CHAPTER III

METHODS

1. The development of the knee electro-orthosis

Specification of the KEO was defined based on the knowledge of gait analysis in patients with hemiplegia. The KEO system consists of a single-channel electrical stimulator, an offset knee orthosis, and a knee or a foot switch sensor. The offset knee orthosis supports the participants' body weight and provides stability for patients with knee extensors weakness (69). The small single-channel electrical stimulator which includes intensity and a frequency adjusted knob is controlled by a switch sensor. The stimulation provides propulsion of walking through the quadriceps stimulation. The configuration of the new proposed KEO system is shown in Figure 6.

Figure 6 The developed knee electro-orthosis system

1.1 Components of the knee electro-orthosis

A. An electrical stimulator

An electrical stimulator was produced by the electrical engineer. The electrical stimulator is a single-channel stimulator with a weight of 220 grams and dimensions of 10.5 x 7 x 4 cm. Two 9-volt batteries provide the main power for the unit. The stimulator gives a 150 μsec rectangular monophasic pulsed current of peak amplitude 180 volts and adjustable frequency between 1.4 to 40 Hz. The stimulator was attached to the waist using a velcro belt. The configuration of the electrical stimulator is shown in Figure 7. Stimulation is applied by means of two 9x5 cm self-adhesive electrodes on the quadriceps muscles. The negative electrode was placed at the motor point of the rectus femoris and the positive electrode was placed at the vastus medialis. The duration of stimulation was controlled by a switch sensor.

Figure 7 The developed electrical stimulator

B. An offset knee orthosis

An offset knee orthosis was produced by an orthotist who is specialized in orthotic devices. The main function of the offset knee orthosis is to improve knee stability and reducing knee buckling in the stance phase of gait cycle. The offset knee orthosis consists of a single lateral upright metal bar, an offset knee axis, two calf bands and two thigh bands. A single axis is more common and is used for knee stabilization in patients with quadriceps weakness (21). An offset knee axis is located posterior to the knee joint and ground reaction force; thus, it facilitates knee extension and provides greater stability during stance phase of the gait cycle. This joint axis provides stability in the knee joint from initial contact through mid stance and allows freely knee flexion during swing phase of the gait cycle (21).

An original orthosis made from aluminum bar with the size of 54x3x0.5 cm and weight 250 to 300 grams. The offset knee orthosis was held together by padded upper and lower thigh bands and the calf bands. The bands made from stainless steel and were covered with leather. The lower thigh band and upper calf band located at 6 cm from the axis and the upper thigh band and lower calf band were attached to the orthosis at 14 cm from the axis. Figure 8 demonstrates the position of the KEO in a patient. The researcher found that patients were fatigue after wearing it for a certain period of time. The calf and thigh bands which were rather stiff could not properly mould to the leg of the patients. So it was difficult to fix the orthosis to patient's lower extremity. Therefore, we reduced an axis bar to a smaller size of 30.5x1.8x0.5 cm which weighted approximately 200 to 250 grams. The calf and thigh bands were made softer than the original orthosis because they were padded with sponge and well fixed to the lower extremity of patients. The total weight of the offset knee orthosis

included all the bands were approximately 400 to 500 grams. The final orthosis is shown in Figure 9.

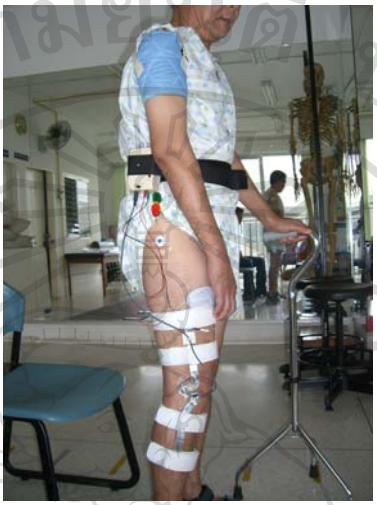

Figure 8 The developed knee electro-orthosis system on the patient

Figure 9 The developed offset knee orthosis with the knee switch sensor

C. Switch sensor

The KEO is controlled through either the knee or the foot switch sensor. A pilot study was performed using the knee switch sensor to trigger the stimulation of the quadriceps muscles during the stance phase. During testing, the researcher found that some participants could not properly extend their affected knee joint which was required to compress the knee switch sensor. Thus, the knee switch sensor could not turn on the stimulator. In some participants, the stimulator did not turn off during the swing phase because of the locked knee problem. Therefore, the knee switch sensor was replaced with the foot switch sensor in the main study.

The knee switch sensor which is a pressure sensitive switch is attached to the top and the lower bar axis of the offset knee orthosis. The size of the knee switch is 2x1 cm and weight 20 grams. The configuration of the knee switch is shown in Figure 10.

The foot switch sensor was placed under the heel of the affected foot. It consisted of 16 sensors (Figure 11) and weighted 30 grams. Functionally, the electrical impulse was activated by a pressure sensitive switch during the stance phase of the gait cycle.

Figure 10 The developed knee switch sensor

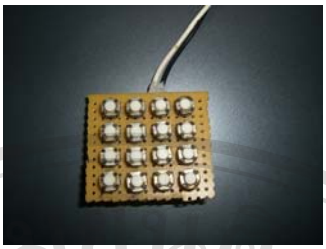

Figure 11 The developed foot switch sensor

1.2 Functional association of the switch sensor, the knee orthosis, and muscle stimulation

1.2.1 The knee orthosis with the knee switch sensor

Changing the angle of the knee orthosis to an extension or flexion turns the knee switch on and off. In other words, when the patients are walking in the stance phase of the gait cycle, the knee orthosis is extended and the knee switch is turned on. Consequently, impulse from the electrical stimulator activates the quadriceps muscle to increase knee stability. On the contrary, when the patients are walking in the swing phase of the gait cycle, the knee orthosis is flexed and the knee switch is turned off. Thus, the patients can flex the hip and the knee joints during the swing phase. The stimulation period are based on the patients' gait cycle. Theoretically, quadriceps is stimulated at the loading response and mid stance phase of the gait cycle. The stimulation period and the stimulated muscles of the KEO which is controlled through the knee switch are presented in Table 4.

1.2.2 The knee orthosis with the foot switch sensor

The foot switch sensor was placed under the heel of the disabled-body. It is also a pressure sensitive switch. The stimulation started at the initial contact and terminated at the terminal stance phase of the gait cycle. When the foot is placed on

the ground, pressure is applied to the switch and the stimulation started. On the other hand, when the foot is raised off the ground, the stimulator is turned off. The stimulation period and the stimulated muscles of the KEO which is controlled through the foot switch sensor are presented in Table 5.

Table 4 The stimulation period and the stimulated muscles of the KEO which is controlled through the knee switch sensor

Basic knowledge (24, 26)				Proposed KEO	
Phase	%gait cycle (duration)*	Motion	Active muscle group	Status of sensor	Stimulated muscles
Initial contact	0-2% (0.02 sec)	Extended knee posture	Ankle dorsiflexors, hip extensors, knee flexors	off	none
Loading response	0-10% (0.1 sec)	Knee flexion (15^{o})	Knee extensors, hip abductors, ankle plantarflexors	on	Quadriceps
Mid stance	10-30% (0.2 sec)	Knee extension	Ankle plantarflexors (isometric)	on	Quadriceps
Terminal stance	30-50% (0.2 sec)	Completion of knee extension	Ankle plantarflexors (concentric)	off	none
Pre-swing	50-60% (0.1 sec)	Passive knee flexion	Hip flexors	off	none
Initial swing	60-73% (0.13 sec)	Knee flexion	Ankle dorsiflexors, hip flexors	off	none
Mid swing	73-87% (0.14 sec)	Passive knee extension	Ankle dorsiflexors	off	none
Terminal swing	87-100% (0.13 sec)	Knee extension	Knee flexors, hip extensors, ankle dorsiflexors, knee extensors	off	none

***** Calculation of duration of each gait phase based on the assumption that a person has a step length of 50 cm, and a walking speed of 1m/sec.

Table 5 The stimulation period and the stimulated muscles of the KEO which is controlled through the foot switch sensor

Basic knowledge (24, 26)				Proposed KEO	
Phase	%gait cycle (duration)*	Motion	Active muscle group	Status of sensor	Stimulated muscles
Initial contact	0-2% (0.02 sec)	Extended knee posture	Ankle dorsiflexors, hip extensors, knee flexors	on	Quadriceps
Loading response	0-10% (0.1 sec)	Knee flexion (15^{o})	Knee extensors, hip abductors, ankle plantarflexors	on	Quadriceps
Mid stance	10-30% (0.2 sec)	Knee extension	Ankle plantarflexors (isometric)	on	Quadriceps
Terminal stance	30-50% (0.2 sec)	Completion of knee extension	Ankle plantarflexors (concentric)	on	Quadriceps
Pre-swing	50-60% (0.1 sec)	Passive knee flexion	Hip flexors	off	none
Initial swing	60-73% (0.13 sec)	Knee flexion	Ankle dorsiflexors, hip flexors	off	none
Mid swing	73-87% (0.14 sec)	Passive knee extension	Ankle dorsiflexors	off	none
Terminal swing	87-100% (0.13 sec)	Knee extension	Knee flexors, hip extensors, ankle dorsiflexors, knee extensors	off	none

***** Calculation of duration of each gait phase based on the assumption that a person has a step length of 50 cm, and a walking speed of 1m/sec.

2. Investigating the effect of the knee electro-orthosis on gait parameters

2.1 Participants

Patients with hemiplegia, including both genders, were recruited from the hospitals and nursing homes in the Chiang Mai province. All participants signed an informed consent prior to their entry into the study. The experimental protocol was approved by the ethical research committee of the Faculty of Associated Medical Sciences, Chiang Mai University.

2.1.1 Inclusion criteria

1. Aged between 18-60 years
2. Had hemiplegia between 2 weeks and 8 months after the onset
3. A level 2 – 3 of FAC (see detailed in Appendix B)
4. Ability to flex hip in standing position at least 10 degrees
5. Quadriceps strength in inner range less than or equal to grade 3
6. Ability to understand and follow simple verbal instructions

2.1.2 Exclusion criteria

1. Had limited range of motion of the lower-limb joints
2. Had spasticity of quadriceps more than 1+ of Modified Ashworth Scale (MAS) (see detailed in Appendix C)
3. Had musculoskeletal injury of the lower limb in the past 3 months
4. Had an inflammation or skin diseases over lower-limb area
5. Had cardiovascular diseases in the past 3 months or other medical conditions severe enough to impair walking
6. Had resting blood pressure more than 140/90 mmHg, or resting heart rate more than 95 beats/min

For a pilot study, six participants with hemiplegia have been tested using the KEO with the knee switch sensor. Thirteen participants with hemiplegia which participated in the main study were tested using the KEO with the foot switch sensor. All participants of the main study were divided into two subgroups, that is, the eight normal knee alignments and the five knee hyperextension during stance phase.

2.2 Study design

The within-subject repeated measures design was used in the study. Participants were randomly selected using drawing lots to determine the testing conditions (walking without the KEO, walking with the KO, and walking with the KEO). Each subject attended two sessions of testing on two different days. They were allowed to use their shoes and walking aids as they normally used during testing.

2.2.1 Measured parameters include;

1. Velocity (cm/sec)
2. Cadence (steps/min)
3. Step length (cm)
4. Swing time (sec)
5. Stance time (sec)
6. Knee angle at the mid stance (degree)

2.2.2 Testing conditions

1. Walking without the KEO
2. Walking with the KO
3. Walking with the KEO, a negative electrode was placed at the motor point of the rectus femoris and a positive electrode was placed at the vastus medialis.

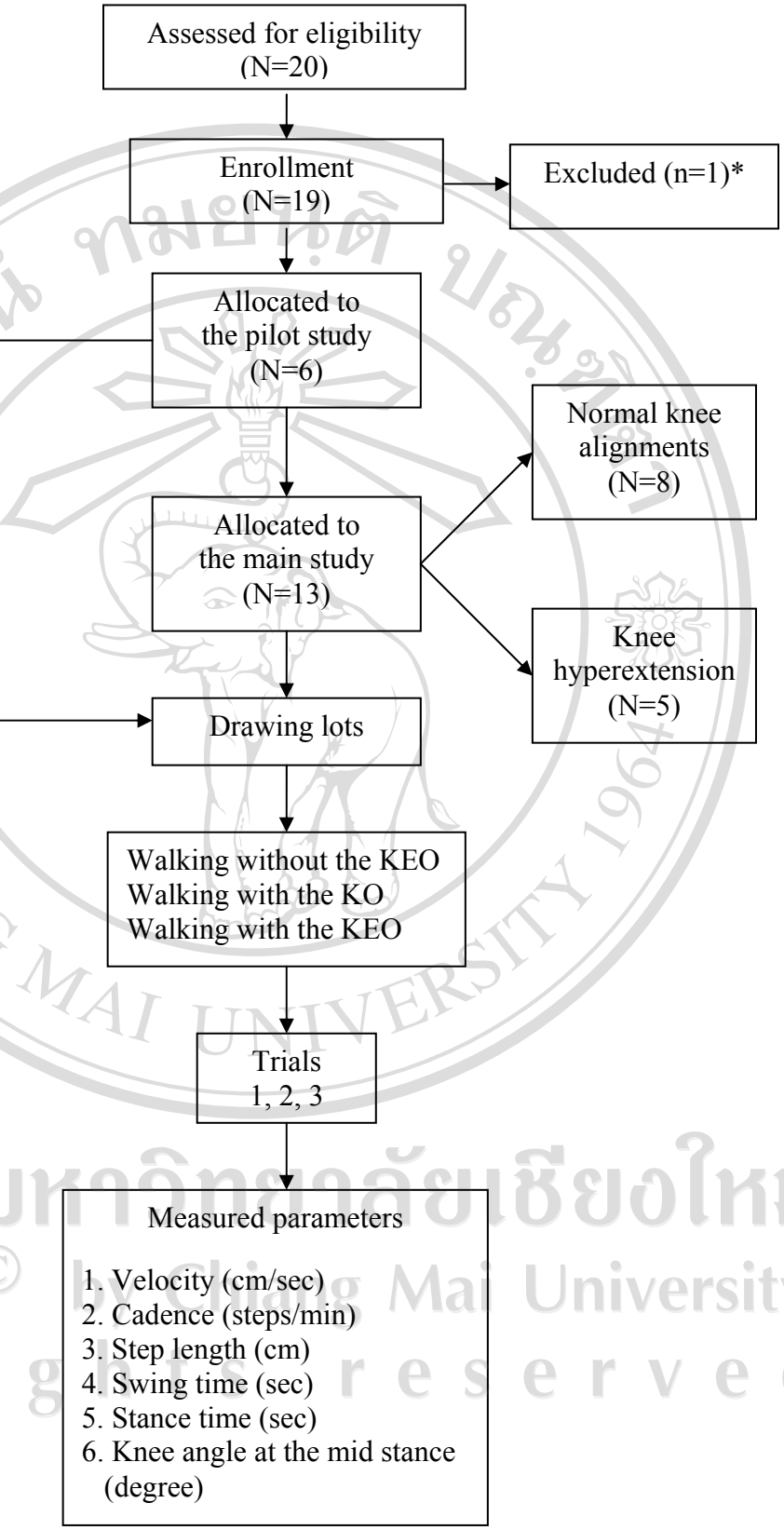

Figure 12 Flowchart of participants through the study. *FAC > 3

2.3 Equipments

1. The knee electro-orthosis; the electrical stimulator, the electrodes, the offset knee orthosis, and the knee switch or the foot switch sensor.
2. GAITRite® system automates (see detailed in Appendix F)
3. SiliconCOACH® digitizer
4. Sony® Handycam DCR-HC 90 E

2.4 Procedures

2.4.1 The first session of testing

Participants were screened using the inclusion and exclusion criteria. Information was given to the participants to inform the purposes and procedures of the study. All participants signed an inform consent before entry into the study. An offset knee orthosis was prepared for individual participants. The outline of the lateral aspect of the affected leg in the supine position was drawn on the paper for making the knee orthosis.

2.4.2 The second session of testing

Participants were requested not to take alcohol, stimulants (e.g. caffeine) or other medications for at least 6 hours prior to entering the experiment. The tester cleaned the skin at the quadriceps muscle for the electrode placing using 70% alcohol. The negative electrode was placed at the motor point of the rectus femoris and the positive electrode was placed at the vastus medialis. The 1-centimeter markers were attached to the participant at the greater trochanter, the lateral epicondyle of the femur, and the lateral malleolus. By drawing lots, the participants randomly selected the order of the three testing conditions. The electrical parameters were adjusted for the individual optimal walking performance and comfort. If participants had foot-drop, the

researcher resolved this problem by bandaging the foot. Participants practiced walking with the KEO on the standard GAITRite electronic walkway until they were familiar with the equipments and the condition. During testing, the researcher's assistant walked behind the participant to prevent falling. Participants were asked to walk rapidly but safely on the walkway for a distance of about 366 cm three times for each condition with a few minutes of resting or until patients feel ready to test the next trial. Five minute interval of resting was also allowed between each condition.

2.5 Data acquisition and analysis

2.5.1 The gait parameters consisting of velocity, cadence, step length, swing time, and stance time were measured using the GAITRite® system automates. The GAITRite® system automates has an electronic walkway connected to the serial port of the computer. The standard GAITRite® electronic walkway contains six sensor pads encapsulated in a roll up carpet to produce an active area 61 cm wide and 366 cm long (85). As the participant ambulates across the walkway, the pressure exerted by the feet onto the walkway activates the sensors. Data were transferred and analyzed using the GAITRite® system software.

2.5.2 The knee angle at the mid stance was measured using the SiliconCOACH® Digitizer. The tester attached the markers to the participants at the greater trochanter, the lateral epicondyle of the femur, and the lateral malleolus. The Sony® Handycam camera was used to record the participants' three walking trials of each condition. The video camera was placed perpendicular and at a distance of six meters from the GAITRite electronic walkway. The tester captured each walking trials of the participants and digitized markers for the measurement of the knee angle. A study of

the reliability of the knee angle was performed in four healthy subjects. The reliability of digitizing and attaching the markers were good (ICC (3, 1) ≥ 0.9).

2.6 Statistical analysis

Analysis was performed using the Statistical Package for the Social Sciences (SPSS) for windows, version 10.0. Descriptive statistics were performed for all variables measured. Regarding the within-subject design, the non-parametric Friedman Test (FT) and Post-hoc Wilcoxon Signed-Ranks Test (WT) were used to compare all variables of participants due to a small sample size. A significance level of less than or equal 05 was used in all the tests.

2.7 Location

The study was conducted in the laboratory room at the Department of Physical Therapy, Faculty of Associated Medial Sciences, Chiang Mai University.