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# The ankle-foot orthosis improves balance and reduces fall risk of chronic spastic hemiparetic patients

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***Background.*** **Ankle foot orthoses (AFO) are commonly used orthotic device in order to restore the ankle foot function and to improve the balance and gait in post-stroke hemiparetic patients. However, there remain some discussions about their effectiveness on long term hemiparetic patients who had mild to moderate spasticity.**
***Aim.*** **To investigate the relative effect of prefabricated thermoplastic posterior leaf spring AFO (PLS-AFO) on balance and fall risk.**
***Design.*** **A cross-over interventional study**
***Setting.*** **The Department of PMR of a tertiary hospital.**
***Population.*** **Twenty-five chronic post-stroke long duration hemiparetic patients who had Ashworth grade 1-2 spasticity at affected calf muscles and lower limb Brunnstrom stage 2-3 and also able to walk independently without an assistive device.**
***Methods.*** **Berg Balance Scale (BERG), and the postural stability test (PST) and the fall risk test (FRT) of Biodex balance systems were used for the assessments. All of the patients were assessed with AFO and without AFO. All assessments were made with footwear.**
***Results.*** **The mean post-stroke duration was 20,32±7,46 months. The BERG scores were 42,12±9,05 without AFO and 47,52±7,77 with AFO; the overall stability scores of FRT were 3,35±1,97 without AFO and 2,69±1,65 with AFO (P<0,001).**
***Conclusion.*** **It was found that the prefabricated thermoplastic PLS-AFO improve balance and provide fall risk reduction in chronic post-stroke ambulatory hemiparetic patients who had mild to moderate spasticity on their affected lower limb.**
***Clinical rehabilitation impact.*** **These results encourage the usage of AFO on long duration hemiparetic patients in order to provide better balance and lesser fall risk.**

**KEY WORDS:** Stroke - Postural balance - Hemiplegia - Orthotic devices.

Impaired balance and altered gait patterns which caused by muscle weakness, abnormal movement synergies and spasticity in post-stroke hemiplegic patients contribute increased fall risk and consequent decreased independence in activities of daily living (ADL).[1-4] Falls are one of the most frequent complications in stroke rehabilitation,[4] and may contribute to serious morbidity and life threatening consequences.[5] Therefore improving balance and gait pattern and consequently reduce falls is one of the major targets of the stroke rehabilitation.

Ankle foot orthosis (AFO) is commonly used orthotic device in order to restore the ankle foot function and

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*Conflicts of interest.*—None.

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to improve the balance and gait in post-stroke hemiparetic patients. There were a lot of different types of AFO such as adjustable metal ones and thermoplastic ones. The metallic AFOs were more preferable in patients with severe spastic inversion of the foot. The thermoplastic orthoses were lighter and had better cosmetic appearances and therefore more preferable by the patients.[6, 7]

It was recommended from a consensus conference of experts that custom-made PLS-AFOs indicated for only isolated dorsiflexor weakness with no significant problem with tone and no significant medio-lateral instability, and prefabricated AFOs should be limited to use as temporary evaluation orthoses and where there is need for early mobilization before a custom AFO can be provided.[8, 9] However, prefabricated posterior leaf spring AFOs (PLS-AFOs) are still one of the commonly used type of ortheses for stroke patients and there were previous studies which investigated the some beneficial effects of various kinds of prefabricated AFOs on gait parameters and balance of different post-stroke patient groups.[7, 10] It was previously reported that plastic AFO improves the symmetry and dynamic standing balances of short duration (<six months) hemiparetic subjects, but these were not observed on the long duration (<12 months) hemiparetic subjects.[11] It was also reported that both plastic and metallic AFOs improved gait parameters, but metallic ones provided better stabilization of the ankle.[7] There was no much study which was investigating the effects of plastic AFOs in the presence of spasticity. In a previous study, it was reported that polypropilen AFO had no effect on spasticity in stoke patients.[12] However, there were some other studies which reported some beneficial effects of PLS AFOs on some spastic patient groups other than stroke.[13, 14]

It is obvious that the data about the effects of different kinds of AFOs on stroke patients with diverse clinical properties were relatively less studied and less is known still. The recommendations generally do not pass beyond the expert opinions. Therefore, this issue needs further investigations in order to determine the appropriate selection criteria for AFO usage on post-stroke patients.

The aim of this study was to investigate the relative effect of prefabricated thermoplastic PLS-AFOs on balance and fall risk of post-stroke long duration ambulatory chronic hemiparetic patients who had mild to moderate spasticity on calf muscles.

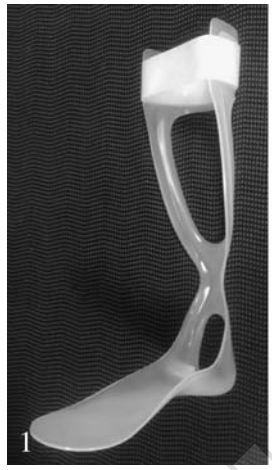



Figure 1.—A photo of a prefabricated thermoplastic PLS-AFO. Figure 2.—The movable balance platform. The coordinates of each foot were recorded in order to provide constant position throughout the consecutive test sessions.

## Materials and methods

### *Patients and study design*

A total of sixty-one chronic hemiparetic post-stroke patients who had applied to the outpatient clinic of the physical medicine and rehabilitation department of a tertiary hospital were examined by physiatrists and twenty-five eligible patients were recruited. All of the patients' informed consents were taken according to the local guidelines [15] and the study approved by local ethical committee. All of the patients had Ashworth grade 1 or 2 spasticity at affected calf muscles and their lower limb Brunnstrom motor recovery stage were 2 or 3 and they were also able to walk independently without an assistive device. The exclusion criteria were cognitive impairment (mini mental test score <24), visual defects of clinical importance, hemineglect, severe heart failure and co-morbidities that would affect mobility, such as severe arthrosis, rheumatoid arthritis or back problems.

The orthoses were commercially available thermoplastic PLS-AFOs (Otto Bock, Otto Bock Healthcare, Germany) (Figure 1). There were all sizes of orthosis and appropriate size was determined by a physiatrist and an orthotist together and patients were trained by a physiotherapist for a session for walking with AFO with footwear. Afterwards, patients were sent back to their daily life with the instruction of regularly use of AFO with footwear during all walking activities.

The assessments for balance and fall risk were performed a week later from the prescription and training in order to provide enough time to the patients to familiarize to their PLS-AFOs.

*Clinical assessments*

The Berg balance scale (Berg), the postural stability test and the fall risk test of Biodex balance system (BBS) were used for the assessment of the patients. The testing order was as follows; Berg, five minutes resting and BBS tests. The patients were firstly assessed without AFO and fifteen minute resting period were allowed and consecutively the tests were performed with AFO in the same order. All assessments were made with footwear.

Berg Balance Scale (Berg) was originally developed for the assessment of balance and risk for falls in older community dwelling adults [16] and Turkish validation was made.[17] It was previously used in various stroke studies including also AFO usage and found valuable for patients with stroke.[11, 18, 19] Fourteen items in the scale assess static sitting and standing balance as well as anticipatory balance during activities that were commonly performed in daily function, including transfers, turnings, and retrieving objects from the floor. The scoring is done on a 5-point scale, which considers whether patient can perform the task safely and independently, often based on for a definite time span. Normal performances are graded from 0 (unable to perform) to 4 points (normal performance). The scores on individual items are summed for a total score, with a maximum point of 56.

Biodex Balance System (BBS, a commercially available balance device, Biodex Medical Systems, Shirley, NY, USA) was used to assess fall risk. The BBS consists of a movable balance platform which provides up to 20° of surface tilt in a 360° range of motion and the platform is interfaced with computer software (Upper display module-firmware version 1.09, Lower control board-firmware version 1.03, Biodex Medical Systems) that enables the device to serve as an objective assessment of balance and fall risk. The movable balance platform had coordinate lines and encoding system on its surface (Figure 2). The system had various difficulty levels for the assessment of balance and fall risk which range from 1 (most difficult) to 12 (the easiest). Following the recommendations of previous studies and Biodex balance system manual, two settings were used to assess the dynamic balance and the fall risk; the postural stability test (PST) and the fall risk test (FRT).[20, 21] The measure of PST includes the overall (OA), the anterior/posterior stability (APS), and the medial/lateral stability (MLS) scores. The FRT result includes overall stability index (OSI) score. The high score in the index indicates poor balance and increased fall risk. The subjects were asked to stand on the platform of the BBS bilaterally with their feet shoulder width apart over midline of the board, to assume a comfortable position and to look straight ahead. The foot position coordinates of patients were recorded and it was provided that the foot coordinates were constant throughout the all test sessions (Figure 2). Subjects were tested with eyes open. No specific data found for the assessment of stroke patients with BBS in the literature and therefore the difficulty level for the assessment of the patients with BBS was determined after a short pilot testing period with five post-stroke patients other than recruited subjects. The level 12 was chosen as the appropriate level because it was well tolerated with all testing subjects. The patients were trained approximately 1 minute for adaptation to the machine in order to reduce any learning effects. During testing, the participants underwent three trials of 20 seconds at each level 12 with ten-second rest periods between each trial. A mean score was calculated from the three test evaluations and the device prepared the report automatically.

*Statistical analysis*

The statistical analyses were performed with SPSS 15 for Windows. Patients' demographic variables were analyzed by using descriptive statistics. Kolmogorov-Smirnov test was used in order to testing the normality of the distribution. The hypothesis about the PLS-AFO usage whether it affects the balance and fall risk of chronic post-stroke spastic hemiparetic patients analyzed with using paired samples t test. $P<0.05$ value was accepted statistically significant.

## Results

All of the recruited subjects finished the study (17 male, 8 female). The mean age of the patients was 60.52±11.43 years (range 35-80 years) and the mean post-stroke duration was 20.32±7.46 months (range 8-36 months). The demographic and the clinical char-

TABLE I.—*Patients' characteristics.*

| Characteristics | N. | |
|---|---|---|
| Age (years)* | 60.52±11.43 | Range 35-80 |
| Gender | | |
| Male | 17 | 68% |
| Female | 8 | 32% |
| Post-stroke duration (months)* | 20.32±7.46 | Range 8-36 |
| Spasticity level (Ashworth)* | 1.80±0.40 | Range 1-2 |

*: mean±standart deviation.

TABLE II.—*The comparison of the participants' balance and fall risk assessment scores with and without ankle-foot orthosis.*

| | Without AFO (mean±SD) | With AFO (mean±SD) | P value |
|---|---|---|---|
| Berg balance scale | 42.12±9.05 | 47.52±7.77 | 0.001 |
| Postural Stability Test | | | |
| Overall | 3.10±1.87 | 3.09±1.58 | 0.96 |
| Anterior/Posterior stability | 1.91±1.38 | 2.00±1.15 | 0.60 |
| Medial/Lateral stability | 1.97±1.28 | 1.86±1.01 | 0.53 |
| Fall Risk Test | | | |
| Overall stability index | 3.35±1.97 | 2.69±1.65 | 0.001 |

Comparisons of the outcomes were made by using paired samples t test. P<0.05 was accepted statistically significant.

acteristics of the patients were summarized in Table I.

Kolmogorov-Smirnov testing revealed no significant deviation from normality for any of the parameters (P>0.05). The use of PLS-AFO did provide no statistically significant change in any of the PST scores (OA, MLS and APS) (P>0.05). On the other hand, the mean Berg score improved from 42.12±9.05 to 47.52±7.77 and OSI score of FRT improved from 3,35 ± 1,97 to 2,69±1,65 and these improvements were statistically significant (P=0.001) (Table II).

## Discussion

Most of the patients experience motor and balance problems after stroke and these lead to walking difficulties and increased fall risk. Therefore balance improvement is one of the main objectives of the stroke rehabilitation. AFOs were commonly used orthosis to provide better balance and walking quality. It was previously reported that they provide ankle spasticity reduction, facilitate the quadriceps muscle activation, correct equinus and recurvatum, decrease anterior pelvic tilt, increase hip extension and consequently restore balance and gait.[6, 22]

Although these reported beneficial effects, the arguments and investigations about the determination of appropriate AFO type and clinical situations were still going on. Wang et al. investigated the effects of prefabricated PLS-AFO on balance and gait performance of post-stroke patients who had hemiparesis of duration of less than 6 months and they found that wearing AFO improved maximal excursion toward the affected side and this correlated with an increase in step length on the non-affected side and as a result, the walking speed was improved on patients.[10] In another study, again Wang *et al.* examined the effects of AFO on balance performance of short and long duration hemiparetic patients. They found that AFO improves weight bearing distribution during quiet standing, body sway during standing, movement velocity of short duration hemipatertic patients (<six months) and such effects were not found in long duration hemiparetic patients (>12 months).[11] Although these two studies investigated the early period and midterm patients which was the major difference from ours, their positive results about prefabricated AFO usage were similar to ours. Simons et al investigated four different mostly prescribed AFO types' effects on balance of twenty chronic hemiparetic post-stroke patients and one of them was identical to ours (only five patients had used this one). They concluded that the usage of AFO provides statistically significant improvement on Berg scores, but they had not evaluated the each of the AFO types separately.[23] On the other hand, Wang et al. had investigated the balance and gait ability with Balance Master System and Berg, and had not reported any beneficial effects of prefabricated plastic AFO at long duration phase (>12 months).[11] We used also Berg intentionally as an outcome measure in order to get more generalized data which might find more chance for the comparison with the previous and further studies because of its simplicity, cost effectiveness and accessibility. We found statistically significant improvement in Berg scores with the usage of PLS-AFO different from previous data. This might result from the mild to moderate spasticity which seemed as the major distinguishing characteristic of our patients. It was previously known that the spasticity might have some beneficial effects on gait and the stability of some spastic patients.[24]

The hemiparetic patients usually have instability on

their affected ankle due to less motor control and spasticity of gastrocnemius-soleus muscle group [7] and this result with poor balance and increased fall risk. The ankle joint had a special importance for the balance evaluation with BBS, because the ankle was the key joint for the transfer of the body weight to the ground and postural stability. Mojika *et al.* investigated the effect of plastic AFO on body sway on 8 post stroke hemiplegic patients (mean post-stroke duration 20.7 weeks, lower limb Brunnstrom motor recovery stage 2-3 and mild to moderate muscular hypertonia at affected lower limb) and reported that center of foot pressure moved toward the unaffected limb without AFO, whereas center of foot pressure shifted toward the mid-position and body sway decreased with AFO.[25] This study had a good similarity with ours in regard to motor status and increased tonicity. In our study, there were no differences on the medial/lateral or anterior/posterior stability scores that might be attributable to the AFO, but the balance improved and fall risk reduced due to PLS-AFO. These two studies had special importance, because it was reported that the 34 -38% of chronic post-stroke hemiparetic patients had spasticity or increased tonus on their affected limbs.[26, 27] However, the studies which had investigated effects of plastic AFO on the spastic post-stroke patients were very rare and reported no beneficial affects,[12] but also they were not confirmed with further studies. On the other hand, there were some novel data about beneficial effects of AFO usage on spastic patients other than stroke that PLS AFO promote knee extension and provide improvements in functional mobility, energy efficiency on children with spastic hemiplegia.[13]

In this present study, the fall risk assessment was a new approach for the investigation of PLS-AFO effects and we could not find any previous similar study. The fall risk reduction that was provided with PLS-AFO wearing in this study had a special significance. Because, it was previously reported that %50 of 99 community dwelling chronic stroke patients who had ability to walk 8 meters (with assistive device, if required) experienced fall and %17.2 (17 patients) were required medical attention within 6 months follow-up period.[28] At this point, AFO seems to be a good supportive choice for the fall risk reduction in appropriate chronic poststroke patients.

There were some limitations of this study. Firstly, the relatively fewer patient number is one of the major limitations of this study. The other major limitation is that the assessments of this study were made in clinical settings with testing scales and devices and it is difficult to generalize these results to daily community life environment. These results do not meet the need for long duration follow-up studies which evaluates the effects of PLS-AFOs on balance, gait and fall risk in the real daily life, but these might probably encourage further such studies.

In conclusion, the prefabricated thermoplastic PLS-AFOs provide better balance and reduced fall risk in chronic post-stroke ambulatory hemiparetic patients who had mild to moderate spasticity at the affected calf muscles. Further studies with more patients and various groups and with longer follow-up duration are needed in order to verify the results and to clarify the action mechanisms.

## References


1. Fatone S, Hansen AH. Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia. J Rehabil Res Dev 2007;44:11-20.
2. Da Cunha IT Jr, Lim PA, Qureshy H, Henson H, Monga T, Protas EJ. Gait outcomes after acute stroke rehabilitation with supported treadmill ambulation training: a randomized controlled pilot study. Arch Phys Med Rehabil 2002;83:1258-65.
3. Geurts ACH, de Hart M, van Nes IJW, Duysens J. A review of standing balance from recovery stroke. Gait&Posture 2005;22: 267-81.
4. Dromerick A, Reding M. Medical and neurological complications during inpatient stroke rehabilitation. Stroke 1994;25:358-61.
5. Divani AA, Vazquez G, Barrett AM, Asadollahi M, Luft AR. Risk factors associated with injury attributable to falling among elderly population with history of stroke. Stroke 2009;40:3286-92.
6. Mauritz KH. Gait training in hemiparetic stroke patients. Eura Medicophys 2004;40:165-78.
7. Gök H, Küçükdeveci A, Altinkaynak H, Yavuzer G, Ergin S. Effects of ankle-foot orthoses on hemiparetic gait. Clin Rehabil 2003;17: 137-9.
8. Bowers RJ. Non-articulated ankle-foot orthoses. In: Condie E, Campbell J, Martina J, editors. Report of a Consensus Conference on the Orthotic Management of Stroke Patients. 1st ed. Copenhagen, Denmark: International Society for Prosthetics and Orthotics; 2004:87-94.
9. Use of ankle-foot orthoses following stroke: Best practice statement [Internet]. Scotland. NHS Quality Improvement Scotland 2009; Available from www.nhshealthquality.org [cited 2010, Jun 10].
10. Wang RY, Lin PY, Lee CC, Yang YR. Gait and balance performance improvements attributable to ankle–foot orthosis in subjects with hemiparesis. Am. J Phys Med Rehabil 2007;86:556-62.
11. Wang RY, Yen LL, Lee CC, Lin PY, Wang MF, Yang YR. Effects of an ankle-foot orthosis on balance performance in patients with hemiparesis of different durations. Clin Rehabil 2005;19:37-44.
12. Beckerman H, Becher J, Lankhorst GJ, Verbeek AL. Walking ability of stroke patients: efficacy of tibial nerve blocking and a polypropylene ankle-foot orthosis. Arch Phys Med Rehabil 1996;77: 1144-51.
13. Buckon CE, Thomas SS, Jakobson-Huston S, Sussman M, Aiona M. Comparison of three ankle-foot orthosis configurations for children with spastic hemiplegia. Dev Med Child Neurol 2001;43:371-8.

14. Buckon CE, Thomas SS, Jakobson-Huston S, Moor M, Sussman M, Aiona M. Comparison of three ankle-foot orthosis configurations for children with spastic diplegia. Dev Med Child Neurol 2004;46: 590-8.
15. Cakar E, Sert G, Durmus O, Dincer U, Kiralp MZ. Informed consent in current medicine: with concomitance of models for common procedures in physical medicine and rehabilitation. J PMR Sci 2009;12:147-60.
16. Berg KO, Wood-Dauphinee S, Williams JI, Maki B. Measuring balance in the elderly: validation of an instrument. Can J Public Health 1992;83(suppl 2):7-11.
17. Sahin F, Yilmaz F, Ozmaden A, Kotevoglu N, Sahin T, Kuran B. Reliability and validity of the Turkish version of the Berg Balance Scale. J Geriatr Phys Ther 2008;31:32-7.
18. Blum L. Korner-Bitensky N. Usefulness of the Berg balance scale in stroke rehabilitation: a systematic review. Phys Ther 2008;88: 559-66.
19. Teasell RW, McRae MP, Foley N, Bhardwaj A. Physical and functional correlations of ankle-foot orthosis use in the rehabilitation of stroke patients. Arch Phys Med Rehabil 2001;82:1047-9.
20. Balance system SD operation/service Manual. Biodex Medical Systems, Inc. 20 Ramsey Road, Shirley, New York, USA.
21. Cakar E, Dincer U, Kiralp MZ, Cakar DB, Durmus O, Kilac H *et al.* Jumping combined exercise programs reduce fall risk and improve balance and life quality of elderly people who live in a long-term care facility. Eur J Phys Rehabil Med 2010;46:59-67.
22. Caillet F, Mertens P, Rabaséda S, Boisson D. Three dimensional gait analysis and controlling spastic foot on stroke patients. Ann Readapt Med Phys 2003;46:119-31.
23. Simons CD, van Asseldonk EH, van der Kooij H, Geurts AC, Buurke JH. Ankle-foot orthoses in stroke: effects on functional balance, weight-bearing asymmetry and the contribution of each lower limb to balance control. Clin Biomech (Bristol, Avon) 2009;24:769-75.
24. Erhan B. Management of Spasticity in Stroke. Turk J Phys Med Rehab 2006;52(Suppl B):B34-B37.
25. Mojica JAP, Nakamura R, Kobayashi T, Handa T, Morohashi I, Watanabe S. Effect of ankle-foot orthosis (AFO) on body sway and walking capacity of hemiparetic stroke patients. Tohoku J Exp Med 1988;156:395-401.
26. Watkins CL, Leathley M, Gregson J, Moore A, Smith T, Sharma A. Prevalence of spasticity post stroke. Clin Rehabil 2002;16:515-22.
27. Welmer AK, von Arbin M, Widen Homqvist L, Sommerfeld DK. Spasticity and its association with functioning and health-related quality of life 18 months after stroke. Cerebrovasc Dis 2006;21:247-53.
28. Harris JE, Eng JJ, Marigold DS, Tokuno CD, Louis CL. Relationship of balance and mobility to fall incidence in people with chronic stroke. Phys Ther 2005;85:150-8.