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Ankle foot orthosis that prevents slippage for tibial rotation in knee osteoarthritis patients*

Go Katsube[1], Song Qi[2], Taku Itami[3], Ken'ichi Yano[4], Ichidai Mori[5], Kazuhiro Kameda[6]

Abstract— **Knee osteoarthritis (OA) is a disease caused by age-related muscle weakness, obesity, or sports injury that leads to gait disability due to pain during walking. Knee OA is characterized by abnormal knee joint alignment and rotational dyskinesia, which are believed to worsen the symptoms. We previously developed an ankle orthosis that mechanically induces the rotation of the lower limb in conjunction with that of the ankle joint. This orthosis can effectively correct the alignment of the knee joint. However, slippage between the orthosis and leg can occur during walking, decreasing the corrective force. In this study, we clarify the effect of slippage between the orthosis and body on the correction force of the orthosis, and develop a lower leg tracking mechanism to suppress slippage and minimize reduction of force. The effectiveness of the proposed mechanism was evaluated by three-dimensional motion analysis of gait. Analysis results confirmed that the proposed mechanism was effective in suppressing slippage and improving correction force, demonstrating the effectiveness of the mechanism for knee OA.**

I. INTRODUCTION

Knee osteoarthritis (OA) is the most frequent form of lower limb arthritis. It is a degenerative disease that is expected to become more common with the rapid aging of the population, and it is estimated that one in two people in the United States will develop OA by the age of 85 [1]. The most common treatment for OA is conservative therapy, with surgical treatment also performed depending on the symptoms. Conservative therapy includes exercise, medication, and physical therapy. In severe cases where the knee joint is deformed inward, knee and plantar orthoses are also used [2]. However, in patients with grade Ⅱ-Ⅲ OA of the Kellgren-Lawrence classification, the inner knee deformity becomes more prominent [3], which may render the orthosis ineffective.

In addition, as the grade of the knee joint worsens, the internal stability of the knee decreases, resulting in lateral thrust in which the knee swings outward and knee rotation abnormalities occur. A report examining the relationship between lateral thrust and rotation found that to reduce lateral thrust during the stance phase, it is important to elicit normal rotation [4]. Therefore, we developed an orthotic device to induce rotation [5]. The developed orthosis (hereafter, the rotational orthosis [RO]) featured a newly developed ankle joint with different shapes on the inner and outer sides. It worked by inducing tibial rotation in conjunction with plantar dorsiflexion of the ankle joint during walking. In addition, the RO functioned to maintain the normal inclination angle of the lower leg by supporting the inner side, thus correcting knee alignment.

When we evaluated the orthosis using three-dimensional (3D) motion analysis of the gait of healthy subjects, however, we found that the amount of correction was insufficient. In addition, it was found that there was a slippage between the RO and the body during walking. It is assumed that slippage was the reason for the decreased amount of correction. Results of the 3D motion analysis suggested that a significant deformation of the cuff during the induction of rotation motion was the cause of the slippage. Therefore, we propose here a mechanism that rotates the bilateral bars in accordance with the lower leg when inducing the rotation movement, thereby suppressing deformation of the cuff and reducing orthotic slippage. To evaluate the effectiveness of the proposed orthosis, we compare orthosis slippage and knee joint alignment in four healthy males in their 20s while walking with the original and revised orthoses.

II. ORTHOSIS WITH A MECHANISM TO INDUCE TIBIALROTATION MOVEMENT

The RO focuses on the change in the angle of plantar dorsiflexion of the ankle joint, and that in the angle of tibia rotation during walking (Fig.1) in order to induce rotation in the knee joint. In normal gait, the ankle joint plantar flexes from 0[%]-15[%] in the early stance phase of the gait cycle, and then dorsiflexes in the late stance phase. It can be seen that plantar dorsiflexion of the ankle joint occurs at the same time as tibial rotation. The magnitude of tibial rotation is about 8-9 [deg] for both internal and external rotation.

The RO has a mechanism to induce tibial rotation in conjunction with ankle joint motion by adjusting the height of the rotational axis and the range of motion; this is accomplished by attaching a double Klenzack joint to the inner ankle joint axes and a ball joint to the outer part, respectively. As shown in Fig.2, the mechanism induces tibial rotation in conjunction with ankle joint motion. We

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[1]Go Katsube is with Department of Mechanical Engineering, Mie University, Tsu-City, Mie, Japan katsube.go@robot.mach.mie-u.ac.jp

[1]Song Qi is with the Department of Mechanical Engineering, Mie University, Tsu-City, Mie, Japan sai@robot.mach.mie-u.ac.jp

[1]Taku Itami is with the Department of Electrical Engineering and Electronics, Aoyama Gakuin University, Shibuya-Ward, Tokyo, Japan itami@ee.aoyama.ac.jp

[1]Ken'ichi Yano is with the Department of Mechanical Engineering, Mie University, Tsu-City, Mie, Japan yanolab@robot.mach.mie-u.ac.jp

[2]Ichidai Mori is with the Keiai Orthopedic Appliance CO., Ltd, Saitama-City, Saitama, Japan mori@kioa.co.jp

[2]Kazuhiro Kameda is with the Keiai Orthopedic Appliance CO., Ltd, Saitama-City, Saitama, Japan tenkazu@kioa.co.jp

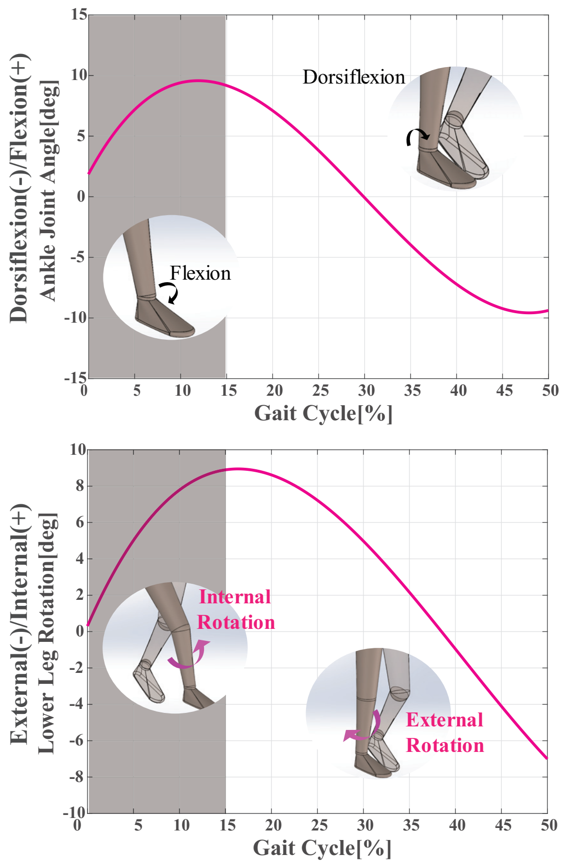

Fig. 1. Relation between ankle dorsiflexion and tibia rotation in gait stance phase: (Top) changes in ankle dorsiflexion; (Bottom) changes in rotation angle of tibia. Shaded areas show time of motion switch.

previously confirmed in actual patient tests that the mechanism can induce tibial rotation in the internal and external directions by generating a difference in the amount of tilting of the inner and outer bar during plantar and dorsiflexion of the ankle. In addition, the RO functions to bring the lower limb alignment closer to the normal by applying a corrective force to the lower leg with the inner bar. However, during gait monitoring, subjects could not feel the corrective force of the orthosis, and we determined that there was slippage between the orthosis and leg throughout the cycle. Otsuka et al. confirmed that orthotic slippage affects torque [6]. We considered this slippage to be a factor in decreasing the corrective force of the orthosis.

The experiments and evaluations in this study were conducted with the approval of the Ethical Review Committee of Chikaishi Hospital (No. 30-1), and analyses were conducted with the approval of the Ethical Review Committee of this university (Approval No. 45).

III. DEVELOPMENT OF A MECHANISM TO CONTROL ORTHOTIC SLIPPAGE

The ankle joints on the inner and outer joint axes of the orthosis have different shapes, and the amount of tilt depends on the ankle joint angle. The parameters were set and the mounting position of the ball joint determined as shown in

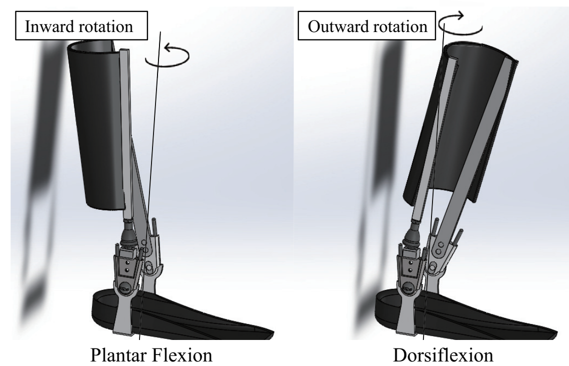

Fig. 2. State of rotation that induces internal rotation of lower leg during ankle flexion (to heel strike), and external rotation during ankle extension (to toe off).

Table I. The distance from the double Klenzack attached to the ankle joint axis on the ball joint was t[mm], and the distance from the ball joint to the top of the strut was $260 - t$[mm].

TABLE I

THE DEFINITION OF ROD END BEARING WITH BALL JOINT

Radius of a lower leg cuff	r	70 [mm]
Required rotation amount	a	10 [deg]
Length of inner bar	l	260 [mm]
Ankle joint angle	h	10 [deg]
Length of outer bar (from the ankle joint on the ball joint)	l_1	t
Length of outer bar (from the ball joint to top of the bar)	l_2	$260 - t$
Movable angle of ankle joint	k	30 [deg]
Movable angle of ball joint	m	25 [deg]

First, since the maximum amount of tibial rotation required during walking is a[deg], the relative difference in movement x[mm] required for the inner and outer bar vertices in the sagittal plane can be obtained from the trigonometric function as Eq. (1):

$$x = r \tan(a\pi/180) = 12.34 \tag{1}$$

Since the maximum dorsiflexion angle of the Klenzack double-channeled joint is 15[deg], the displacement y[mm] in the sagittal plane of the inner strut apex is given by Eq. (2):

$$y = l \tan(k\pi/180 \times 2) = 45.85 \tag{2}$$

From the above, it can be seen that the ball joint needs to be installed at a height t[mm] from the double Klenzack such that the value of the movement of the inner bar apex y[mm] and movement of the lateral bar apex is the relative movement difference x[mm] of the inner and outer bar apexes from the required maximum tibial rotation.

Next, Fig. 3 shows that with the ball joint in place, the maximum movement of the lateral bar apex o[mm] during plantar and dorsiflexion of the ankle joint walking can be calculated as Eq. (3), and the maximum movement of the inner bar apex i[mm] as Eq. (4).

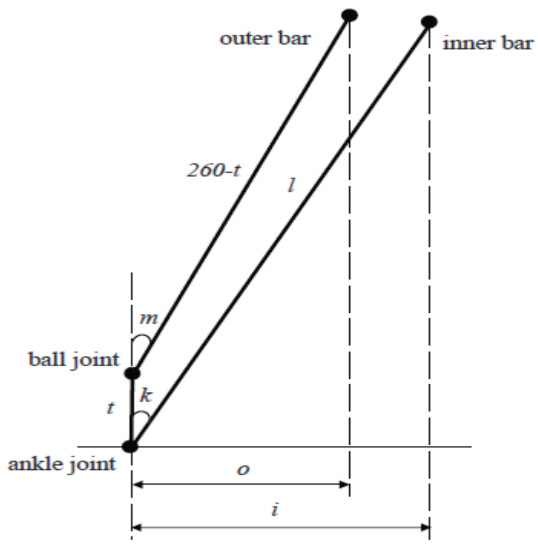

Fig. 3. Behavior of the top of the inner and outer bars.

$$o = (260-t)\sin(m\pi/180) = (260-t)\times 0.2164 \quad (3)$$

$$i = t\sin(k\pi/180) = 0.2588t \quad (4)$$

From these results, the relative amount of movement of the inner and outer bar apexes d[mm] due to the ankle joint angle during walking is expressed as Eq. (5).

$$d = o - i = 56.264 - 0.4752t \quad (5)$$

Since this orthosis is designed to correct the tibia from the surface of the skin of the lower leg, it is considered that the soft tissues and muscles may absorb the rotation-assisting force if the relative movement of the inner and outer bar apexes d[mm] is simply set to the relative movement x[mm] calculated from the required rotation of the tibia. Therefore, the height t[mm] is derived from $d = 2x$[deg], taking into account the absorption of the rotation force by the soft tissues. Thus, the height t[mm] was calculated to be 60[mm] from Eq. (6) and (7).

$$d = 56.264 - 0.4752t = 2x \quad (6)$$

$$t = 60 \quad (7)$$

The outer bar of the RO rotates with the rotation motion. However, the inner bar does not rotate, resulting in slippage between the rotated lower leg and the orthosis. Therefore, we developed a mechanism to rotate the bar and developed a rotation-inducing orthosis (RIO) with improved inducing performance on the lower leg. The width of the mechanism should be less than 15[mm], considering the distance between the two endopods, to prevent interference with the healthy leg. In order to reduce the width of the mechanism and yet be able to rotate even under high loads, a fairly narrow bearing-like feature was needed. As shown on the left side of Fig. 4, one cylinder was attached to the upper part of the Krenzack joint side of the bar and another to the lower part of the cuff. The right of Fig. 4 shows an ankle foot orthosis with the proposed mechanism. The intersection of the rotational part was determined based on the Japanese Industrial Standard. In order to prevent the lower and upper parts of the support from detaching, a pin was fixed to the cylinder, and a long hole was drilled so that the pin could turn. The mechanism was designed to rotate within the range of motion of the pin. Since the induction range of the rotation mechanism is 40[deg], the rotation range of the inner bar should be more than 40[deg].

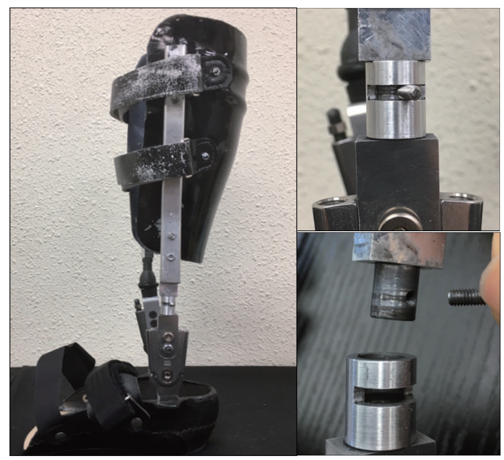

Fig. 4. Left, Walking rotation orthosis with rotation tracking system; Right, rotation tracking system

Fig. 5 shows a comparison of the RO and RIO movements. The proposed mechanism allows the rotation of the orthosis to adapt to tibial rotation, and by following the rotation of the orthosis, it is possible to apply corrective force to the lower leg without slippage.

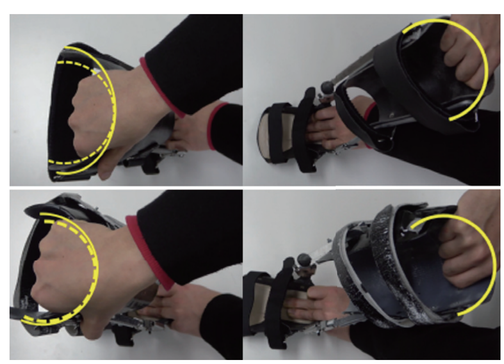

Fig. 5. Top,Axis motion in RO; Bottom, Axis motion in RIO

IV. VERIFICATION OF THE EFFECTIVENESS OF THE PROPOSED MECHANISM

Four healthy males in their 20s were asked to walk on a treadmill at a speed of 3.5 [km/h], and we analyzed the tracking and correction effects of the orthosis with and without the proposed mechanism. Himawari CV90C (Library Co., Ltd.), a GigaNet image input system was used for measurement, and Move-tr/3D (Library Co., Ltd) a 3D motion measurement software was used for the analysis.

Markers were placed on the metatarsus of the fifth toe, external capsule, head of the fibula, and top of the lateral bar of the orthosis. The followability of the orthosis was evaluated by calculating a point on the straight line between the external capsule and fibular head equal to the height of the top of the outer bar of the orthosis, and comparing the distance in the horizontal section of the lower leg between that point and the marker position on the top of the bar. Alignment was assessed by the angle of lower leg inclination and was calculated as the angle between the straight line connecting the fibular head and the external capsule, and the vertical line.

In this study, we made insoles to increase the lower leg inclination angle to verify the effectiveness of orthotics. Fukuyama et al. confirmed an increase in the lower leg inclination angle and decrease in the range of knee joint motion when the navicular part of the insole was raised by 6[mm] [7]. Based on the results of Kato et al.'s experiments on 23 healthy adults, the normal value of the lower leg inclination angle is 7.1 $\pm$ 2.4[deg] [8]. By wearing the manufactured insoles, the subject's lower leg inclination angle was 11.2[deg] on average, which was 1.7[deg] higher than without the insoles.

The values for one gait cycle of the subject are shown in Fig. 6. As for the slippage, as is shown in Fig. 6(top), it increased during the initial contact phase in RO, decreased during the loading response phase, and then increased until the pre swing phase. In RIO, although the graph shape was the same as that in RO, the slippage in the mid-stance phase was suppressed to about 2[deg]. We also confirmed that the proposed RIO was more effective for both alignment and lateral thrust (Fig. 6, bottom). It is assumed that the orthotic slippage was reduced, leading to greater application of the corrective force of the orthotic applied to the lower leg and improved lower limb alignment.

V. SUMMARY

We previously developed an orthosis to induce tibial rotation for knee OA, but discovered there was a decrease in orthosis correction force due to slippage during wear caused by cuff deformation. In this study, we developed an improved orthosis that follows tibial rotation during walking to reduce the slippage, and evaluated it by 3D motion analysis. We confirmed that the proposed orthosis reduced the slippage and improved the correction effect. In addition to reducing pain, adjusting alignment to normal during walking can lead to improvement in QOL.

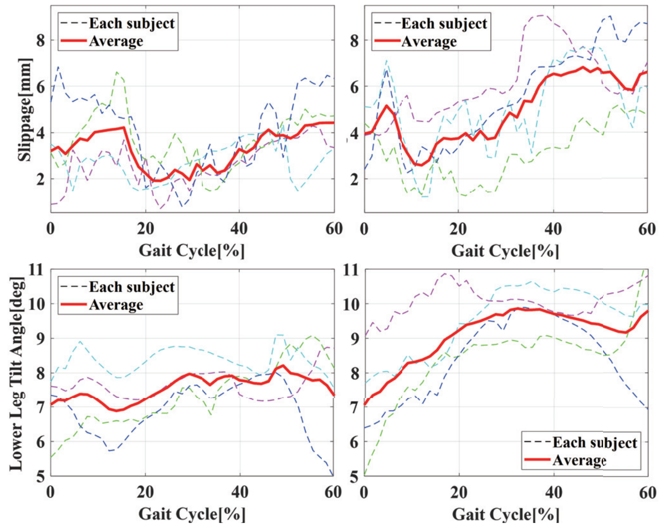

Fig. 6. Top, Lower leg tilt angle during stance phase; Bottom, slippage during stance phase

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