Newly designed computer controlled knee-ankle-foot orthosis (Intelligent Orthosis)

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Abstract

The authors have developed a knee-ankle-foot orthosis with a joint unit that controls knee movements using a microcomputer (Intelligent Orthosis). The Intelligent Orthosis was applied to normal subjects and patients, and gait analysis was performed. In the gait cycle, the ratio of the stance phase to the swing phase was less in gait with the knee locked using a knee-ankle-foot orthosis than in gait without an orthosis or gait with the knee controlled by a microcomputer. The ratio of the stance phase to the swing phase between controlled gait and normal gait was similar. For normal subjects the activity of the tibialis anterior was markedly increased from the heel-off phase to the swing phase in locked gait. The muscle activities of the lower limb were lower in controlled gait than in locked gait. The ground reaction force in locked gait showed spikes immediately after heel-contact in the vertical component, and unusual patterns were observed at heel-contact in the sagittal and lateral component. Therefore, compared to locked gait, gait with the Intelligent Orthosis is smooth and close to normal gait from the viewpoint of biomechanics. Even in patients with muscle weakness of the quadriceps, control of the knee joint using the Intelligent Orthosis resulted in a more smooth gait with low muscle discharge.

Introduction

Recent advances in electronics and control engineering have been introduced into the medical field. In rehabilitation medicine, a walking rehabilitation robot (Siddiqi *et al.*, 1994) and a trans-femoral prosthesis in which the swing phase is controlled by a microcomputer according to the walking rate (Nakagawa *et al.*, 1985) were developed and have been put to practical use. In orthoses, joint units have been improved to control joint movements. However, in the knee-ankle-foot orthoses presently used, the support of the joint is considered to be more important than its mobility, and the knee is locked during walking. Therefore, patients generally use such an orthosis only during walking training and not in daily life.

The authors have developed a knee-ankle-foot orthosis with a metal upright containing a joint unit that controls the angle and strength of knee fixation (Intelligent Orthosis: IO). This orthosis can be used according to the degree of functional impairment in various activities of daily life.

An IO was applied to normal subjects and patients with muscle weakness of the quadriceps, and gait analysis was performed identifying, muscle activities of the lower limb, and the ground reaction force.

Constitution of IO and control method

The IO consists of a microcomputer (PC-9801NS/A, NEC Co Ltd), a brake controlling the braking power (internally expanding hub brake for wheelchairs), a servomotor as the power source of the brake (Digital AC Servo Motor-BNE006BC, Driver-DSAOS, Waco Co Ltd), a rotary encoder for detection of the angle of the knee (Micro Encoder, Microtech Laboratory Co Ltd), a heel switch (on-off type contact switch), and a knee-ankle-foot orthosis with a metal upright (KAFO). The entire orthosis weighs 4.2 kg. The microcomputer, the

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Microcomputer

Driver of the Servomotor
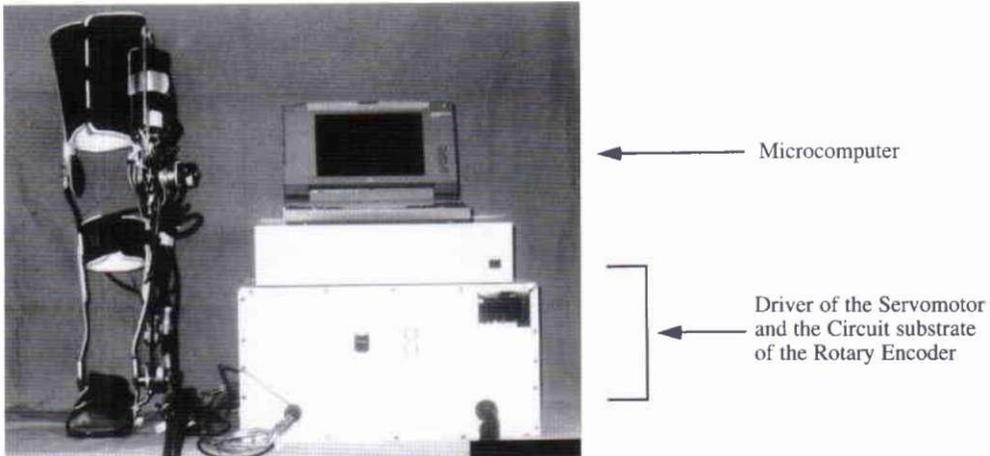and the Circuit substrate
of the Rotary Encoder

Fig. 1. Intelligent Orthosis (pat. 594050898).

driver of the servomotor and the circuit substrate of the rotary encoder were connected to the brake and the servomotor using 3 codes. The brake and the servomotor were placed on the lateral side of the femoral portion of the KAFO, the rotary encoder was placed on the lateral side of the knee and the heel switch was attached to the heel (Fig. 1). For the control of the knee, the resistance to joint movements was increased from the late swing phase so as to fix the knee at the time of heel-contact and it was decreased at the time of heel-off to release the fixation. The brake that adds resistance to the knee was controlled by inputting the knee flexion angle detected by the rotary encoder and signals from the heel switch into the microcomputer and sending commands from the microcomputer to the servomotor. The operation of the brake was initiated by signals from the rotary encoder and discontinued by signals from the heel switch (Fig. 2).
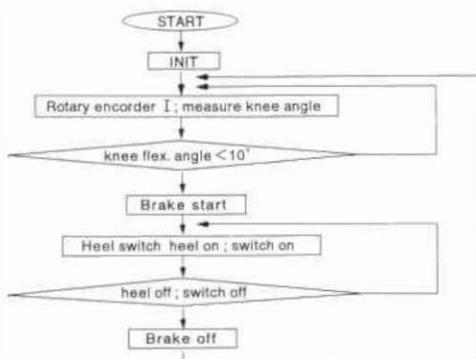
The brake provides braking torque when it is connected to the servomotor via the screw nut, and the servomotor rotates. To examine the characteristics of the braking torque of the brake, a weight was applied at a site 40 cm from the rotational centre in joint extension, and the maximum weight that allows maintenance of joint extension was measured. The maximum braking torque was 28.81 Nm at the extension position of the joint. A marked positive correlation ($r=0.983$, $p<0.0001$) was observed between the braking torque of the brake and the rotation rate of the servomotor (Fig. 3).

Subjects and methods

The subjects were 15 healthy adult males aged 20-35 years (mean, 26.8 ± 4.2 years). An IO was applied to the left lower limb.
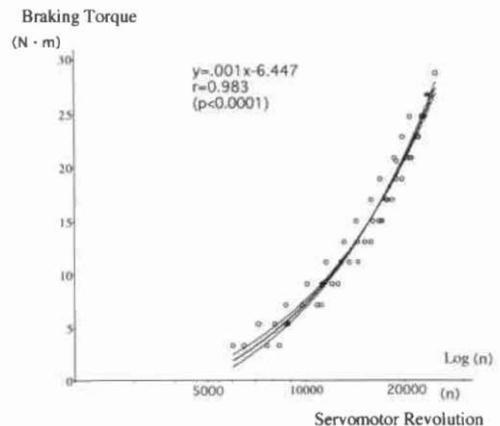

Fig. 2. Flow chart of control programme.

Fig. 3. The Relationship between braking torque and servomoter revolution in the experimental study.

The subjects were requested to walk: 1) without the orthosis (normal gait); 2) with an IO without knee fixation using the ring lock (braced gait); 3) with the knee fixed in extension (locked gait); and 4) with the knee controlled using a microcomputer (controlled gait). Gait analysis was performed based on measurements values in each phase of the gait cycle (Dubo *et al.*, 1976; Winter *et al.*, 1972), records of muscle activities of lower limb muscles on dynamic electromyograms (EMGs) (Bigland-Ritchie *et al.*, 1978; Bogery *et al.*, 1992; Branch *et al.*, 1989; van Lent *et al.*, 1994; Winter and Yack, 1987; Winter and Sienko, 1988), and results of the measurements of the ground reaction force (Engsberg *et al.*, 1993; Hermodsson *et al.*, 1994).

In the gait cycle, the period from heel-contact to toe-contact was defined as the early stance phase (heel-strike), that from toe-contact to heel-off as the mid-stance phase flatfoot, that from heel-off to toe-off as the late stance phase (heel-off), and that from toe-off to heel-on as the swing phase. The ratio of each phase to the gait cycle was calculated, and each gait was compared with normal gait. The events in the gait cycle were identified using a foot switch sensor system (Takei Kiki Co Ltd, T.K.K., 1901), and the foot pressure was detected at 3 sites, i.e., the heel, head of the first metatarsal bone, and the head of the fifth metatarsal bone.

Muscle activities of the lower limb were measured on the vastus medialis (Vm), rectus femoris (Rf), biceps femoris (Bf), tibialis anterior (Ta), and lateral head of the gastrocnemius (Gl) with surface electrodes using a Synafit 1000 (band pass filter 5-500 Hz, NEC San-ei Co Ltd). Surface electrodes were attached in parallel to muscle fibre arrangement with the motor point of each muscle between them (Warfel, 1974). The EMG records were analogue/digitally (A/D) converted and converted into those per gait cycle by full-wave rectification. Data for 10 steps were added and averaged. In addition, the obtained waves were integrated, and the discharge in each muscle during walking was obtained. The percentage of the muscle discharge to that during the maximum voluntary muscle contraction per unit of time in the manual muscle testing position was calculated as percent manual muscle test (%MMT) (Perry *et al.*, 1985/86). The discharge during the maximum voluntary muscle contraction in the manual muscle testing

position was measured in the sitting position at rest (hip flexion, 90°; knee flexion, 90°; ankle neutral position). Dynamic EMG records were processed (A/D conversion, full-wave rectification, averaging addition, and standardization) using a Signal Processor DP-1100 (sampling rate 5,000 points, NEC San-ei Co.Ltd). The discharge pattern of muscle activity during walking was compared using %MMT, and the amount of muscle activity using full rectified waves (Hong *et al.*, 1990; Winter, 1984; Winter, 1985).

The ground reaction force, vertical (Fz), sagittal (Fx), and lateral (Fy) components were recorded using a one-layer frame type Osaka Electro-Communication University force plate (15 cm x 33 cm) with the natural frequencies as shown in Table 1. (The measurement plane of this plate is supported by 4 struts for detection in the horizontal direction and 4 for detection in the vertical direction, and the distortion of these struts and the moment are measured.) This force plate was buried on the left side in the middle of a walking route (10 m), and ground reaction force as recorded. The obtained ground reaction force waves were normalized for body weight and the stance time, and data for 5 steps were added, averaged, and standardized (Engsberg *et al.*, 1993).

Measurement of each phase in the gait cycle and recording of dynamic EMG and ground reaction force were performed after the subject's gait became constant by practice.

Gait analysis was performed in 10 patients with decreased strength of the quadriceps muscle of the left lower limb (Table 2). With informed consent for this experiment from the patients, an IO was applied to the left lower limb. The gait cycle, muscle activities of the lower limb during walking, and ground reaction force (vertical and sagittal components) were measured. Locked gait and controlled gait were analysed.

Statistical analysis of difference was performed on Apple Macintosh system (Coppertino, California) using Microsoft Excel (Microsoft,

Table 1. The sensitivity of the force plate.

	Sensitivity	Natural frequency
Fx	30μ ╱ 980 N	1300 Hz
Fy	380μ ╱ 980 N	391 Hz
Fz	30μ ╱ 980 N	1300 Hz

Table 2. Patient profile.

Number	Age	Diagnosis	Operation	Post operation
1	46	Medial meniscus tear	Scopic partial menisectomy	1 week
2	21	Chondromalacia patellae	Scopic lateral release	1 week
3	23	Anterior cruciate ligament rupture	Reconstruction of ligament	1 month
4	36	Anterior cruciate ligament rupture	Reconstruction of ligament	1 month
5	22	Chondromalacia patellae	Scopic lateral release	1 week
6	32	Medial meniscus tear	Scopic partial menisectomy	1 week
7	25	Medial meniscus tear	Scopic partial menisectomy	1 week
8	67	Patellae tendon old rupture	Reconstruction of ligament	1 month
9	29	Fracture of femoral shaft	Open reduction and internal fixation	2 weeks
10	26	Fracture of femoral shaft	Open reduction and internal fixation	2 weeks

Redmont, Washington) and Statview (Abacus Concepts, Berkeley, California) software.

Results

Measurement of gait cycle

Gait analysis in terms of gait cycle was performed in 10 normal subjects in whom the gait cycle was clearly identified.

On the left side (braced leg side), the ratio of the stance phase to the gait cycle in locked gait was reduced. Significant differences were observed between normal gait and braced gait ($p<0.05$) or locked gait ($p<0.01$) but not between normal gait and controlled gait (Table 3). On the right side (non-braced leg side), the ratio of the stance phase to the gait cycle in controlled gait was increased. A significant difference was

observed between normal gait and controlled gait ($p<0.05$) but not between normal gait and braced gait or locked gait (Table 3). The ratio of the stance phase on the left side (braced leg side) to that on the right side in controlled gait was increased. A significant difference was observed between normal gait and locked gait ($p<0.05$) but not between normal gait and braced gait or controlled gait (Table 4).

Muscle activity of lower limbs as identified by dynamic EMG

The discharge pattern of the muscle (Fig.4)

Concerning the discharge pattern of the lower limb muscles in normal gait, vastus medialis (Vm) and rectus femoris(Rf) showed activity during the transition from the swing to stance

Table 3. The ratio of the stance phase in the gait cycle (10 healthy volunteers).

phase / gait	Braced leg				Non-braced leg
	Heel-strike	Flat-foot	Heel-off	Stance	Stance
Normal gait	0.08±0.03	0.35±0.04	0.18±0.04	0.61±0.03 [a,b]	0.60±0.03 [c]
Braced gait	0.10±0.03	0.32±0.05	0.20±0.05	0.62±0.03 [a]	0.60±0.03
Locked gait	0.10±0.04	0.30±0.09	0.17±0.06	0.57±0.03 [b]	0.62±0.03
Controlled gait	0.10±0.03	0.31±0.03	0.20±0.06	0.61±0.04	0.64±0.04 [c]

n = 10 (Mean±SD)
a,c: p<0.05   b: p<0.01
Wilcoxon signed-rank test

Table 4. The ratio of the stance phase of non-braced leg: comparison with the stance phase of braced leg (10 healthy volunteers).

Non-braced leg Stance / Braced leg Stance	Normal gait	Braced gait	Locked gait	Controlled gait
	0.98±0.04	0.98±0.04	1.08±0.05 *	1.03±0.04

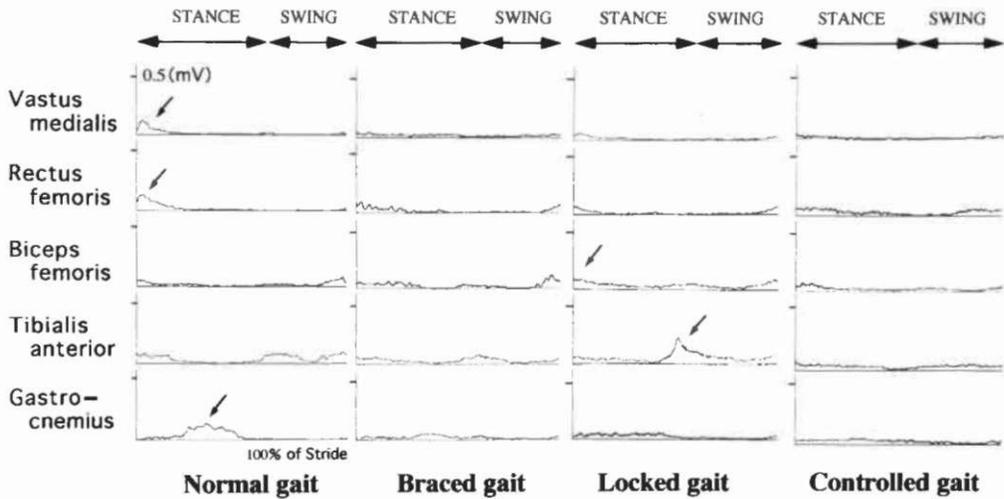n = 10 (Mean±SD)   *p<0.05
Wilcoxon signed-rank test

Fig. 4. Normalised fully rectified EMG of healthy volunteers.

phase and especially marked activity in the heel-strike. These findings were consistent with previous reports (Kameyama *et al.*, 1990; Kameyama *et al.*, 1994). Biceps femoris(Bf) showed activity in the bilateral leg support phase before and after heel-contact, and tibialis anterior (Ta) in each transition phase to the stance phase or to the swing phase. Lateral head of the gastrocnemius(G1) exhibited activity in the entire stance phase and especially marked activity in the heel-off phase. The state of muscle activity was compared among gait types. The activities of Vm and Rf observed in the heel-strike phase in normal gait were decreased in braced gait, locked gait, and controlled gait. The activity of G1 observed in the heel-off phase in normal gait was also decreased in the 3 gait types. On the other hand, the activity of Ta observed from the heel-off phase to the swing phase in normal gait was markedly increased in locked gait. The activity of Bf did not markedly differ among the 4 gait types.

Muscle discharge (Fig. 5, Table 5)

The percent manual muscle test (%MMT) values for Vm, Rf, and Ta were higher in braced gait and locked gait than in normal gait, showing
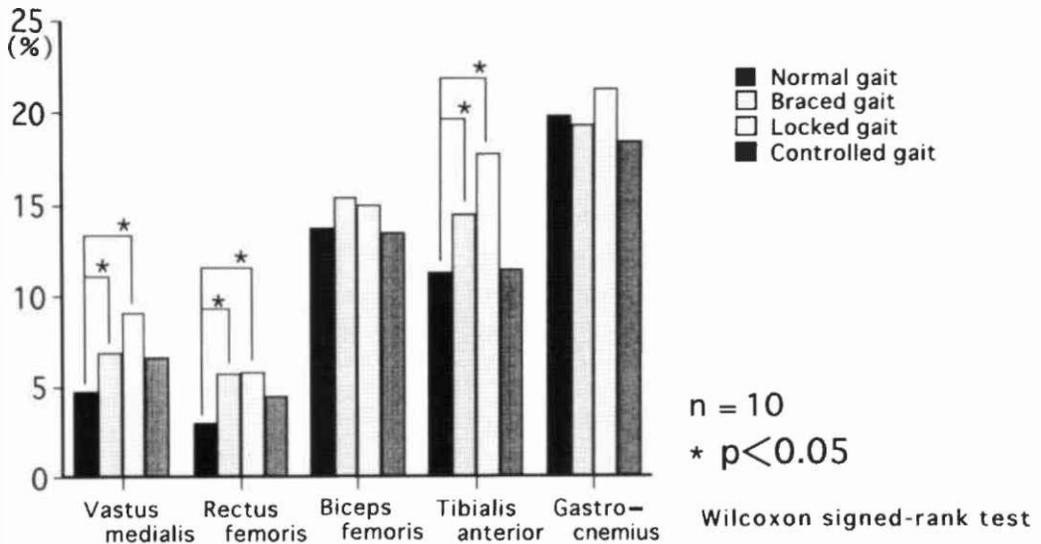

Fig. 5. %MMT of normalised fully rectified EMG (10 healthy volunteers).

Table 5. %MMT of normalised fully rectified EMG (10 healthy volunteers).

gait \ muscles	Vastus medialis	Rectus femoris	Biceps femoris	Tibialis anterior	Gastrocnemius
Normal gait	4.73±1.70 [a] [b]	2.80±2.03 [c] [d]	12.45±3.10	11.45±1.18 [e] [f]	19.83±5.91
Braced gait	7.28±0.85 [a]	5.88±0.65 [c]	16.38±2.04	14.05±1.47 [e]	19.83±8.59
Locked gait	7.46±2.09 [b]	5.30±0.33 [d]	15.90±2.92	17.30±3.83 [f]	18.83±6.44
Controlled gait	5.53±1.03	4.65±0.99	14.05±4.13	9.65±2.51	18.68±5.84

$n = 10$ (Mean±SD)
a,b,c,d,e,f: $p < 0.05$

a significant difference between normal gait and braced gait ($p<0.05$), but they did not markedly differ between controlled gait and normal gait. The %MMT values for Bf and G1 did not markedly differ between normal gait and other types of gait. All 5 muscles showed a lower %MMT in controlled gait than in braced or locked gait.

Ground reaction force

The ground reaction force waves are shown in figure 6. In normal gait, vertical component waves showed a nearly trapezoid pattern with two peaks indicating a deceleration phase and an acceleration phase. Sagittal component waves consisted of waves in a deceleration phase and those in an acceleration phase, and these waves showed similar patterns with the baseline between them. Lateral component waves consisted of a wave indicating inward force and that indicating outward force; the former showed a positive value, and the latter, a negative value. When the types of gait were compared, the vertical component showed spikes immediately after heel-contact in locked gait but not in normal or controlled gait. In the sagittal component, the maximum value in an acceleration phase was higher, and its rise was more acute in locked gait than in normal or controlled gait. In the lateral component, a large outward wave was observed at the time of heel-contact in locked gait. The wave patterns of the sagittal and lateral components in controlled gait were similar to those in normal gait.

Clinical cases

After application of an IO to the 10 patients with muscle weakness of the quadriceps in the left
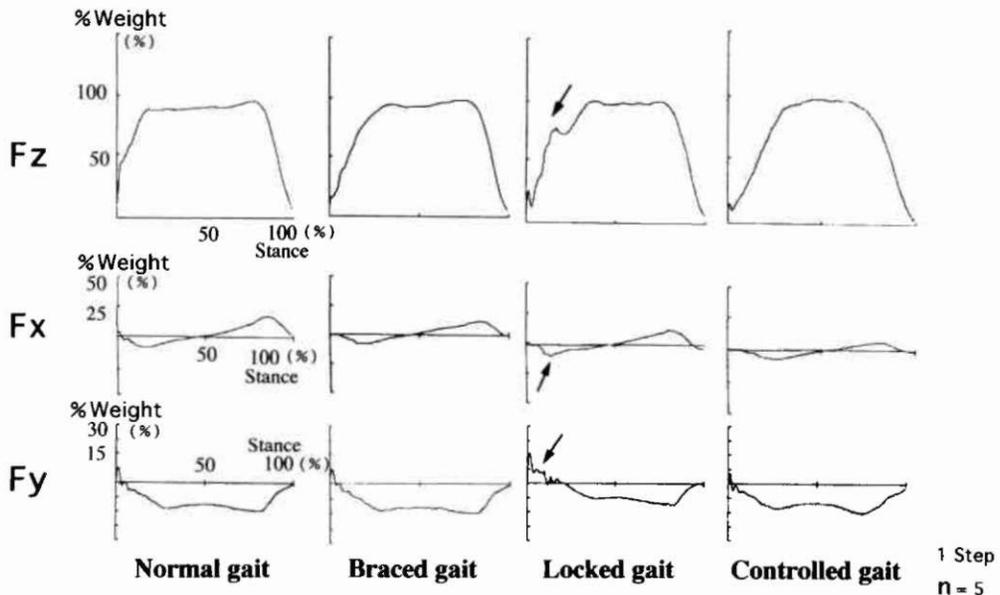

Fig. 6. Normalised ground reaction force of healthy volunteer.

Fig. 7. Walking with IO (Case 1: 46y, M, meniscus tear).

Fig. 8. %MMT of normalised fully rectified EMG of a patient (Case 3: 23y, M, ACL rupture).

lower limb, the gait cycle, the muscle activity of the lower limb during walking, and ground reaction force (vertical and sagittal components) were measured. In all patients, walking without aid was difficult due to buckling during walking, but the use of the IO enabled safe walking. However, the patients reported that the brace is too heavy and complained of fatigue after walking for a long time (Fig. 7).

In a patient with chondromalacia patellae showing a postoperative muscle weakness of the quadriceps, the gait cycle was measured in locked gait and controlled gait. On the left side (braced side), the ratio of the stance phase to the gait cycle was shorter in locked gait than in controlled gait. The ratio of the stance phase on the right side (non-braced side) to that on the left side was increased in locked gait (Table 6).

In a patient with anterior cruciate ligament rupture showing a postoperative muscle weakness of the quadriceps, the muscle discharge was compared between locked and controlled gait. The %MMT values for Bf, Ta and G1 were lower in controlled gait than in locked gait (Fig. 8).

In a patient with meniscus tear showing a postoperative muscle weakness of the
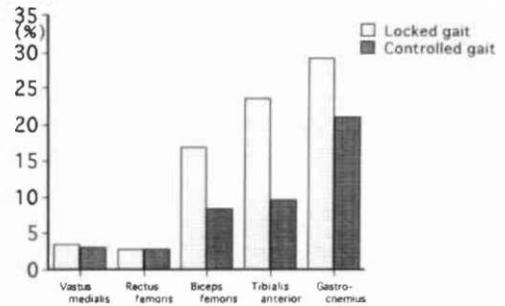
quadriceps, ground reaction force waves were compared between locked gait and controlled gait. In the vertical component, spikes were observed immediately after heel-contact in locked gait. In the sagittal component, the maximum value of the deceleration phase component was higher, and its rise was more acute in locked gait than in controlled gait (Fig. 9).

Discussion

Various devices have been reported to control the mobility and support of the joint unit in limb prostheses. As a result trans-tibial prostheses in which the swing phase of the shank is controlled using a computer were developed and have been put into practical use. In the orthotic field, knee-ankle-foot orthoses with a pelvic band such as the hip guidance orthosis (HGO) or a reciprocating gait orthosis (RGO) have been developed as functional orthoses (Beckham, 1987; Douglas et al., 1983; Major et al., 1981; Petrofsky and Smith, 1991). However, there have been few studies on the joint unit of orthoses to control joint movements, and only a few have been put into practical use. Unlike lower limb prostheses, an affected limb is present for orthoses wearers. Therefore, the method and mechanism of the control of joint movements used in lower limb prostheses can

Table 6. The ratio of the stance phase in gait cycle of a patient
(Case 2: 21y, M, chondromalacia patellae)

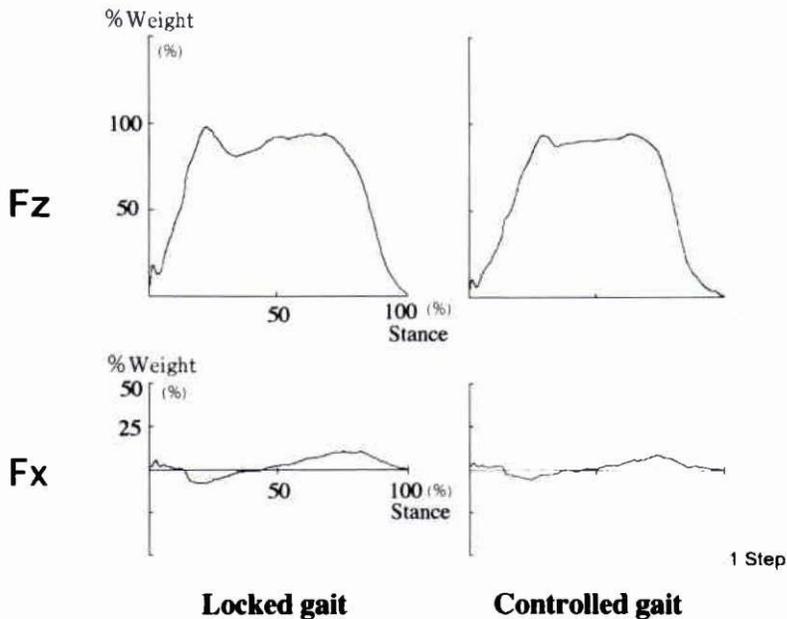| gait \ phase	Braced leg stance	Non-braced leg stance	Non-braced leg stance / Braced leg stance
Locked gait	0.56±0.01	0.68±0.01	1.21
Controlled gait	0.61±0.04	0.67±0.03	1.12

(Mean±SD)

Fig. 9. Normalised ground reaction force of a patient (Case 7: 25y, M, meniscus tear).

not be applied to orthoses.

In the orthotic field, the authors developed a knee-ankle-foot orthosis with a knee unit that allows control of joint movements using a computer (IO). To evaluate the effects of the use of his IO on gait, gait analysis was performed measuring the muscle activity of the lower limb and the ground reaction force.

On the left side (braced side), the stance phase was shorter in locked gait than in normal gait. The ratio of the stance phase on the right side (non-braced side) to that on the left side was the highest in locked gait. Gait analysis showed that controlled gait is closer than locked gait to normal gait. However, on the right side, the stance phase was longer in controlled gait than in normal gait. This may be due to the weight of the IO.

In locked gait, since the knee cannot be flexed, the lower limb is abducted, resulting in circumduction gait. Therefore, from the heel-off phase to the swing phase, the ankle is dorsiflexed. Dynamic EMG showed abnormal discharge in Ta only in locked gait. In controlled gait, the activities of Vm and Rf were decreased in the heel-strike phase compared with normal gait. These decreases may be due to adequate knee fixation using the IO.

In locked gait, the lower limb swings downward from the lateral to the medial side, and the knee that absorbs the impact at the time of the heel-contact is fixed. Therefore, an acute large braking force acts on the ground at the time of heel-contact. Each component of the ground reaction force showed spikes suggesting strong impact only in locked gait. Controlled gait did not show the abnormalities observed in locked gait.

Recently, rehabilitation for various diseases such as cerebral palsy has been actively initiated in an early stage. However, since the physical function markedly changes in patients during early therapy, changes in their pathological condition cannot be promptly coped with using the present orthoses. The authors designed an Intelligent Orthosis with a joint unit that controls movements of the knee joint for the purpose of adjusting to the degree of functional impairment and changes in pathological conditions.

In the IO, the driver of the servomotor, the circuit substrate of the rotary encoder, and the microcomputer are placed outside. The output capacity of the servomotor was 60 Watt. Improvement in the material of the IO, the performance of the brake, and the output capacity can reduce the weight of the IO to make it portable.

Conclusion

1. A knee-ankle-foot orthosis was developed with a joint unit that controls knee movements using a microcomputer (Intelligent Orthosis).

2. Analysis of the gait cycle, the muscle activity of the lower limb, and the ground reaction force suggested that gait with control of knee movements using an Intelligent Orthosis is closer than knee-locked gait to normal gait in terms of the gait cycle and the state and amount of muscle activity.

3. In patients with muscle weakness of the quadriceps, the control of knee movements using an IO allowed smoother gait with lower muscle discharge than knee-locked gait.

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