MAS 3, and MAS 4.
- viii. The inclusion criteria of patients are:
 - a. Presence of any central nervous system pathology.
 - b. Good cognitive function determined by Mini-Mental State Examination (MMSE) with a score ≤ 24 .
- ix. The exclusion criteria of patients are:
 - a. Elbow joint or forearm pathology secondary to the non-neurological cause.
 - b. Presence of elbow joint contracture secondary to bone pathology.
- x. The developed framework is for the development of medical computer-assisted diagnosis system.

- xi. The developed framework/system is for Proof of Concept (PoC) purpose, which ends at the pre-clinical validation phase with the clinicians.

1.5 Novelty

The main objective of this study is the development of a clinically compliant smart diagnosis system for upper limb spasticity, which is to assist the clinicians diagnosing the upper limb spasticity. The main novelty of this work is the completion of a computer-assisted diagnosis system for upper limb spasticity based on MAS and comprises all the six MAS levels, which could revolutionise the current clinical practice in Malaysia in the upper limb spasticity diagnosis. This main novelty encompasses three sub-novelty under its umbrella, which come along during the development process. The details of the novelty are summarised in Figure 1.1.

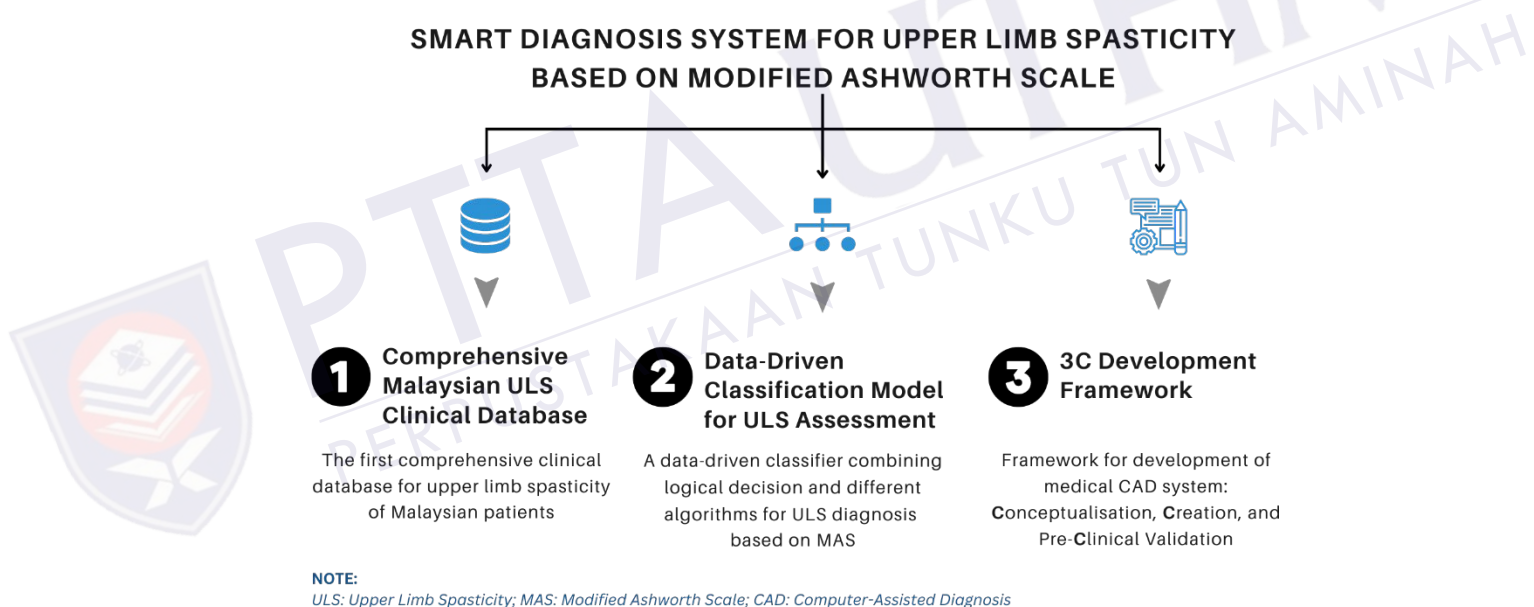


Figure 1.1: Novelties of the study

This work involves the development of a local clinical database of upper limb spasticity for the Malaysian population. The clinical database includes the time-series data of the patients' spastic arm for elbow angular motion, elbow resisting force, and the sEMG of bicep. The establishing of such clinical database can be used for future reference to enhance the healthcare quality of the medical and rehabilitation experts in Malaysia. The clinical database can serve as a foundation, and the data collected in the future can increase and expand the clinical database. The processes involved in

establishing the clinical database includes: the development and integration of sensors into a data collection system, the proper design of data collection phases, and the clinical data collection sessions conducted by the certified clinicians at UiTM Private Specialist Centre (UPSC).

Additionally, this work includes the development of a data-driven classification model based on conventional algorithms and logical decision-making process. The classification model combines the strength of individual classifiers on specific MAS Level and the decision-making logic of medical expert in upper limb spasticity diagnosis. The classifiers include the Random Forest (RF) algorithm and Support Vector Machine (SVM). It is known that one team in Korea carried out a similar research by using artificial neural network (ANN) for the purpose of identifying and imitating the MAS clinical assessment of spasticity in the diagnosis process [10], though only for MAS Level 0 to 3. The developed classifier includes a logical flow of the mentioned conventional classifiers and some logic rules to determine the spasticity severity level based on MAS clinical assessment scale. The data-driven classification model development process involves the data processing pipeline to extract important features from the data for the training of different classifiers before the classifiers are combined for classification performance enhancement. The features for the model training are determined with the inputs from the medical expert, thus making it a medical expert system.

Development of a medical computer-assisted diagnosis system includes the systems engineering of a mechatronics system with the integration of data analytics project. There are different systems engineering approaches and frameworks available for the development of mechatronics system or data analytics project. However, none of the frameworks could serve as a development blueprint for a smart diagnosis system (or computer-assisted diagnosis system). This study provides a framework with the name of 3C Development Framework, which is the short form for Conceptualisation, Creation, and Pre-Clinical Validation. The framework is designed in such a way that it encompasses the important phases in the design and deployment of a computer-assisted diagnosis system in a clinical setting. The framework starts with the conceptualisation of the whole system and ends with the pre-clinical validation and verification by licensed clinicians. Several existing tools or canvases are employed in the framework as they have been tested and validated. The development framework involves the consultation of important stakeholders, especially the voice of the end

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VITA

The author was born on 17 June 1993 in Klang, Selangor, Malaysia. He attended SJK(C) Khee Chee for primary study, and then SMK Abu Bakar Temerloh for secondary school, both schools are located in Temerloh, Pahang, Malaysia. Upon the completion of his Malaysian Certificate of Education (SPM), he enrolled for Diploma in Mechanical Engineering at the Universiti Tun Hussein Onn Malaysia, Johor, Malaysia and graduated in year 2014. He has then pursued his degree at the same university, and graduated with the Bachelor Degree of Mechanical Engineering with Honours in 2017. In the same year, he was admitted into the Ph.D. programme in Mechanical Engineering, with the main research areas on application of artificial intelligence and machine learning into the medical domain. As he is pursuing his Ph.D., he works as a graduate research assistant under a research project funded by the Ministry of Energy, Science, Technology, Environment & Climate Change (MESTECC) Malaysia, which is later known as the Ministry of Science, Technology & Innovation (MOSTI) Malaysia. At the same time, he works also as a laboratory tutor for the Faculty of Mechanical and Manufacturing Engineering in conducting laboratory sessions of Statics, Electrical & Electronics Technology, and Solid Mechanics II. From October 2021 to February 2022, he was attached to the Fraunhofer Institute for Mechatronic Systems Design, Paderborn, Germany as a Student Research Assistant during his one semester period as an exchange student at the Heilbronn University of Applied Sciences, Heilbronn, Germany.