Hybrid Functional Electrical Stimulation with Medial Linkage Knee-Ankle-Foot Orthoses in Complete Paraplegics

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We have previously restored ambulation in paraplegics by performing hybrid functional electrical stimulation (FES) with medial linkage knee-ankle-foot orthosis (MLKAFO). The most common MLKAFO (hinge-type MLKAFO) has the hypothetical axis that is lower than the physiological hip joint position, resulting in slow velocity and short step length. A new MLKAFO (sliding-type MLKAFO), which uses sliding medial linkages, has been developed to correct the axial discrepancy of the hinge-type MLKAFO that causes limited hip joint excursion. There have been reports of instability associated with sliding medial linkages, but the mechanism of this instability is unclear. The purpose of the present study was to evaluate the effects of FES with MLKAFOs on ambulation in paraplegics. Two complete paraplegic patients (levels T8 and T12, respectively) participated in this study. Kinematics data during ambulation were obtained using a motion analysis system. We measured gait velocity and hip progression during the standing phase. The sliding-type MLKAFO produced faster gait velocity than did the hinge-type MLKAFO, but it caused pelvis instability without FES. Pelvis instability was controlled by hybrid FES using the sliding-type MLKAFO. With hybrid FES, the sliding-type MLKAFO provides better gait performance than the hinge-type MLKAFO, but the hinge-type MLKAFO provides greater pelvis stability during walking. Moreover, FES provides sufficient propulsion to allow the complete paraplegics to walk. Functional electrical stimulation; complete paraplegia; medial linkage knee-ankle-foot orthosis; ambulation

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Restoration of ambulation in paraplegics has physiological, psychological and functional benefits: reduction of osteoporosis and subsequent fracture, reduction of spasticity, maintenance of joint range of motion, and improvement of psychological well-being (Marsolais et al. 1991; Middleton et al. 1997). Because paraplegic gait has a high energy cost, we have performed hybrid
functional electrical stimulation (FES) using several types of orthotic devices (Fig. 1 A and B); we have obtained improved stability in the lower extremities using the Floor Reaction Orthosis (FRO), the Akita Knee Joint (AKJ), and the Reciprocating Gait Orthosis (RGO) (Kagaya et al. 1996). We have conducted several studies of use of hybrid FES to increase gait performance, prevent muscle fatigue and reduce energy consumption (Kagaya et al. 1996; Shimada et al. 2001, 

Fig. 1. Gait with hybrid FES using the medial linkage knee-ankle-foot orthosis in a complete paraplegic patient.
A: A T8 complete paraplegic patient can walk with the hybrid FES using the medial linkage knee-ankle-foot orthosis.
B: Medial linkage knee-ankle-foot orthosis.

Fig. 2. Axis of the hinge-type MLKAFO and the sliding-type MLKAFO.
A: hinge-type MLKAFO. B: sliding-type MLKAFO.
●, The axis of the joint is shown.
The hinge-type MLKAFO caused a twist in the pelvis rotation due to discrepancy of the hip joint.
The axis of the slide-type MLKAFO is close to the physiological hip joint. The sliding-type MLKAFO does not restrict movement of the pelvis.
Kirtley and McKay (1992) developed a hinge-type medial linkage knee-ankle-foot orthosis (hinge-type MLKAFO) (Fig. 2A). The hinge-type MLKAFO contains a medially mounted hinge joint that links two knee-ankle-foot orthoses, and has been found to help improve paraplegic ambulation (Middleton et al. 1998). The hinge-type MLKAFO produces stability during standing and walking, is wheelchair-compatible, has cosmetic benefits, and provides easy don-doff. The subject’s weight is shifted to the standing forward leg, and only a few degrees of tilt are needed to obtain clearance of the swinging leg using the effects of gravity (Harvey et al. 1997). However, the hinge-type MLKAFO has the hypothetical axis that is lower than the physiological hip joint position, resulting in slow velocity and short step length. Saitoh et al. (1997) developed a sliding-type MLKAFO (Fig. 2B), which resolves the axial discrepancy that causes the limited hip joint excursion of the hinge-type MLKAFO. The sliding-type MLKAFO has a virtual axis that is based on a sliding arc guide. The hip joint position of the sliding-type MLKAFO is nearer to the physiological hip joint position, compared to the hinge-type MLKAFO. Consequently, the sliding-type MLKAFO produces better results than the hinge-type MLKAFO in terms of walking velocity, step length and cadence.

The only reported studies of FES with MLKAFOs have involved hybrid FES with surface electrodes (Saitoh et al. 1997). However, surface electrodes have several disadvantages, including potential loosening, skin irritation, and poor cosmetic appearance. In addition, surface electrodes cannot stimulate deep muscles. Reliability is also a problem with surface electrodes, because small differences in electrode placement create large differences in response, and because habituation of the reflex can occur (Shimada et al. 1996a). FES with percutaneous intramuscular electrodes has been found to provide movement rapidly, controllably, quietly, efficiently and functionally (Peckham et al. 1980). Since 1990, we have used percutaneous intramuscular electrodes to restore movement in paralysed limbs (Shimada et al. 1996a, b).

Percutaneous intramuscular electrodes are practical for long-term use (Shimada et al. 1996a). However, there have been no English-language reports of hybrid FES using a combination of a MLKAFO and percutaneous intramuscular electrodes.

The purpose of the present study was to evaluate the effects of FES with MLKAFOs on ambulation in paraplegics.

Materials and Methods

The subjects were a 32-year-old man with T8 complete paraplegia and a 22-year-old man with T12 complete paraplegia. They were injured in traffic accidents 12 years and 8 years before the present study, respectively. Before this study, they could not stand or walk by themselves, and used a wheelchair for activities of daily living. We restored their ambulation by performing FES using percutaneous intramuscular electrodes (Shimada et al. 1996a). For the T8 paraplegia, we used 34 percutaneous intramuscular electrodes. The following areas received FES stimulation (Shimada et al. 1996b): the iliopsoas muscle (for flexion of the hip); the gluteus medius muscle, and the superior gluteal nerve (for abduction of the hip); the femoral nerve, the rectus femoris, and the quadriceps muscle including the vastus medialis and vastus lateralis (for extension of the knee); the hamstrings, and the common peroneal muscle (for dorsiflexion of the ankle); the gastrocnemius muscle (for plantar flexion of the ankle); the peroneous longus muscle (for eversion of the ankle); and the spinal erector muscles (for extension of the trunk). For the T12 paraplegic, the electrodes were inserted at the common peroneal nerves, to induce the withdrawal reflex.

Using a wheeled walker, the subjects walked for 5 meters at a self-selected speed using the hinge-type MLKAFO with FES, the sliding-type MLKAFO without FES or the sliding-type MLKAFO with FES. Each subject performed the trial 10 times. The kinematics data was obtained using a three-dimensional motion analysis system (PEAK, Peak Motus, Centennial, CO, USA). The movements of the markers were recorded at a frequency of 60 Hz using 6 infrared cameras. Each pair of cameras was placed 2.5 m above the ground. The coordinates of the light-reflecting markers were calculated using the PEAK system. Light-reflecting markers were placed on the following bilateral anatomic landmarks: acromions, elbows, processus styloideus, head of the third metacarpales, edge of the ribs, greater trochanter,
external part of the lateral femoral condyles, lateral malleoli, fifth metatarsal heads, calcaneus, top of the head, and sternum. Written informed consent was obtained from each subject.

An Akita Stimulator III was used for the FES. This apparatus has a 16-channel output (8 each for left and right), and each channel has a dial that controls its stimulation voltage. The conditions of electrical stimulation were the same as those used for therapeutic electrical stimulation (TES): a rectangular pulse with a width of 0.2 msec, a pulse interval of 50 msec, and voltage ranging from 0 to -15 volts. The stimulator has 2 pressure-sensor hand switches (1 each for left and right), and the region to be stimulated can be easily changed by pressing or releasing the switches. With the T8 patient, pressing the hand switch stimulated the psoas major muscle, the paraspinal muscle, and the rectus femoris muscle; and releasing the hand switch stimulated the gluteus maximus muscle and the long head of the biceps femoris muscle. The bilateral paraspinal muscles were continuously stimulated during walking. With the T12 patient, pressing the hand switch stimulated the common peroneal nerves, thus inducing the withdrawal reflex for hip flexion.

Using the PEAK motion analysis system, we measured gait velocity and the hip progression during the standing phase when the weight shifted to the forward limb. In the swing phase, the T12 paraplegic exhibited pelvis rotation on the stick picture of the bilateral greater trochanter on the horizontal plane. The center of gravity (COG) was calculated using Ae’s methods (Ae et al. 1992).

An unpaired t-test was used to compare gait velocity between the hinge-type MLKAF0 with FES and the sliding-type MLKAF0 with FES. An unpaired t test was used to compare hip progression between the hinge MLKAF0 and the sliding MLKAF0. For all statistical tests, a probability level of $p < 0.05$ was considered to indicate significance.

**RESULTS**

When the T8 paraplegic used the sliding-type MLKAF0 without FES, he reported pelvic instability during walking, particularly during the weight shift to the forward limb in the double stance phase. His pelvis was stabilized when he used the hinge-type MLKAF0 or the sliding-type MLKAF0 with FES. When the T12 paraplegic used the sliding-type MLKAF0 without FES, he felt no pelvic instability during walking.

**Gait velocity**

Using the hinge-type MLKAF0 with FES, the gait velocity was 5.2 ± 0.9 m/min for the T8 patient and 16.9 ± 0.6 m/min for the T12 patient. Using the sliding-type MLKAF0, the gait velocity was 9.3 ± 0.5 m/min for the T8 patient and 17.9 ± 0.4 m/min for the T12 patient. Using the sliding-type MLKAF0 with FES, the gait velocity was 12.8 ± 0.6 m/min for the T8 patient and 18.2 ± 0.8 m/min for the T12 patient (Table 1).

With both subjects, there was a significant difference in walking velocity between the sliding-type MLKAF0 with FES and the hinge-type MLKAF0 with FES ($p < 0.01$).

**Coordinates of hip progression during the double stance phase**

The coordinates of hip progression dramatically changed when the weight shifted to the forward limb during the double stance phase. With the T8 paraplegic, the hip position moved 1.1 ± 1.8 cm using the hinge-type MLKAF0 with FES, −2.4 ± 1.9 cm using the sliding-type MLKAF0 with FES, −2.4 ± 1.9 cm using the sliding-type MLKAF0 without FES, and −0.8 ± 2.3 cm using the sliding-type

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<th>Hinge-type with FES</th>
<th>Slide-type without FES</th>
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<tr>
<td>Gait velocity</td>
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<td>T8</td>
<td>5.2 ± 0.9</td>
<td>9.3 ± 0.5</td>
<td>12.8 ± 0.6</td>
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<td>T12</td>
<td>16.9 ± 0.6</td>
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<td>Hip progression</td>
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<td>T8</td>
<td>1.1 ± 1.8</td>
<td>2.4 ± 1.9</td>
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<td>T12</td>
<td>2.2 ± 1.7</td>
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MLKAFO with FES. With the T12 paraplegic, the hip position moved 2.2 ± 1.7 cm using the hinge-type MLKAFO with FES, 4.4 ± 2.8 cm using the sliding-type MLKAFO without FES, and 4.6 ± 3.3 cm using the sliding-type MLKAFO with FES. With the T8 patient, there was a significant difference in hip progression between the sliding-type MLKAFO without FES and the sliding-type MLKAFO with FES (p < 0.01). There was very little movement of hip position when the complete T8 paraplegic used the hinge-type MLKAFO, whereas hip position always clearly moved backward with the sliding-type MLKAFO. With the complete T12 paraplegic, the hip joint moved slightly forward using the hinge-type MLKAFO. With both paraplegics, the coordinates of the hip moved further forward during progression with the sliding-type MLKAFO than with the hinge-type MLKAFO (Table 1).

Pelvis rotation during the swing phase

With the T12 patient, during the swing phase, there was a great difference in pelvis rotation between the hinge-type MLKAFO and the

Fig. 3. The stick picture at the bilateral greater trochanter on the horizontal plane in the swing phase. It descripts the hip movement (the line between the bilateral greater trochanter) in the right swing phase. During the right swing phase, right hip move to posterior direction, therefore the velocity was decreased substantially in the hinge-type MLKAFO. On the other side, in the sliding-type MLKAFO, the right hip sway to the gait direction during the right swing phase.

Fig. 4. Velocity of COG on the sagittal plane. Use of the hinge-type MLKAFO markedly decreased COG velocity, causing the COG to move regularly. Use of the sliding-type MLKAFO only slightly decreased COG velocity, causing the COG to move irregularly.
sliding-type MLKAFO. Using the hinge-type MLKAFO, the hip moved opposite to the gait direction; using the sliding-type MLKAFO, the hip moved in the gait direction (Fig. 3).

**Velocity of the COG**

The velocity of the COG differed significantly between the hinge-type MLKAFO and the sliding-type MLKAFO. Use of the hinge-type MLKAFO markedly decreased COG velocity, causing the COG to move regularly. Use of the sliding-type MLKAFO only slightly decreased COG velocity, causing the COG to move irregularly (Fig. 4).

**DISCUSSION**

**Gait performance**

In the present study, the highest gait velocity was obtained using the sliding-type MLKAFO with FES, followed by the sliding-type MLKAFO without FES, and the hinge-type MLKAFO, in that order. The virtual axis of the sliding arc guide mechanism reduces the degree of freedom of the hip and pelvis motions, and produces high gait velocity and long stride by resolving the discrepancy between the axes of MLKAFO and the physiological hip joint. Middleton et al. (1998) developed an orthosis that resembles the sliding-type MLKAFO, and obtained results similar to those of the present study.

The FES system is useful for correction of paraplegic gait. The present stimulation method, using percutaneous electrodes, has the advantage that it stimulates deep muscles such as the iliopsoas muscle (Shimada 1996a, b, 2000). The stimulation of the iliopsoas muscles and the rectus femoris muscles makes it easy to swing the leg during the swing phase. In addition, stabilization of the standing leg and pelvis by FES greatly facilitates movement of the swing leg. Consequently, the hybrid FES causes an increase in gait velocity and step length, compared to orthotic walking. Hybrid FES using the sliding-type MLKAFO improves the walking parameters of paraplegics.

**Pelvis instability**

The present T8 paraplegic complained of pelvis instability using the slide-type MLKAFO in the standing phase, and preferred to use the hinge-type MLKAFO. It has been reported that sliding medial linkages can produce instability (Middleton et al. 1998). However, the mechanisms that cause such instability are unclear. Using the hinge-type MLKAFO, the bilateral hip joints moved only slightly when the weight shifted to the forward limb at the standing phase. In contrast, with the T8 paraplegic using the sliding-type MLKAFO, the hip joints always moved backward. The axis of the hinge-type MLKAFO was positioned 130 mm below the axis of the physiological hip joint position. When the leg swung forward, the hip joint on the same side was forced to move in the opposite direction (Fig. 2), not only restricting hip motion but also decreasing pelvis movement. Consequently, the pelvis and both legs were stabilized due to the fixation of the pelvis during walking. In contrast, the sliding-type MLKAFO did not produce restriction of the pelvis, due to the high degree of freedom. The hip joint moved backward due to resistance to the force in the posterior direction when the COG moved forward. For this reason, the sliding-type MLKAFO is associated with greater hip joint instability than the hinge-type MLKAFO.

Pelvis instability can be controlled by FES. In order to stabilize the pelvis using the sliding-type MLKAFO, the lower trunk must be controlled as follows: 1) stimulation of the paravertebral muscles, 2) coordination of the lower trunk muscles with the hip muscles, the gluteus maximum muscles, the iliopsoas muscles, the quadriceps muscles and the hamstrings. Stimulation of the paravertebral muscles and quadriceps muscles is especially important for lower trunk stability (Hatakeyama et al. 2000). FES with the sliding-type MLKAFO can substantially control pelvis instability.

Hybrid FES can improve paraplegic walking in several ways. The sliding-type MLKAFO is more suitable for hybrid FES than the hinge-type MLKAFO. The sliding-type MLKAFO provides high velocity during walking and high stability in
FES. Hybrid FES using the hinge-type MLKAFO provides the greatest stability in paraplegic walking.

**CONCLUSIONS**

With hybrid FES, the sliding-type MLKAFO provides better gait performance than the hinge-type MLKAFO. Moreover, FES provides sufficient propulsion to allow the complete paraplegics to walk. By reducing the degree of freedom in the hip joint, the sliding-type MLKAFO produces greater pelvis instability. By stimulating the trunk muscles and pelvis muscles, FES increases pelvis stability. Consequently, hybrid FES with the sliding-type MLKAFO improves gait performance and pelvis stability. For complete paraplegics, hybrid FES with the hinge-type MLKAFO provides greater pelvis stability during walking.

**References**


