CASE STUDY

Evaluation of the Pressure Relief Ankle Foot Orthosis in Individuals with Hemiparesis Using Three-Dimensional Gait Analysis

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A normal gait cycle is characterized by a smooth advancement of the limb from initial contact (heel strike) on one side to the subsequent (initial contact) on the same side. Four fundamental prerequisites are necessary for safe and energy efficient walking.[1] First, the stance limb must be stable and supportive in both the single and double support periods. Second, there must be adequate swing phase clearance to preclude a toe catch phenomenon during elevated limb advancement. Third, the foot must be properly prepositioned to accept weight just before initial contact with the ground. Fourth, there must be adequate control and movement of the foot, knee and hip to enable efficient step length for functional ambulation to be realized. If any of these four prerequisites are severely compromised, the potential for functional gait becomes adversely affected.

An individual who has sustained an injury to the central or peripheral nervous system often experiences difficulty with lower limb control during the gait cycle. Depending on the origin and resultant clinical manifestations, deformity and pathomechanics may be present in the sagittal, coronal, and transverse planes relative to the three joints of the lower limb. One of the primary problems in this patient population is a "drop foot" or excessive equinus in swing. This compromises the second prerequisite of normal gait mentioned earlier. If uncompensated, excessive equinus will lead to poor clearance with associated increased incidence of tripping and ultimately falling in some individuals. Another issue related to excessive equinus in swing is inappropriate prepositioning of the foot for initial contact (third prerequisite) with an associated toe initial contact gait. This also leads to an unstable gait pattern and may ultimately result in ankle injuries or falling. An excessive equinus in swing can be corrected for by an ankle foot orthosis (AFO) that holds the ankle in the neutral position.

Dorsiflexion Assist Ankle Foot Orthoses for Hemiplegic Gait

For these reasons, dorsiflexion assist AFOs are commonly used for treatment of hemiplegic gait. Some assist with the use of thinner plastic, posterior metal struts, or new technology that actually uses spring-loaded dorsiflexion assist during different phases of gait. The dynamic AFO (DAFO) is used to assist gait of hemiplegic patients with the thin plastic device, whereas the experimental dorsiflexion assist models are being tested to find a niche in the AFO market.

Dieli et al[2] studied the effects of DAFOs on three hemiplegic patients who have suffered from a stroke within the past 19 months. All three participants were males. All subjects were fitted with DAFOs with plantarflexion stop and dorsiflexion moment by the means of plastic reformation. The subjects must have been able to ambulate on their own and have a flexible spastic extensor pattern in the lower leg. The study focused on these main characteristics of gait: velocity, cadence, swing time, and single limb support. The DAFO was tested against the posterior leaf spring (PLS) AFO.

Dieli et al. also found that the DAFO's velocity was 7.34 m/minute faster than the barefoot trial and 2.64 m/minute faster than the PLS trial. The cadence of the hemiplegic patients' gait was measured in steps/minute. The cadence of the patient in the DAFO trial was 0.17 greater than the barefoot trial and 0.06 greater than the

PLS trial. Percentage of time in stance and swing phase was shown to be insignificant between the DAFO, PLS, and barefoot trials. Single limb support in the DAFO was shown to be 2.54% over the barefoot trial and 1.97% greater than the PLS trial.[2] This study shows that velocity, cadence, and single leg support increased with the application of the DAFO. The single limb support is probably the best indicator of the stance limb's support during gait. This indicates prolonged weight acceptance was acquired when the subject donned the DAFO.

A study performed by Yamamoto et al.[3] observed the gait characteristics of the 33 hemiplegic patients who currently used plastic AFOs on a daily basis. The patients were analyzed to find the most sufficient dorsiflexion assist moment necessary to provide the most effective walking velocity. Also, the best initial ankle angle at foot contact was found for each patient. These tests were used to calculate the optimal moments and angles necessary to optimize the hemiplegics' gait.

The results from this study stated that the AFOs should have an articulated ankle joint and a moderate corrective ability in the inversion or eversion direction. The initial ankle angle of the AFOs should be adjustable in the range of 0°–10° of dorsiflexion. The range of the dorsiflexion of the ankle joints should be 30° from the initial ankle angle, taking into consideration rotation during gait, ascent and descent of stairs and slopes, and squatting. The AFOs should generate no plantarflexion assist moment during dorsiflexion. The range of plantarflexion of the ankle joints should be 10° from the initial ankle angle, taking into consideration rotation during gait and descent of stairs and slopes. The AFOs should generate a dorsiflexion assist moment during plantarflexion. The magnitude of the dorsiflexion assist moment should be variable in the range of 5–20 Nm per 10° of plantarflexion. The design of the AFO can be modified to each patient's requisites.[3]

In a follow-up study, Yamamoto et al.[4] tested what is called a dorsiflexion assist controlled by spring AFO (DACS). This DACS is an AFO that has adjustable springs on the anterior and posterior ankle joints of the AFO. This is an experimental AFO that is being tested to see whether it may be applied to the treatment of hemiplegic gait. The DACS, a conventional AFO with metal uprights, and a PLS were compared in this study. The gait analysis was performed with VICON computer software and force plates. The walking velocity was measured to delegate the success of the DACS against that of the PLS, conventional AFO, and barefoot when able.

The dorsiflexion of the ankle joint was restricted when the PLS and conventional AFO were used. The DACS showed knee extension throughout the entire stance phase except at initial contact, whereas hyperextension was reduced over that of the other AFOs. The rotational angle was very large with the PLS but was reduced with the DACS. The velocity of the patients was increased with the DACS over that of the PLS and conventional. The extra weight from the spring loading on the DACS was not a problem when subjects were interviewed postexamination.[4] The DACS can be adjusted to format to the specific dorsiflexion angle and also to format to the specific moment around the ankle. This will enable the ankle to counteract the spastic extensor pattern with a certain amount of torque delivered by the spring-loaded system.

Although these custom AFO systems have been proven to dramatically improve hemiplegic gait, there is a place for application of interim or temporary AFO systems for the management of the aforementioned functional deficits.

The pressure relief AFO (PRAFO® orthosis) was designed originally to minimize pressure on the heel for those persons with hemiplegia who have limited mobility and spend a majority of their time bedridden. The PRAFO® orthosis has a similar design to a typical recumbency AFO with the addition of a rubber sole on the plantar surface to facilitate ambulation and eliminate the need for shoes during activities of daily living (Fig. 1, photo of a PRAFO® orthosis). Visual observation suggests that this brace also provides the benefit of controlling ankle motion in swing and thus minimizing the risk of tripping and falling. It is, therefore, the purpose of this study to evaluate the effect of the PRAFO® orthosis on ankle motion using three-dimensional gait analysis techniques.

Fig. 1: PRAFO® orthosis

Materials and Methods

Following chart reviews, subjects were identified by the investigating orthotic practitioner and contacted by mail and follow-up telephone call. Patients meeting the inclusion criteria listed below were provided a detailed explanation of the study and afforded the opportunity to ask any questions of the investigator. A total of eight subjects were chosen for this study. All had unilateral involvement (left or right sided) and were able to ambulate functionally with or without a single assistive device (cane/crutch).

Inclusion Criteria

The subjects were selected according to the following inclusion criteria: 1) diagnosis of hemiparesis with known functional gait deficiencies, 2) passive dorsiflexion range of motion at the ankle to 90° (neutral) or higher, 3) manual muscle test of at least 3/5 for knee extension and 3/5 for ankle plantarflexion, and 4) documented excessive equinus in swing phase based on visual assessment. Subjects were excluded from the study based on the following exclusion criteria: 1) severe spasticity, ataxia, or athetosis, 2) severe medial lateral instability/deformity at the ankle, and 3) poor balance precluding safe ambulation. All subjects were current patients of Hanger Prosthetics & Orthotics facilities in the greater Hartford area of Connecticut.

Testing

At the initial visit, subjects were examined and fit with an appropriate PRAFO® orthosis, given their relative weight, height, and ambulating potential. Standard instructions were provided on fitting criteria, use, and care of the PRAFO® orthosis. The subjects were then instructed to use the PRAFO® orthosis daily over the period of 1 week (minimum) or longer. This provided an opportunity for the subjects to acclimate their gait pattern with the PRAFO® orthosis.

Gait Analysis

After the initial trial period with the PRAFO® orthosis, each subject returned to the Center for Motion Analysis Laboratory at Connecticut Children's Medical Center for a complete gait analysis. A gait analysis included a full clinical examination, bi-planar video and acquisition of motion, and kinetic data using three-dimensional gait analysis techniques.[5] Motion data were completed during barefoot walking and while wearing the PRAFO® orthosis. Multiple trials were collected in each condition and representative trial selected for analysis following routine protocols.

The clinical evaluation was completed by a physical therapist in the Center for Motion Analysis and included the following components: height, weight, passive joint range of motion, estimate of bony torsional measurements, and manual muscle test. Motion analyses that were then completed using the routine clinical procedures 5,6 were summarized below:

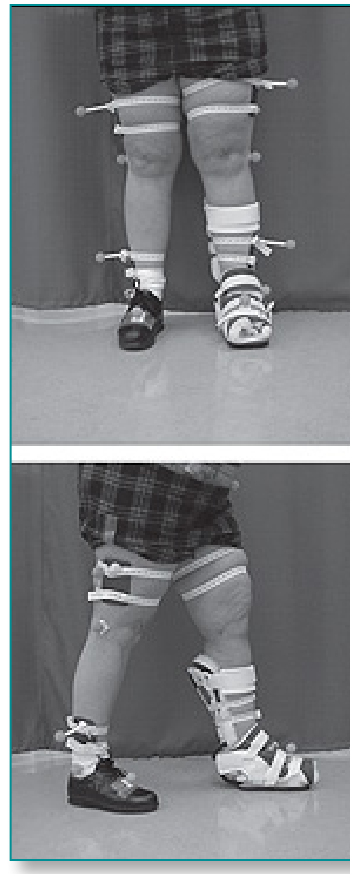

Figure 2

- Reflective markers were placed relative to bony landmarks on the lower limbs, pelvis, and trunk (Fig. 2).
- Each subject was instructed to walk at a self-selected pace along a designated walkway. Multiple trials were collected first from barefoot and then from PRAFO® orthosis walking.
- The three-dimensional location of each reflective marker was determined using custom software and a VICON motion measurement system (Oxford Metrics Inc., Oxford, UK).
- Force plate date was collected simultaneously using three AMTI force plates (Advanced Medical Technologies Limited, Newton, MA) embedded into the walkway.
- Joint angles and joint moments were computed using Euler Angles and Inverse Dynamics,[7] respectively.

All gait analysis data were plotted and tabulated, and descriptive statistical analyses were performed. A Student t-test was used to determine whether there were statistically significant differences between the barefoot and PRAFO® orthosis walks. A probability of $p < 0.05$ was considered statistically significant. All gait parameters were determined improved if they showed changes toward the normal reference data collected in the same laboratory.[8]

Results

A summary of the clinical examination findings for all subjects can be found in Table 1. Minor plantarflexor contractures were found in the 5–10° range in three subjects with the knee at 0°. Two of the patients were unable to isolate dorsiflexion, which indicates a lack of voluntary control of this muscle group even though it may have antigravity strength.

Subject	Ankle dorsiflexion knee at 0°	Ankle dorsiflexion knee at 90°	Ankle plantarflexion	Ankle dorsiflexion strength	Ankle plantarflexion strength
1	−10	0	Full	U	2
2	0	5	Full	U	1
3	5	10	Full	0	5−
4	5	15	Full	0	3−
5	−5	0	Full	0	2+
6*	−10	0	Full	4	3−
7*	0	5	Full	3−	2
8*	0	5	Full	4	2

* Subjects who did not show a drop foot in swing.
U, unable to isolate motion.

Table 1

	Ankle angle at initial contact (°)	Peak dorsiflexion in stance (°)	Peak plantarflexi on in swing (°)	Peak dorsiflexion mid swing (°)	Ankle sagittal plane ROM (°)	Peak dorsiflexor moment (N×m/kg)	Peak power generation terminal stance (W/kg)
Barefoot							
Mean	−19	15	−25	−18	40	0.02	2.51
SD	5	2	8	10	8	0.04	1.16
PRAFO							
Mean	−5	13	−8	−5	21	−0.12	1.66
SD	4	4	3	2	2	0.04	0.57
Student *t* test	0.006	0.165	0.006	0.029	0.006	0.002	0.050

Those parameters that are considered statistically significant show probability values that are in bold type.
PRAFO, pressure relief ankle foot orthosis.

Table 2

Of the eight subjects selected for the study, three were actually able to achieve normal dorsiflexion in the mid swing phase by substituting for anterior tibialis function and were excluded from the summary findings. The ankle joint kinematic and kinetic results for the remaining five subjects who showed excessive equinus in swing are summarized in Table 2 . The mean ankle dorsiflexion in mid swing for these subjects showed a significant excessive equinus, which was corrected with the PRAFO® orthosis into a normal range of motion (Fig. 3). The difference between the barefoot and PRAFO® orthosis walk was significantly different (p = 0.029). As would be expected, there was a significant drop in the peak plantarflexion in swing from -25° ± 8° to -8 ± 3° (p < 0.006) with an associated significant (p < 0.006) decrease in the sagittal plane range of motion of the ankle. With the PRAFO® orthosis, there was a heel contact pattern noted with an associated dorsiflexion moment in first rocker (Fig. 4). Power generation in terminal stance was reduced with the PRAFO® orthosis in comparison with barefoot walking. Also, of note, there was a significant improvement

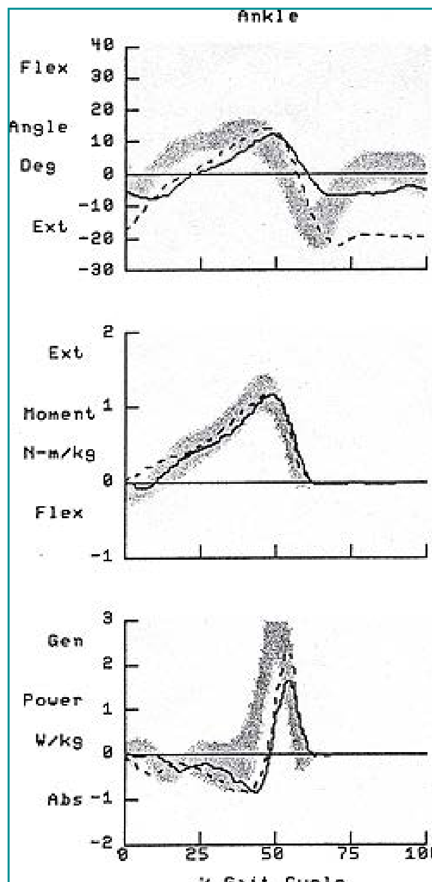

Figure 3

in knee function with the PRAFO® orthosis with an increase in knee flexion at toe off from 33°–43° ($p < 0.037$) and an increase in sagittal plane knee motion from 60 to 65 degrees ($p < 0.001$; Fig. 4). These subjects also showed a significant ($p<0.024$) improvement in their step length from 57±7 to 63±8 cm when using the PRAFO® orthosis. There was a trend toward increased walking velocity with the PRAFO® orthosis, when compared with barefoot; however, this was not statistically significant.

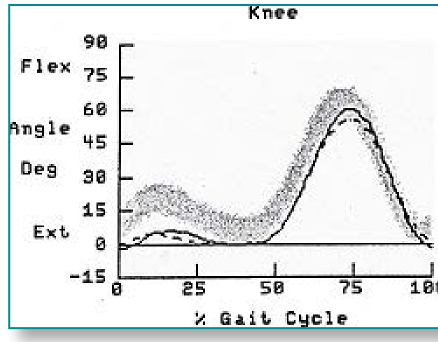

Figure 4

The three patients who did not show excessive equinus in swing all had reduced peak knee flexion in swing and reduced knee extension at initial contact. An example of the barefoot versus PRAFO® orthosis walk for the knee and ankle of one of these subjects is plotted in Figure 5 . The abnormal knee position during barefoot walking changed the orientation of the foot with respect to the floor: that is, the toe was pointing more downward than normal. With the PRAFO® orthosis, the degree and timing of peak knee flexion in swing was improved.

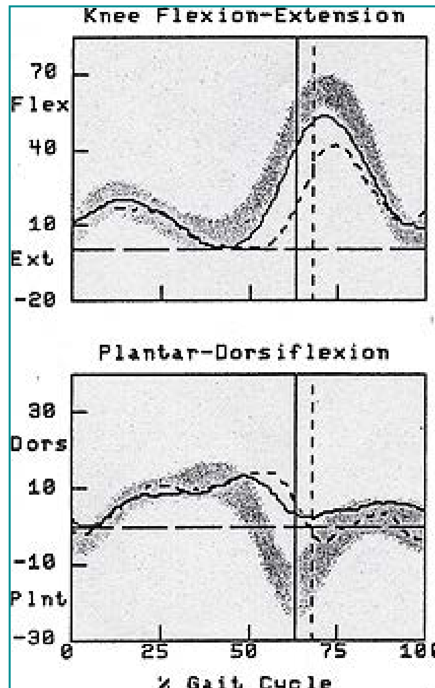

Figure 5

Discussion

The purpose of this study was to evaluate the effect of the PRAFO® orthosis on the motion of the ankle joint during gait. The kinematic data in those patients showing a drop foot in swing confirm that the PRAFO® orthosis is capable of supporting the foot in swing and thus eliminating the excessive equinus in the swing phase. This has the benefit of improving clearance in swing with the associated risk of falling. The improved ankle positioning also extended to initial contact with the elimination of the excessive equinus and the associated ability to attain a heel contact gait. This was further substantiated by the increase in internal dorsiflexor moment at the ankle in the PRAFO® orthosis during loading response, when compared with barefoot walking. Again, this will have a functional benefit in terms of the prerequisites of normal gait with improved stability associated with a heel contact pattern and normal first rocker[9] during loading response.

According to the gait analysis, the PRAFO® orthosis also had an unexpected benefit at the knee. With the PRAFO® orthosis, there was an increase in knee sagittal plane range of motion and a more normal knee flexion angle at toe off. The increase in knee range of motion was due, in part, to increased peak knee flexion in swing. This will also have an associated functional benefit of improving foot clearance in swing. This benefit was seen in both the patients who showed an excessive equinus in swing and those who did not, and this benefit is consistent with previously published results.[10]

As mentioned, there were three subjects in this study who did not have an excessive equinus in swing during barefoot walking.

Their sagittal plane ankle kinematics showed normal dorsiflexion in the swing phase on the involved side. Visually, however, their foot orientation was abnormal. That is, the toe was pointing down in swing. Further evaluation of the kinematic data showed that these subjects had abnormal knee motion in swing, or more specifically, reduced peak knee flexion in swing. This results in a change in orientation of the foot segment, with a resulting visual drop foot. In these patients, it seems that clearance problems reported were a result of the knee joint and not the ankle joint. These three patients, however, still benefited from the PRAFO® orthosis. This was possible through increased peak knee flexion in swing with the PRAFO® orthosis in comparison with barefoot walking. Therefore, changes in knee function resulted in improved clearance in swing and the associated orientation of the foot segment. These findings indicate that the PRAFO® orthosis has functional benefits that go beyond the ankle joint and would still be considered beneficial for patients without excessive equinus. These findings also suggest that it is difficult to determine the presence of excessive equinus in swing (unless it is severe) from visual observation alone, the method used to recruit the subjects for this study. This points to the important role of three-dimensional gait analysis in documenting human gait. Furthermore, the test condition measures only static forces and the orthoses were much more solidly attached to the calf segment of the test fixture than if they were being worn by real patients. Because dynamic forces generated by human subjects wearing the AFOs were not measured in this study, caution must be used in drawing inferences about clinical prescription criteria.

Golay et al[2] used a measurement strategy similar to ours but looked exclusively at dorsiflexion resistance. They showed that for custom-made, polypropylene AFOs, such variables as the final wall thickness of the plastic and the degree of malleolar build-up significantly affected the amount of resistance to dorsiflexion. Sumiya et al[4] reported that for the flexible plastic AFOs tested, the overall resistance to both plantarflexion and dorsiflexion increased almost in proportion to the width of the posterior portion of the device. Singerman et al[8] recently published a more comprehensive look at four AFO types and noted that changes to the trimlines intended primarily to alter the resistance inevitably altered the effective axis of rotation of the device as well.

These studies all underscore the fact that the movement of plastic ankle-foot orthoses is multiplanar, and the resistance in each plane varies due to a variety of interactive factors. Although it may be useful to focus on single-plane forces to improve our conceptual understanding of how these devices function, such limited data cannot provide a complete picture of the clinical performance of the orthoses.

Summary

The results of this study show that the PRAFO® orthosis provides sufficient support of the ankle in swing to prevent excessive equinus and allow for more normal prepositioning of the foot for initial contact; both of these benefits are prerequisites of normal gait. As a result, these patients will be able to ambulate more safely when wearing the PRAFO® orthosis, when compared with barefoot walking. Of interest, even those three subjects who did not show an excessive drop foot in swing also showed a benefit due to the PRAFO® orthosis. The increased peak knee flexion in swing seen in these subjects ultimately suggests improved function with respect to clearance in swing. As cited, many different custom AFO designs have been used traditionally to achieve these objectives and improve various temporal measurements of gait.

The PRAFO® orthosis, while drawing some of its design characteristics from the family of recumbent ulcer prevention devices, was found to exceed the parameters of a limited ambulatory system. The posterior structural element was found to have sufficient integrity to provide deceleration of foot slap at initial loading as well as toe clearance in swing. As such, in those instances where immediate management of the drop foot patient is indicated, the PRAFO® orthosis can be applied successfully not only for recumbent positioning and heel protection but for assistance with functional ambulation as well.

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