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Effect of trim line on stiffness in dorsi- and plantarflexion of posterior leaf spring ankle-foot orthoses

TAKAHIRO GO, MS[1)*], YUKIO AGARIE, MS[1)], HIRONORI SUDA, PhD[1)], YU MAEDA, PhD[1)],
JUNJI KATSUHIRA, PhD[2)], YOSHIHIRO EHARA, PhD[1)]

[1)] Department of Prosthetics & Orthotics and Assistive Technology, Faculty of Rehabilitation, Niigata
    University of Health and Welfare: 1398 Shimami-cho, Kita-ku, Niigata-shi, Niigata 950-3198, Japan
[2)] Department of Human Environment Design, Faculty of Human Life Design, Toyo University, Japan

Abstract. [Purpose] This study aimed to objectively clarify the effect of the trim line setting on the stiffness of posterior leaf spring ankle-foot orthoses. [Participant and Methods] Posterior leaf spring ankle-foot orthoses were fabricated with two thickness levels and three trim line conditions for the posterior upright width and the dorsi- and plantarflexion moments and stiffness exhibited by the orthoses were measured using an evaluation tester. [Results] The trim line of the posterior upright width affected the dorsiflexion moment generated by the orthoses in plantarflexion. [Conclusion] A strong linear correlation was found between posterior upright width and orthotic stiffness, suggesting that it is highly feasible to standardize orthotic settings according to individual conditions of patients after stroke, even for posterior leaf spring ankle-foot orthoses.
Key words: Posterior leaf spring ankle-foot orthoses (PLS-AFO), Trimming line, Stiffness

INTRODUCTION

An ankle-foot orthosis (AFO) has a structure that spans from the lower leg to the foot and uses the principle of three-point fixation to control the movement of the ankle joint. The objectives of AFO use are (1) constraint (restriction) of ankle joint motion, (2) stabilization of the foot and ankle joint, (3) control of the knee, and (4) unloading[1]. AFOs are prescribed for various lower limb dysfunctions, including hemiplegia due to central nervous system disorders such as stroke, foot drop due to peripheral neuropathy, and other conditions due to orthopedic diseases or sports injuries[2]. In particular, stroke is the leading cause of disability in Japan, and AFOs are often prescribed to minimize difficulties in gait during rehabilitation or in daily life[3]. The goal of AFO use is acquisition of stable gait by appropriately controlling the musculoskeletal system, which is difficult for patients to do voluntarily. Therefore, therapists such as physical therapists and prosthetists and orthotists (POs) need to select and fabricate appropriate AFOs from among various types based on the patient's condition.

A study of AFOs for patients with stroke in Japan found that posterior leaf spring AFOs (PLS-AFOs) were the most frequently prescribed[4]. The PLS-AFO controls the direction of plantarflexion and dorsiflexion by flexing of the posterior upright, and the stiffness of the orthosis can be varied by the design of the trim line at the posterior part of the ankle joint[5]. Here, AFO stiffness is defined as resistance to ankle rotation in the sagittal plane and can be determined from the slope of the ankle torque versus ankle angle curve (Nm/deg) of an AFO[6]. This trim is designed according to the individual condition of the hemiplegic stroke patients, including the degree of spasticity and deformity of the ankle joint. In addition, for a PLS-AFO to properly restrict ankle joint motion, the orthotic stiffness must be optimized according to the biomechanical requirements of the individual patient. This provides toe clearance by limiting plantarflexion during swing phase, effective foot landing at

initial contact, and external stability of the foot and ankle joint in all three planes of motion during stance phase[7]. In recent years, simulation methods such as finite element analysis using 3D-CAD software have made it possible to objectively calculate the strength and stiffness required for AFOs and to determine their design[8]. In clinical practice, however, the trim line and the resulting stiffness of PLA-AFOs are conceptually classified only qualitatively as rigid, semi-rigid, and flexible types. In addition, there is no objective data on the stiffness values of PLA-AFOs corresponding to each type, and their design is qualitatively and subjectively determined based on the experience of therapists, taking into account the physical functioning and degree of paralysis of the patient. Previous studies have investigated the effect of using an articulated AFO (AAFO) on orthotic stiffness[9], as well as the stiffness of PLS-AFOs for foot drop[10], but the stiffness of PLS-AFOs for hemiplegia after stroke has not been clarified. Furthermore, in clinical practice, it is difficult for each patient to try on various evaluation AFOs with different stiffness levels, and there are no guidelines for selecting the optimal AFO[11]. Therefore, if the specific trim line of the PLS-AFO and the corresponding orthotic stiffness are standardized, it will become possible to prescribe an appropriate orthotic without walking trials using evaluation AFOs as have been necessary in the clinical setting up to now. This would enable orthotic intervention in a shorter period of time, allowing for earlier gait training. If the effect of the trim line design of PLS-AFOs on the respective stiffness levels for dorsiflexion and plantarflexion can be clarified, then dorsi- and plantarflexion could be independently controlled with PLS-AFOs, as with AAFOs, which will further enhance the value of PLS-AFOs in clinical practice.

Therefore, for selecting and fabricating PLS-AFOs according to individual conditions, it is necessary to objectively clarify the relationship between each trim line setting and the stiffness of PLS-AFOs fabricated by the conventional method. The purpose of this study was to fabricate polypropylene PLS-AFOs with three different trim lines and to objectively evaluate their stiffness in the directions of dorsi- and plantarflexion in bench tests using an evaluation tester.

PARTICIPANT AND METHODS

In this study, PLS-AFOs were fabricated for measurement, based on the trim lines and thicknesses that are frequently used in clinical practice. The trim line was varied only for the width of the posterior upright, which was expected to affect the stiffness of the orthosis. The trim width of the posterior upright was defined as the width of the PLS-AFO covering the anterior–posterior diameter (AP) of the lower leg at the level of the distal one-third of the orthosis length (the narrowest part) in the sagittal plane. The width of the area covered by the orthosis was varied to give three conditions. The rigid type (which covers half of the AP) is defined as 6/12AP, the flexible type (which covers one-third of the AP) is defined as 4/12AP, and the semi-rigid type (which is intermediate between the other two types) is defined as 5/12AP (Fig. 1). The trim lines other than the posterior upright passed through the center of the lateral malleolus in the distal part, and in the proximal part (calf shell), the trim lines covered two-thirds of the lower leg at the level of the proximal one-third of the orthosis length. The metatarsophalangeal joint covers the first metatarsal head on the medial side and half of the fifth metatarsal head on the lateral side, and the sole part extends under the toes. In addition, the toe part was made flat so that it would be in contact with the floor when not lifting the toes. Two types of polypropylene sheets with thickness of 3 mm and 4 mm, which are
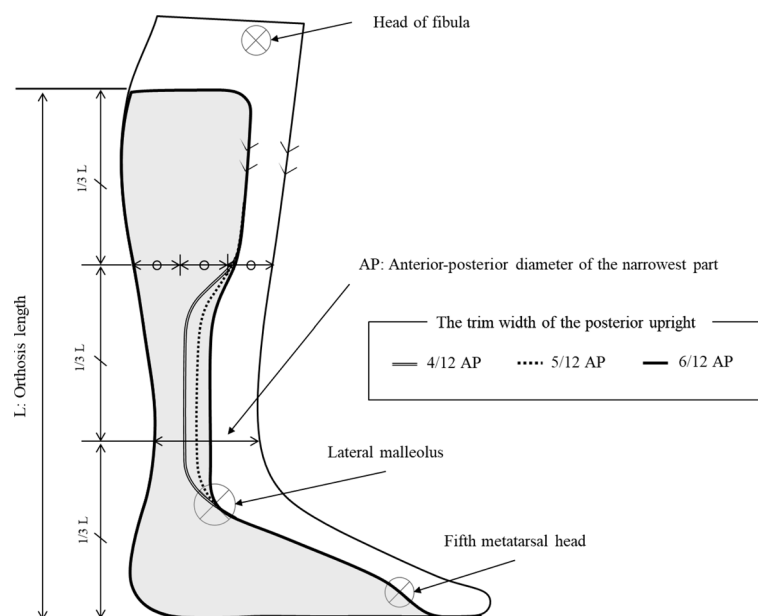

Fig. 1. Trimming line condition of the measurement posterior leaf spring ankle-foot orthosis (PLS-AFO).

frequently used in the clinical setting, were used to set the thickness of the orthosis. In fabricating the PLS-AFOs, sheets of each thickness were used for each trim line. Thus, a total of six PLS-AFOs were fabricated for measurement with three trim line conditions with two thicknesses.

The PLS-AFOs were fabricated based on the lower leg shape of a healthy adult (21 years old, female, no history of lower leg problems). First, the lower leg was cast with a plaster bandage according to the conventional fabrication process, and then a positive plaster model was fabricated and modified. During casting, the alignment of the lower leg was set so that the lower leg was perpendicular to the floor in the frontal plane and the ankle joint was between dorsi- and plantarflexion in the sagittal plane. In the model modification, relief was adjusted in the regions of the lateral and medial malleolus, the navicular bone, and the first and fifth metatarsal heads. Then, the modified plaster positive model was 3D scanned and a 3D positive model was 3D-printed for molding the PLS-AFOs with each trim line setting. In this 3D positive model, rim-like protrusions were modeled by 3D-CAD for the three patterns of trim lines described above. By determining the trim line according to this rim-like projection, it is possible to standardize the shape of the orthosis and make the shape uniform except for the posterior upright area. It was considered that this method would minimize the shape error of the manually fabricated PLS-AFOs for measurement. A total of six PLS-AFOs were then fabricated by vacuum forming polypropylene sheets (3 mm and 4 mm) on the 3D positive models using the conventional fabrication method. All these processes were performed by a PO with more than 5 years of clinical experience, and the trimming of the PLS-AFOs was performed by the same PO.

To measure the stiffness of the fabricated PLS-AFOs in the dorsi- and plantarflexion directions, an evaluation tester for bench tests was developed (Fig. 2). A rotating torque meter (UTM II-50Nm, Unipulse, Tokyo, Japan), was installed in the tester. The PLS-AFO was fixed to the tester and the moment [Nm] was calculated from the load torque when the orthosis was subjected to dorsi- and plantarflexion in passive movement.

First, the PLS-AFO was fixed to the tester. At this time, a straight line connecting the medial aspect of the calcaneus and the medial aspect of the first metatarsal head was regarded as the direction of progress of the AFO, and it was fixed so that this direction was perpendicular to the axis of rotation of the tester. The assumed center of the lateral malleolus was aligned with the axis of rotation of the tester. The calf shell and sole of the AFO were fixed to the tester to prevent the orthosis from shifting during measurement. In the calf shell area, a lower leg model was placed from 5 mm below the upper edge of the AFO to the proximal one-third of the orthosis length to match the shape of the orthosis formed by the 3D printer. A band was then wrapped around the lower leg model and the orthosis to secure it in place. The foot was fixed at two points inside the orthosis (heel and toe) so that it was held down along the vertical axis. Then, the lower part of the AFO was moved in the directions of dorsi- and plantarflexion and held in place in 1° increments, and the load torque at each angle was measured. Measurements were performed from 8° of dorsiflexion to 8° of plantarflexion, based on the range of motion of the ankle joint in the gait of hemiplegic stroke patients[12]. For the measurement, the starting point was the position between dorsi- and plantarflexion, and the movement was first made to 8° of dorsiflexion, and then to 8° of plantarflexion, and then back to between dorsi- and plantarflexion. Six trials were performed under each set of conditions, and a total of five trials (trials 2 to 6, excluding the first measurement) were used for analysis. The force measurements were calibrated at 300 mm from the axis of rotation of the tester, and the dorsi- and plantarflexion moments [Nm] of the PLS-AFO were calculated. In addition, the hysteresis curve obtained from the dorsi- and plantarflexion moment of PLS-AFO measured with the tester was approximated by a cubic function, and the slope at the origin (0°) was calculated as the orthotic stiffness [Nm/deg]. Each result of moment and stiffness was analyzed from the average value of five trials (mean ± SD). In addition, to investigate the relationship between trim width and orthotic stiffness, linear regression analysis was performed using add-in analytical function of Microsoft Excel (Microsoft 365 MSO; Microsoft, Redmond, WA, USA) to calculate the coefficient of determination.

The study was approved by the ethics committee of Niigata University of Health and Welfare (approval number: 18246-190717).

Fig. 2.   Evaluation tester.

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RESULTS

For each trim line setting, the dorsi- and plantarflexion moments versus the angle of the PLS-AFO for the orthosis thicknesses of 3 mm and 4 mm are shown in Figs. 3 and 4, respectively. Each result represents the average value of five trials for each condition. The vertical axis is the dorsi- and plantarflexion moment [Nm] applied to the AFO, where positive values indicate dorsiflexion moment and negative values indicate plantarflexion moment. The horizontal axis indicates the angle of dorsi- and plantarflexion [deg]. In dorsiflexion (resp., plantarflexion), the orthosis generates a plantarflexion (resp., dorsiflexion) moment. Overall, the results show that the plantarflexion moment was larger than the dorsiflexion moment. Comparing the differences due to the trim line, it can be seen that the dorsiflexion moment decreased in a stepwise manner as the setting of the trim line became progressively narrower to cover a smaller area of the lower limb.

For the PLS-AFO with thickness of 3 mm, the plantarflexion moment at the maximum dorsiflexion angle (8°) was 7.56 ± 0.3 (mean ± SD) Nm for 4/12AP, 7.86 ± 0.2 Nm for 5/12AP, and 11.22 ± 0.5 Nm for 6/12AP. The largest moment was observed for the 6/12AP trim line, but there was no difference between the 4/12AP and 5/12AP trim lines. On the other hand, at the maximum plantarflexion angle (8°), the dorsiflexion moment increased in a stepwise manner with the width of the posterior upright: −16.92 ± 0.2 Nm for 4/12AP, −20.76 ± 0.2 Nm for 5/12AP, and −25.44 ± 0.2 Nm for 6/12AP. The moments for the 6/12AP trim line, which was assumed to correspond to the rigid type commonly used in clinical practice was about 1.5 times larger than that for the 4/12AP trim line, which was assumed to correspond to the soft type.

For the PLS-AFO with thickness of 4 mm, the plantarflexion moment at the maximum dorsiflexion angle (8°) was 15.06 ± 0.4 Nm for 4/12AP, 15.42 ± 0.5 Nm for 5/12AP, and 20.40 ± 0.4 Nm for 6/12AP. As with the PLS-AFO with 3 mm thickness, the largest plantarflexion moment was observed for the 6/12 AP trim line, but there was no difference between the 4/12 AP and 5/12 AP trim lines. At the maximum plantarflexion angle (8°), the results were −25.86 ± 0.1 Nm at 4/12AP, −31.62 ± 0.2 Nm at 5/12AP, and −41.10 ± 0.1 Nm at 6/12AP, showing results similar to those for the PLS-AFO with thickness of 3 mm. Comparing the moments of 4/12AP and 6/12AP, there was a difference of about 1.6 times.

The moment of the 4-mm AFO was 1.5 times larger than that of the 3-mm AFO for the 4/12AP and 5/12AP trim lines. Furthermore, for the 6/12 AP trim line, the moment of the 4-mm AFO was 1.6 times larger than that of the 3-mm AFO.

A scatter plot of trim width versus orthotic stiffness is shown in Fig. 5. The horizontal axis shows trimming width as the percentage of the lower leg covered by the orthosis, so "6/12AP" is equivalent to "50%". The vertical axis shows the stiffness of the orthosis (Nm/deg) calculated from the approximate hysteresis curve. The results show a strong linear correlation between the trim condition of the posterior upright and the orthotic stiffness of the PLS-AFO.

DISCUSSION

In this bench test of PLS-AFOs using an evaluation tester, the moment and stiffness generated by the orthoses were found to vary depending on the trim line setting of the posterior upright. In particular, the effect on the dorsiflexion moment generated by the orthosis in plantarflexion was substantial, and the dorsiflexion moment could be reduced by narrowing the width of the posterior upright. The dorsiflexion moment of the rigid type (6/12AP) was 1.5 to 1.6 times higher than that of the soft
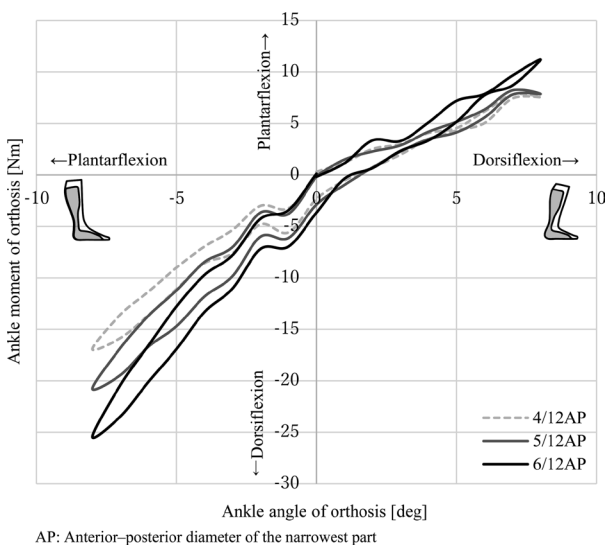
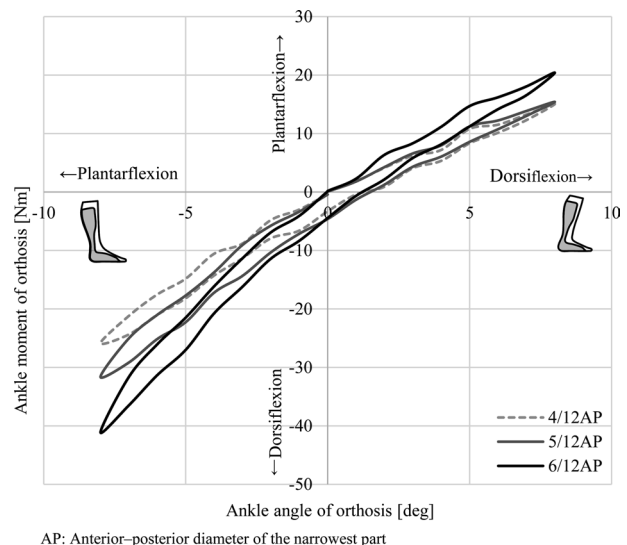

Fig. 3. Moment of 3-mm ankle-foot orthosis (AFO).

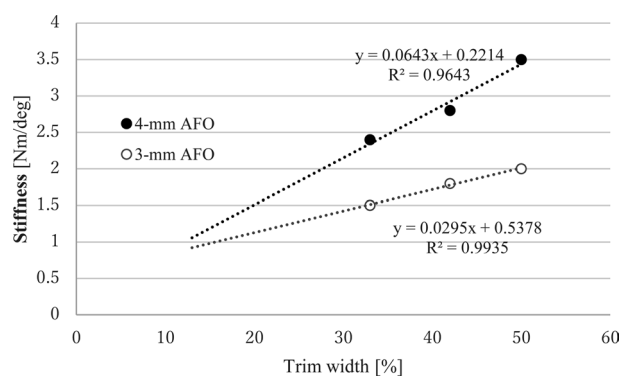**Fig. 4.** Moment of 4-mm ankle-foot orthosis (AFO).

Fig. 5. Scatter plot of trim width versus orthotic stiffness.

type (4/12AP) for both the 4-mm and 3-mm orthoses. On the other hand, the effect of the trim line on the plantarflexion moment generated in dorsiflexion was small, and it was presumed that this was due to the effect of areas other than the posterior upright. In addition, the trim width of the posterior upright and the stiffness of the orthosis showed a strong linear correlation. This suggests that the orthotic stiffness of the PLS-AFO, which previously could not be determined without actual fabrication, can be controlled under standardized conditions. It was considered that the shape error of the AFO could be suppressed by using a 3D positive model that was accurately designed using 3D-CAD for each trim condition. In addition, the width of the posterior upright was set as a percentage of the AP diameter at the narrowest part of the orthosis, not as an absolute shape value[13], and the measurement was performed for six PLS-AFO conditions, including two different thicknesses.

Previously, Sumiya et al.[14] found that in plantarflexion, the posterior upright of PLS-AFOs flexes backward due to tensile load, and the center of rotation of the orthosis converges into that region. In the case of dorsiflexion, the wide area from the posterior upright to the proximal part of the shoe insert expands inward and outward as a result of compressive loading, and the center of rotation of the orthosis moves into this area. Furthermore, Chu and Reddy[15] also used finite element analysis to analyze stresses in PLS-AFOs and found that the highest stresses were generated in the posterior upright. Taken together with the results of these previous studies, our results objectively show that the dorsiflexion moment generated by PLS-AFO can be controlled in a stepwise manner by setting the trim line in the posterior upright, because the center of rotation of the PLS-AFO moves to this area in plantarflexion. In addition, it was inferred that the plantarflexion moment was affected by the heel and the height of the lateral wall of the foot rather than the posterior upright, which is consistent with a previous study[16].

An important function of PLS-AFOs is to exert an appropriate dorsiflexion moment to prevent rapid plantarflexion of the ankle joint after initial contact. On the other hand, excessive resistance moments generated by AFOs have been shown to decrease gait efficiency by reducing both forward propulsion and Achilles' tendon function during push off[17]. In the past, when prescribing a PLS-AFO, the trim line was determined based on the resistance moments to dorsi- and plantarflexion in combination. However, it is necessary to consider the resistance moments for plantarflexion and dorsiflexion as independent controls and to set appropriate moments for each direction. In recent years, AAFOs have been the only way to achieve independent control in the directions of plantarflexion and dorsiflexion[18]. However, the results of this study suggested that PLS-AFOs with appropriate trim lines could be used for these cases.

Mechanical properties such as the stiffness of AFOs play an important role in assisting gait[19], and if this stiffness is not adapted to the patient's condition, gait will deteriorate and knee joint motion will be adversely affected[20]. In stroke rehabilitation, the first 3 months after the onset of stroke is the period of motor function recovery in most cases[21]. Therefore, in prescribing orthotics, there is a need to predict the prognosis of recovery from an early stage. For therapists, such as a physical therapists or POs, being able to select an appropriate type of orthosis early in rehabilitation is a necessary skill to increase its effectiveness. If the required stiffness for the orthosis can be determined by assessing the level of muscle tension using the Modified Ashworth Scale or other means, the ideal PLS-AFO design can be determined based on the results of this study.

A limitation of this study is that it was a bench test measuring only the stiffness of the orthosis itself. As such, the conditions when a patient wears the orthosis on the lower limb were not fully reproduced. The presence of the lower limb in the orthosis may affect its stiffness characteristics. In addition, walking involves the three-dimensional motion of multiple joints, not just simple dorsi- and plantar flexion of the ankle joint, and ground contact of the sole of the orthosis changes during the gait cycle. In the future, it is necessary to evaluate the stiffness of the orthosis in each plane of motion and to measure motions with high degrees of freedom.

In this study, the effects of the trim line setting of PLS-AFOs on dorsi- and plantarflexion moments and the orthotic stiffness were investigated in bench tests using a developed evaluation tester. As a result, it was found that the trim width of the posterior upright had an effect on the dorsiflexion moment generated by the orthosis in plantarflexion. In addition, because the plantarflexion moment was presumed to be influenced by the heel and foot trim lines, it was considered that the

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plantarflexion and dorsiflexion moments can be controlled independently. Furthermore, there was a strong linear correlation between the trim width and stiffness of the PLS-AFO. Therefore, the stiffness of PLS-AFOs can be predicted from the trim width, suggesting that it is highly feasible to standardize PLS-AFO settings according to the individual condition of patients following stroke.

Conflicts of interest

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