CHAPTER V

DISCUSSION

1. The knee electro-orthosis and a switch sensor

The pilot study was performed to test if the KEO can be applied to the walking performance of patients with hemiplegia. Our KEO was designed for use in patients with hemiplegia who had quadriceps strength in the inner range, less than or equal to grade 3. Because the knee joint is the key to stance stability, and the quadriceps is the most direct source of extensor control (24) while standing and part of the stance phase while walking (31). We hypothesized that the KO combined with the quadriceps stimulation which was triggered by the knee switch sensor might improve patients' performance while walking.

Generally stroke patients with quadriceps weakness may learn to walk using different strategies to compensate for the knee extensor weakness. Some patients may be able to stabilize their knees in a rather flexed position but the others may extend their knees into a locking mechanism. Theoretically, our KEO should stimulate quadriceps at the loading response and mid stance phase of the gait cycle. The quadriceps stimulation at the proposed phase of gait cycle should add more stance stability. However, during testing, the researcher found that some participants could not properly extend their affected knees joint to compress the knee switch sensor. Thus, the knee switch sensor could not turn on the stimulator during the stance phase. Besides, in some participants, the stimulator did not turn off during the swing phase because of the locked knee problem. Therefore, using the KEO with knee switch sensor might not be suitable for patients who could not control the knee movement.

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To solve the inappropriate timing of quadriceps stimulation, the knee switch sensor was replaced with the foot switch sensor. The foot switch sensor, which was placed under the heel of the affected foot, turned on the stimulator when pressure was applied during the stance phase of the gait cycle. On the other hand, when the patient lifted the foot off the ground, the stimulator is turned off. Control of knee movement was less demanded to turn on and turn off the foot switch. Therefore, the quadriceps muscle was stimulated starting at the initial contact and was terminated at the terminal stance phase of the gait cycle. The foot switch is also convenient and uncomplicated for the patient and also provides a regulating signal to control electrical stimulation for selected gait events. Therefore, the KEO with the foot switch sensor was used in the main study. We found that the foot switch sensor showed better temporal control of the stimulator than the knee switch sensor.

It was also found that the knee orthosis was difficult to put onto the patient because of the long length of the orthosis and the semi-rigid thigh and calf bands which were hard to wrap tightly around the lower extremity. To solve these problems, we decreased the length and the width of the single bar of the KO, and the material used to make to thigh and calf bands. These changes made the KO easier to put on and off and also lighter. The weight of the KEO was 28.6 % lighter than that of a knee locker with closed-loop FES (8). The lighter of the KO is more desirable and may decrease the rate of muscle fatigue.

We also found that the instruction given to the patients might affect the results. At first, the researcher asked the participants to walk at a self-selected walking speed and found that the participants walked with different exertion for each condition. Gait performance showed a high variation between trials. Thus, the instruction given to

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the participants was changed, asking them to walk as fast as they could. We found that the participants presented the same effort in three different conditions when the command to walk as fast as possible was used.

The information from the pilot study suggested that we should adjust the KO and used the foot switch sensor to control the stimulator. Furthermore, patients should be requested to walk as fast as possible to ensure the same effort during different condition of testing.

2. The gait parameters in normal knee alignment walked without the KEO and with the KEO

In this study, the researcher studied the immediate effect of the KEO. The walking velocity and cadence improved significantly by 11.25% and 8.25%, respectively whereas the swing time of the affected side and stance time of the unaffected side were significantly decreased when the participants walked with the KEO. The mechanism of the improvement in gait velocity was discussed on page 69.

We could not find other studies that presented the immediate effect of KEO on the walking speed in stroke patients. However, the present results were in accordance with reports worked at the training effects of the KEO. Yu-luen Chan et al. (8) developed the knee locker with a closed-loop FES for patient with hemiplegia. This system was triggered by the foot switch to stimulate the tibialis anterior and the quadriceps muscles. The walking velocity and cadence significantly improved by 65.12% and 37.6%, respectively after the training period of 16 weeks.

Another study was performed in patients with paraplegia. Simcox et al. (81) developed a hybrid orthosis using the MMLO with a computer-controlled portable transcutaneous stimulator. The button switches mounted in the handles were used to

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stimulate the quadriceps of the swing leg while simultaneously stimulating the contralateral gluteal. The subject showed an increase in gait velocity from 10.2 cm/s to 12 cm/s after 18 months of training. In addition, Kagaya et al. (16) have designed an electrical knee lock system (AKJ) for a single patient with completed paraplegia. The quadriceps and iliopsoas muscle were stimulated. Walking velocity in the patient was increased from zero to about 10 cm/s after training 6 months.

At the end of the test period, subjects were asked for their opinions about walking with the KEO. Six participants responded that their walking was improved and that the KEO helped them during walking. Subjects reported that using the KEO allowed them to move their legs more easily; that the walking process could be completed with less effort and that the KEO also enhanced their sense of well-being. They would like to continue using the KEO for walking. Two participants indicated that walking with the KEO did not help. For all participants, stimulation did not induce complications requiring medical attention, such as skin burns, falls, or fractures, occurring during the testing. The KEO could increase the participant's feeling of safety and confidence in walking and therefore, as a result improve their walking performance.

3. The gait parameters in normal knee alignment walked without the KEO and with the KO

Only the cadence was significantly increased whereas the other gait parameters did not change when the participants walked with the KO compared to walking without the KEO. The offset knee axis is positioned behind the anatomical knee axis, increasing the biomechanical stability for the patients. The greater knee stability may be indirectly demonstrated by increasing of cadence. To our knowledge, there was no

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study determined the effect of the KO on the hemiplegic gait. Another study performed in patients with intact nervous system but had quadriceps weakness (86). These authors showed that with the Dynamic Knee Brace System, with sensors at the knee and footplate, the walking velocity and cadence immediately increased.

4. The gait parameters in normal knee alignment walked with the KO and with the KEO

The walking velocity, cadence, and the stance time of the unaffected side were significantly different when walking with the KEO compared to walking with the KO, whereas the other gait parameters did not change. These differences may result from the electrical stimulation on the quadriceps muscle during the stance phase.

Many reviewed articles have concluded that electrical stimulation can improve walking velocity in patients with hemiplegia (3, 5, 29, 46). However, these works stimulated different lower limb muscles. Robbins et al. (5) conducted a meta-analysis of the effectiveness of electric stimulation in poststroke rehabilitation. They concluded that FES significantly improved gait velocity. Most of the studies used the ODFS which provides electrical stimulation to the common peroneal nerve and motor point of the tibialis anterior muscle during the swing phase of gait cycle (3). The ODFS has been tested in a randomized controlled study, which demonstrated that the system increased walking speed and decreased walking effort (50). The Finetech Dropped Foot System® is a relatively new implanted system and increased walking speed by 24% (52).

Nevertheless, in the present study, a single-channel stimulator was used to stimulate the quadriceps muscle during the stance phase of gait cycle to preventing knee collapse and improving propulsion of walking. There was no study performed

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quadriceps stimulation in patient with hemiplegia. The previous studies were tested in the patients with complete SCI which required at least four channels of stimulation or more channels of stimulation may be needed for greater speed and better quality of gait (56). Kim et al. (73) has also reported moderate improvements in walking velocity 20% to 28% with FES-assisted walking in persons with incomplete SCI. Stein and colleagues (56, 57) studied such FES system with 1 to 4 channels in patients with SCI. They found that participants had better gait speed with FES than without it. In addition, the long-term study in the multicenter trial of FES for subjects with incomplete SCI was encouraging with a 45% increase in walking speed (56).

5. The gait parameters between normal knee alignment group and knee hyperextension group

The gait parameters of participants who had knee hyperextension were different from those with normal knee alignment. The walking velocity and cadence tend to decrease when patients with knee hyperextension walked with the KEO.

The hyperextended knee may be used to preserve weight-bearing stability during stance phase of the gait cycle when the quadriceps is incapable of controlling a flexing knee. Patients keeping the knee extended until the complete transfer of body weight to the other limb occurred (24). Patients may intentionally used this mechanism to prevent knee buckling (33) or may be due to their impotent knee control. Other mechanisms may cause the knee hyperextended problem, that is, the spasticity of the quadriceps, the spasticity of the gastrocnemius, the shortening of the gastrocnemius or the weakness of the gastrosoleus during the push off event of gait cycle (24, 87). Therefore, the knee hyperextension combined with the KEO may create too rigid knee movement and requires more effort to move the lower limb

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forward during the swing phase. This situation caused a decrease in walking velocity and cadence. As a result, it was concluded that the KEO with quadriceps stimulation was not suitable for the patients with hemiplegia who have knee hyperextension.

6. The mechanism of the KEO to improve gait performance

As normal people increase walking velocity, their cycle duration, single-limb support, and double limb support decrease while stride length and cadence increase (33). Walking velocity for normal subjects is strongly correlated with stance time but not with swing time (33), whereas walking velocity for the patients with hemiplegia correlated with both stance time and swing time of the affected limb (33). According to several researchers, the swing/stance ratio in patients with hemiplegia was reported abnormal. The swing/stance ratio was typically characterized by a shortened stance phase and lengthened swing phase in the affected leg when compared with that of normal subjects (33). The overall results of the compensatory movements generated by the patient with hemiplegia included a decrease in walking velocity with a shorter duration of stance phase, a decreased in weight bearing, and an increased in swing time of the affected leg. The unaffected leg has an increased stance time and decreased step length (7). This limitation in walking velocity may be associated with advancing the affected side inefficiently during swing and inappropriate shifting weight to the unaffected side during stance (33). The inability of the patients with hemiplegia to move their affected limb quickly through the swing phase may be an important factor that limits walking velocity (33).

In this study, it was clearly seen that using the simple KEO produces positive benefits for the patients with hemiplegia; the result was immediate improvement of the gait performance. The walking velocity and cadence were increased. The

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walking velocity was increased due to the improving of cadence. The cadence was increased through faster swing time of the affected side; consequently the stance time of the unaffected side shorter, while the step length did not change. The shorter of the swing time of the affected leg may be due to the indirect effect of KEO. The KEO provides greater knee stability during stance. This stability may promote the extension of the affected hip in the terminal stance phase. This hip extension in the terminal stance consequently facilitated hip flexion of the affected side in the swing phase (79, 81). Thus, the KEO may be associated with advancing the affected side efficiently in swing and in shifting weight to the affected side in stance.

The combination of the offset knee orthosis along with the electrical stimulation in the KEO creates superior advantages and produce positive benefits for the patients. The KEO assistance in counteracting the quadriceps' weakness may result from two factors. The first factor is the offset knee orthosis in which the hinge is aligned with its axis of rotation behind the midline of the leg, posterior to the axis of the anatomical knee. In early stance, during the period of double support, the ground reaction force passes close to the center of the axis of the offset knee orthosis, reducing the magnitude of the external flexion moment that is acting to flex the limb. With continued forward progression of the body, the ground reaction force quickly moves anterior to the offset knee orthosis. This creates an extensor force that mechanically augments stance phase stability during single limb support. Thus, it extends the knee and provides greater stability from the initial contact through midstance in the gait cycle and allows the joint to flex the knee freely during swing phase (21, 68). The second factor is the knee extensor torque produced by the stimulation. The electrical stimulation provides an additional means of propulsion, in

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addition to the patients' efforts alone, as the propelling force experienced without stimulation. Simcox et al (81) showed that the addition of a FES system to the MMLO provides an additional means of propulsion. The SCI subjects showed an increase in gait velocity, an otherwise impossible propulsion movement without the aid of FES. On the other hand, the electrical stimulation provided sensory feedback to participants. Evidence showed that afferent inputs evoked reached both sensory and motor cortices (88). Peurala et al (89) showed that cutaneous stimulation of the affected hand or foot improved limb sensation and motor performance together with somatosensory. The use of electrical stimulation as a biofeedback modality has proven very effective to increase volitional control (90). For this reason, the participants could have fast motor learning that is evidenced by initial within-session improvements across trials (91). Therefore, the participants demonstrated the indirect effect of the sensory feedback though the improvement of gait parameters.

7. The knee angle at the mid stance

The knee angle at the mid stance did not change when the participants walked with the KO and the KEO compared to walking without the KEO, both in the normal knee alignment and the knee hyperextension subgroups. The insignificant results may due to the small sample size and the variability of the knee angle during the stance phase, although the reliability of the knee angle measurement was high. The reliability test was performed using healthy subjects who did not use the KEO. In the actual study, the marker at the knee joint was placed on the offset knee orthosis, which may not be at the same location that we attached a marker to the skin, because of the movement of the orthosis during walking. Moreover, we used 2-dimension analysis which may not be sensitive enough to measure the changes of the knee angle

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in which the rotation of the hip joint may affect the view of the marker in the sagittal plane.

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CONCLUSION

It is concluded that this simple KEO immediately improved the gait performance, especially the walking velocity, cadence, swing time of the affected side, and stance time of the unaffected side in the patients with hemiplegia who had normal knee alignment. The KEO successfully provided knee stability during the stance phase in the gait cycle and improve propulsion of walking. In other words, the combination of the offset knee orthosis along with the electrical stimulation of the quadriceps creates superior advantages and produces positive benefits for the patients with hemiplegia who have normal knee alignment.

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CLINICAL APPLICATION

Concerning the results of this study, the developed KEO improved selected gait parameters for the participants with hemiplegia immediately after they used the KEO. If the patient were to train long term using the KEO, the researcher believes that it would result in positive long term effects for the patient. However, this assumption needs to be verified. The improvement in gait parameters when the KEO is used as a walking aid emphasizes the role of the KEO device as an important additional to treatment modality in rehabilitation after hemiplegia, although this project did not address this application. In the future, the KEO is an attractive device for several reasons: it is possible to perform the treatment modality within the hospital setup and the KEO treatment may shorten hospitalization and lower the economic burden of hospitalization. The KEO provides a possibility for prolonged and continuous treatment in the home due to the KEO being a friendly and convenient device.

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LIMITATION

One limitation of this study is the small sample size. A post hoc analysis found that the power of the tests were moderate. The KEO could not apply to the participants who had quadriceps spasticity more than 1+ of MAS and patients with knee hyperextension. Besides, the KEO with offset knee orthosis brings considerable stability during the stance phase on a flat floor, but instability when walking on an uneven road or a downhill slope. In addition, the characteristics of hemiplegic gait usually result from the impairments of the hip, the knee, or the ankle joint. The KEO function was focused on the management only the knee joint and can not remedy foot-drop problem during the swing phase of the gait cycle. Furthermore, the researcher could not measure knee stability of the affected side using weight-bearing measurement during the stance phase because of the limitation of the available equipment.

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FUTURE STUDY

In the future, a greater number of participants with hemiplegia must be recruited for testing and the tracking time of each patient's testing should also be prolonged. At the same time, an evaluation of the physiological aspects could be incorporated to prove more objectively that using the offset knee orthosis plus electrical stimulation can effectively assist the standing and walking performance of the affected side. These aspects could include oxygen consumption, blood pressure, PCI and even measurement of floor reaction forces. In addition, the stimulation of other muscles, such as the hip extensors which enhanced propulsion, could be achieved by adding an additional stimulation channels for the gluteal muscles. Furthermore, the KEO could not control ankle foot drop during swing phase. Therefore, the later study should add the AFO to the KEO. Future research may focus on the overall management of the hip, the knee, and the ankle joint in the patients with hemiplegia. Especially, the KEO should have the hyperextension stop of the knee joint set at a neutral position, by placing a guard against knee hyperextension. In addition, the stimulated muscle may change to the gastrocnemius or hamstring to help patients with knee hyperextension to unlock their extended knee during the stance phase. Moreover, at this early stage the KEO may be used as a training aid during standing and walking rehabilitation. In the situation where a patient is unable to walk, the KEO may decrease the task demand required for standing and weight-shifting. This idea can be further developed and determined in the future.

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