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# Comparative analysis and quantitative evaluation of ankle-foot orthoses for foot drop in chronic hemiparetic patients

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***Background.*** **Ankle-foot-orthoses (AFOs) are frequently prescribed for hemiparetic patients to compensate for the foot drop syndrome. However, there is not a systematic study either on the effectiveness of AFOs in the gait recovery process or pointing out the therapeutic differences among the various types of AFOs available on the market.**
***Aim.*** **To perform a comparative evaluation of solid and dynamic Ankle-Foot-Orthoses (AFOs) on hemiparetic patients affected by foot drop syndrome by means of spatio-temporal, kinematic and electromyographic indicators.**
***Design.*** **Crossover design with randomization for the interventions.**
***Setting.*** **A rehabilitation center for adults with neurologic disorders.**
***Population.*** **Ten chronic hemiparetic patients with foot drop syndrome met inclusion criteria and volunteered to participate.**
***Methods.*** **Biomechanical gait analysis was carried out on hemiparetic subjects with foot drop syndrome under 3 conditions with randomized sequences: 1) without AFO; 2) wearing a solid AFO; 3) wearing a dynamic AFO. Significant changes in spatio-temporal, kinematic and electromyographic features of gait were investigated.**
***Results.*** **Gait analysis outcomes showed that there were no significant differences among the solid and the dynamic AFO on the spatio-temporal parameters. Both AFOs led to a reduction of the range of motion of the ankle dorsi-plantar-flexion during stance with respect to the ambulation without AFO. They also had the effect of reducing the asymmetry between the paretic and the contralateral limb in terms of ankle angle at initial contact and hip flexion. The solid AFO generally led to an increase of the co-contraction of the couples of muscles involved in the gait.**
***Conclusion.*** **The proposed set of indicators showed that the AFOs were capable of limiting the effect of the foot-drop in hemiparetic patients and balancing the two limbs. Main differences between the two orthoses were related to muscular activity, being the level of co-contraction of the two couples of analysed muscles typically lower when the dynamic AFO was worn and closer to a normal pattern.**
***Clinical Rehabilitation Impact.*** **A more extensive use of the proposed indicators in the clinical practice is expected in order to enable the definition of clinical guidelines for the prescription of the two devices.**

KEY WORDS: Gait - Evaluation studies as topic - Rehabilitation - Stroke.

The "foot drop" syndrome is a well-known disorder affecting hemiparetic patients. It is characterized 97 Otro ->T /V "Ni,1:99" d by the inability or difficulty to move ankle and toes upward (*i.e.* dorsi-flexion). Ankle-Foot-Orthoses (AFOs) are frequently prescribed to compensate for malfunctioning of the neuromuscular system and improve subject walking ability.

Research works on new prototypes of AFOs can be found in the literature.[1, 2] Also, the effects of commer-

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cial AFOs on gait capabilities were widely studied. In Parker JH *et al.*[3] the changes in the gait due to anterior and posterior AFOs were investigated. No statistically significant differences were reported. On the contrary, in Chen C-C *et al.*[4] it was shown that a posterior AFO was able to improve rear-foot dorsi-flexion during the whole gait cycle with respect to an anterior AFO and decrease rear-foot inversion with respect to the absence of AFO. In Lehmann JF *et al.*[5] the effect of different trim lines of plastic AFOs on ankle motion was studied; in Hiroaki A *et al.*[6] the effect of plastic AFOs on gait stability was investigated.

Spatio-temporal parameters,[7, 8] kinematic and kinetic indicators,[9-11] walking speed,[12-14] balance,[15, 16] and energy cost functions [7, 10, 17, 18, 25] were proposed in the literature to assess patient walking capabilities. Some studies [7-18] showed the beneficial effects of wearing AFOs, while studies in Ridgewell E *et al.*,[19] Morris C,[20] Figueiredo EM *et al.*[21] reported very limited advantages. In Don R *et al.*[23] and Merlo A *et al.*[24] quantitative indexes were used to assess Charcot-Marie-Tooth patients with foot drop and plantar flexion failure. As explained in Bregman DJJ,[22] the controversial results found in the literature could be justified by the orthosis mechanical properties, which differently matched patients' individual impairment.

This paper focuses on a specific pathology not addressed in the literature (*i.e.* foot drop syndrome in hemiparetic patients) and carries out a comparative evaluation of two commercial AFOs with different mechanical properties, *i.e.* solid versus dynamic AFO, by means of quantitative indicators of subject gait capabilities.

Two commercial orthoses (*i.e.* the Codivilla Spring and the Toe-Off) were considered for this study. The Codivilla Spring is a solid AFO with a rigid structure that increases both plantar-flexion and dorsi-flexion resistance.[26] The Toe-Off is a dynamic AFO with a flexible structure capable of storing elastic energy during stance and releasing it during swing. The analysis resorts to quantitative indicators describing patient performance during gait in terms of spatio-temporal, kinematic and muscular features. The main subgoals of this study are: 1) to assess the capability of the AFOs to improve walking in the case of a specific disorder, *i.e.* the foot drop, thus focusing on dorsi-plantar flexion correction; 2) to compare the corrective action of two different off-the-shelf orthoses, i.e. solid and dynamic AFOs; 3) to evaluate the capability of the orthoses to rebalance the behaviour of the two limbs (paretic and contralateral); 4) to verify the effect of the AFO on the behaviour of the contralateral limb.

Ten subjects were enrolled in this study. A biomechanical gait analysis through a stereo-photogrammetric system (BTS Smart D) was carried out in three different conditions: shoes without AFO, shoes with a solid AFO and shoes with a dynamic AFO. From the recorded gait patterns a set of 22 quantitative indexes were extracted. Finally a statistical analysis based on Friedman non-parametric tests with Wilcoxon *post-hoc* test and Bonferroni correction was carried out to compare patients' gait performance in the three aforementioned conditions.

## Materials and methods

### Subjects

Ten chronic hemiparetic patients (7 men, 3 women) with foot drop syndrome met inclusion criteria and volunteered to participate in this study. Table I shows patients anamnestic data.

Inclusion criteria were the following: 1) diagnosis of a single, unilateral stroke at least six months prior to enrolment, verified by brain imaging; 2) sufficient walking capability to walk without assistance, with or without support; 3) sufficient cognitive and language abilities (Mini-Mental Status Score ≥ 22 or interview for aphasic subjects). None of the subjects was hemiplegic or affected by chronic deformities of the lower limb. Subjects neither had other types of ankle foot anomalies, such as the equinus varus foot, nor was affected by other pathologies involving locomotion.

All subjects gave informed consent to take part in the pilot study, which was approved by local scientific and ethical committees.

### Materials

Two commercial models of AFOs were analysed and compared in this study (Figure 1). They are a solid and a dynamic AFO typically prescribed in the

i In the following affected and unaffected will be used as synonymous of paretic and contralateral limbs, respectively.

TABLE I.—*Demographic and etiologic characteristics of the hemiparetic subjects.*

| Subject | Gender | Age (years) | Diagnosis | Affected limb | Height (cm) | Weight (Kg) | Time from |
|---|---|---|---|---|---|---|---|
| 1 | F | 74 | ISC | L | 152 | 53 | 18 |
| 2 | M | 66 | HAE | R | 174 | 78 | 17 |
| 3 | M | 76 | ISC | R | 163 | 88 | 205 |
| 4 | F | 69 | ISC | R | 165 | 66 | 24 |
| 5 | M | 74 | ISC | R | 167 | 80 | 183 |
| 6 | M | 44 | HAE | R | 170 | 75 | 12 |
| 7 | M | 71 | ISC | L | 173 | 75 | 69 |
| 8 | M | 55 | HAE | L | 174 | 90 | 21 |
| 9 | F | 52 | ISC | R | 174 | 70 | 84 |
| 10 | M | 62 | ISC | L | 168 | 80 | 11 |

F: female; M: male; ISC: ischemic; HAE: hemorrhagic; R: right; L: left.

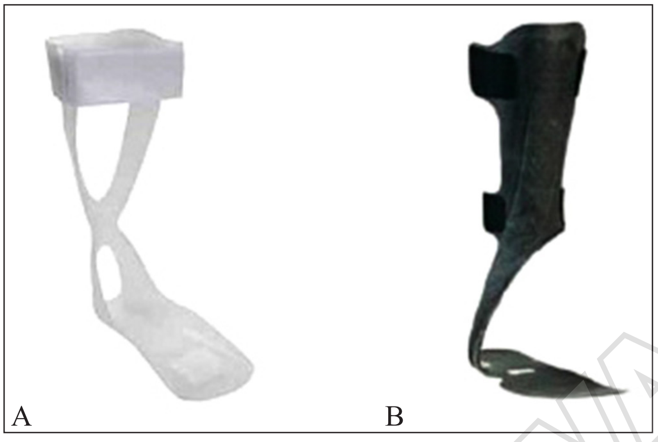

Figure 1.—A) Solid AFO; B) dynamic AFO.

clinical practice. The solid orthosis (by M.T.O. Spa) is made of polypropylene, has a posterior leaf and is called "Codivilla-spring". The dynamic orthosis, called "Toe-Off" (by Allard International), is made of carbon fibre, fiberglass and Kevlar and has an anterior leaf.

A biomechanical gait analysis was carried out through a stereo-photogrammetric system (BTS Smart D) (Figure 2) made of 8 infrared cameras capturing the movement of 20 passive and retro-reflecting markers, 2 digital cameras for the simultaneous acquisition of the video (BTS VIXTA) and 8 miniaturized probes with active EMG electrodes (BTS FREEEMG 300) positioned on the lateral gastrocnemius, tibialis anterior, biceps femoris and rectus femoris muscles. The markers were placed on the patient's body according to the Davis protocol (Figure 3A).[27]

### *Experimental protocol and evaluation*

The clinical protocol included a preliminary wash-out phase followed by three randomly ordered walking sessions, performed in the same day: 1) 5 walking trials without orthosis; 2) five walking trials with the Codivilla-spring; 3) five walking trials with the Toe-Off. Each subject was instructed to walk with a self-paced speed along a 3-m walkway (Figure 3). During the trials the subjects were allowed to use ambulation aids.

Patient evaluation was carried out through clinical scales and quantitative indicators extracted from the gait motion analysis. The following clinical scales were used: Lower Extremity Fugl-Meyer, Mini Men-

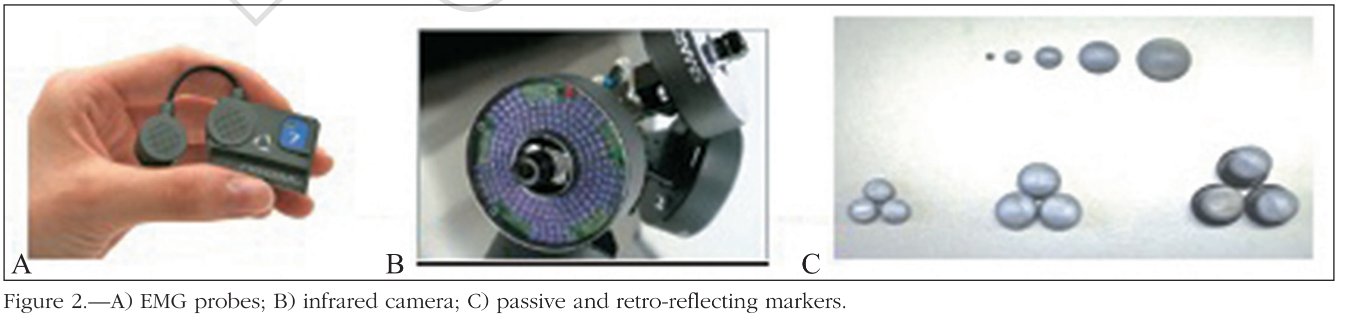

Figure 2.—A) EMG probes; B) infrared camera; C) passive and retro-reflecting markers.

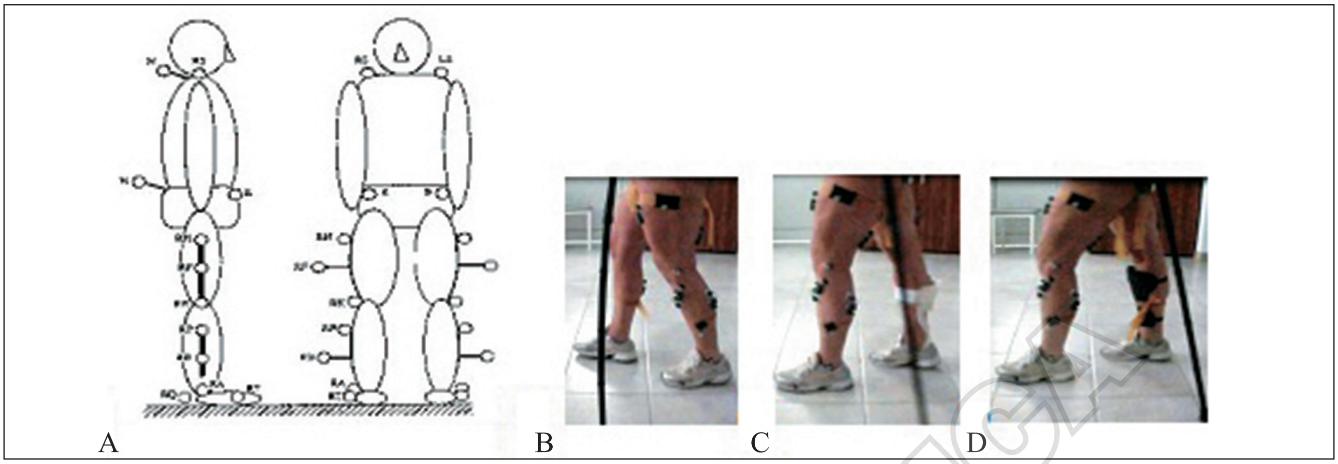


Figure 3.—A) Markers positioning in the Davis protocol; Ambulation of a patient during the gait analysis; B) without AFO; C) with solid AFO; D) with dynamic AFO.

tal State Examination, Modified Ashworth Scale, passive Ranges of Motion (pROM), and Timed Up and Go Test.

### *Data analysis*

Spatio-temporal, kinematic and electromyographic indicators were used for the biomechanical analysis. Friedman non-parametric tests with Wilcoxon post-hoc test were used to carry out three comparative analyses of patient performance: 1) without orthosis versus Codivilla-spring; 2) without orthosis versus Toe-Off; 3) Codivilla-spring *versus* Toe-Off. A Bonferroni correction was applied ($P<0.167$). Also the behaviour of the two limbs (paretic and contralateral) was compared through a Wilcoxon test. Finally, the effect of the orthosis on the contralateral limb was evaluated.

### *Spatiotemporal indicators*

A stride is the time between two consecutive heel-floor contacts of the same limb, and is segmented in a stance phase and a swing phase. Cadence, step length, stride length, stride time, percentage of swing phase and percentage of double stance phase were evaluated.

### *Kinematic indicators*

Twelve kinematic indicators were computed to quantify patient motion capabilities at ankle, knee and hip levels. For the ankle the following parameters were evaluated: angle between the floor and the foot at initial contact;[ii] range of motion (*i.e.* ROM) of the dorsi-plantar-flexion during swing and stance phases; dorsi-flexion peak during the swing phase. Because of the specific pathology addressed by this study, *i.e.* the foot drop, only ankle dorsi-plantar flexion was monitored.

For the knee ROM of the flexion-extension angle was computed.

For the hip the following indicators were calculated: ROM of the flexion-extension angle (during swing and stance phases); flexion peak during the swing phase; ad/abduction ROM during the swing phase; pelvic frontal ROM (during swing and stance phases).

### *EMG indicators*

The following four electromyographic parameters were computed:

a) Co-Activation Index (CI), expressed as:[28]

$$CI = \frac{EMG_L}{EMG_H} * \left(\frac{EMG_L + EMG_H}{2}\right)$$

where $EMG_L$ is the activity of the less active muscle and $EMG_H$ the activity of the more active muscle. CI is used to evaluate the simultaneous activation

ii) It is null when tibia and foot are orthogonal each other (*i.e.* the angle between them is 90°); it is positive when the angle between them is less than 90°; it is negative when the angle between tibia and foot is higher than 90°.

of agonist/antagonist muscles in four different intervals of the stance phase (*i.e.* loading response, mid-stance, terminal stance and pre-swing) and in three different intervals of the swing phase (*i.e.* initial swing, mid-swing and terminal swing).

b) Tibialis Anterior Activation Index (TAAI), calculated as:[29]

$$\frac{\text{sum of TA activity between toe off and toe strike}}{\text{sum of TA activity during one complete gait cycle}}.$$

It represents the capacity of the TA to be active during the swing phase.

c) Push-off index (POI), used to determine the activity of the calf during the push-off phase and computed as:[29]

$$\frac{\text{sum of calf activity from 11\% of gait cycle before heel rise to 9\% of gait cycle after heel rise}}{\text{sum of calf activity during one complete gait cycle}}.$$

d) Premature Calf Activation Index (PCAI), defined as:[29]

$$\frac{\text{sum of calf activity toe strike + 20\% of the gait cycle}}{\text{sum of calf activity during one complete gait cycle}}.$$

It allows identifying abnormal premature calf activity in early stance.

## Results

### *Clinical evaluation*

The results of the clinical evaluation are reported below in terms of mean value and SD:

— Fugl-Meyer: 26.70 (±1.49);

— Mini Mental State Examination: 26 (±2.29);

— Modified Ashworth Scale for ankle dorsi-plantar flexors: 1.10(±0.31);

— Timed Up and Go Test:

- No AFO: 27.86 (±9.35) s;
- solid AFO: 28.57 (±11.5) s;
- dynamic AFO: 26.73 (±8.84) s.

Detailed values for each patient of Modified Ashworth Scale (used to assess spasticity), Lower Extremity Fugl-Meyer and passive joint Ranges of Motion (to assess impairment) are reported in Tables II-V. In particular, Table II reports the scores of the Lower Extremity Fugl-Meyer and the Modified Ash-

TABLE II.—*Lower-extremity FM scores and Modified Ashworth Scale scores for ankle dorsi-plantar flexors for each subject.*

| Subject | FM/34 | Modified Ashworth Scale |
|---|---|---|
| 1 | 25 | 1 |
| 2 | 28 | 1 |
| 3 | 25 | 1 |
| 4 | 25 | 1 |
| 5 | 26 | 1 |
| 6 | 28 | 1 |
| 7 | 28 | 1 |
| 8 | 26 | 2 |
| 9 | 29 | 1 |
| 10 | 27 | 1 |

TABLE III.—*Passive rotations and Range of Motion of Hip and Knee joints in the sagittal plane for each subject.*

| Subject | Hip (A) | | | Knee (A) | | | Hip (U) | | | Knee (U) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Flex | Ext | ROM | Flex | Ext | ROM | Flex | Ext | ROM | Flex | Ext | ROM |
| 1 | 85° | 10° | 95° | 90° | 5° | 95° | 95° | 15° | 110° | 110° | 0° | 110° |
| 2 | 80° | 15° | 95° | 100° | -5° | 95° | 95° | 20° | 115° | 110° | 0° | 110° |
| 3 | 90° | 15° | 105° | 90° | 0° | 90° | 90° | 20° | 110° | 105° | 0° | 105° |
| 4 | 85° | 10° | 95° | 80° | -5° | 75° | 95° | 20° | 115° | 95° | 5° | 100° |
| 5 | 85° | 15° | 100° | 95° | 0° | 95° | 100° | 20° | 120° | 105° | 0° | 105° |
| 6 | 95° | 20° | 115° | 95° | 5° | 100° | 105° | 25° | 130° | 110° | 0° | 110° |
| 7 | 95° | 20° | 115° | 100° | 5° | 105° | 100° | 25° | 125° | 120° | 0° | 120° |
| 8 | 90° | 20° | 110° | 85° | -5° | 80° | 100° | 20° | 120° | 110° | 5° | 115° |
| 9 | 95° | 20° | 115° | 100° | -5° | 95° | 105° | 25° | 130° | 120° | 0° | 120° |
| 10 | 85° | 10° | 95° | 100° | -5° | 95° | 100° | 20° | 120° | 110° | 0° | 110° |

A: affected limb; U: unaffected limb.

Table IV.—*Passive rotations and Range of Motion of Ankle joint in sagittal, transverse, and coronal planes for each subject for the affected limb.*

| Subject | Ankle (A) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Dorsiflex | Plantiflex | D/P ROM | Abduct | Adduct | A/A ROM | Inversion | Eversion | I/E ROM |
| 1 | 10° | 25° | 35° | 10° | 15° | 25° | 35° | 15° | 50° |
| 2 | 10° | 25° | 35° | 15° | 15° | 30° | 30° | 15° | 45° |
| 3 | 15° | 25° | 40° | 10° | 20° | 30° | 30° | 10° | 40° |
| 4 | 10° | 25° | 35° | 15° | 25° | 40° | 30° | 20° | 50° |
| 5 | 15° | 30° | 35° | 15° | 25° | 40° | 35° | 20° | 55° |
| 6 | 20° | 30° | 50° | 20° | 25° | 45° | 35° | 20° | 55° |
| 7 | 20° | 25° | 45° | 20° | 25° | 45° | 40° | 25° | 65° |
| 8 | 15° | 25° | 40° | 15° | 25° | 40° | 30° | 20° | 50° |
| 9 | 20° | 30° | 50° | 15° | 30° | 45° | 35° | 15° | 50° |
| 10 | 20° | 35° | 55° | 15° | 25° | 40° | 30° | 15° | 45° |

A: affected limb; U: unaffected limb.

Table V.—*Passive rotations and Range of Motion of Ankle joint in sagittal, transverse, and coronal planes for each subject for the unaffected limb.*

| Subject | Ankle (U) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Dorsiflex | Plantiflex | D/P ROM | Abduct | Adduct | A/A ROM | Inversion | Eversion | I/E ROM |
| 1 | 25° | 30° | 55° | 15° | 25° | 40° | 35° | 20° | 55° |
| 2 | 20° | 30° | 50° | 15° | 20° | 35° | 30° | 15° | 45° |
| 3 | 25° | 25° | 50° | 15° | 20° | 35° | 30° | 15° | 45° |
| 4 | 20° | 25° | 45° | 15° | 25° | 40° | 35° | 20° | 55° |
| 5 | 25° | 35° | 60° | 15° | 25° | 40° | 35° | 25° | 60° |
| 6 | 25° | 35° | 60° | 20° | 25° | 45° | 35° | 25° | 60° |
| 7 | 25° | 30° | 55° | 20° | 25° | 45° | 40° | 25° | 65° |
| 8 | 25° | 30° | 55° | 15° | 25° | 40° | 35° | 20° | 55° |
| 9 | 25° | 35° | 60° | 15° | 30° | 45° | 35° | 15° | 50° |
| 10 | 20° | 30° | 50° | 15° | 25° | 40° | 35° | 15° | 50° |

A: affected limb. U: unaffected limb.



worth Scale for ankle dorsi-plantar flexors. Table III reports rotation values and pROMs for hip and knee in the sagittal plane, while Tables IV and V shows rotation values and pROMs for the ankle in the sagittal, coronal and transverse planes.

The clinical evaluation also testifies that the enrolled patients had not other types of ankle foot anomalies, such as the equinus varus foot, in addition to foot drop. In fact, as shown in Table II the level of spasticity of all patients, except for patient 8, was 1. For patient 8, the Modified Ashworth value was 2 (thus indicating the capability to easily move the affected part, despite a more marked increase of muscle tone through most of the ROM) but the pROM of the ankle in the sagittal plane was 40°, comparable with the pROM values for the other enrolled patients.

### *Quantitative evaluation*

The computed spatio-temporal indices are shown in Table VI. The Friedman test showed that there were no statistically significant differences among the three analysed walking conditions. A statistical significant difference was observed only in the comparison between the paretic and contralateral limbs for the percentage of swing phase ($P=0.0018$ without orthosis; $P=0.0022$ for the solid AFO; $P=0.0235$ for the dynamic AFO) as well as for the percentage of double support phase ($P=0.0154$ without orthosis; $P=0.0185$ for the solid AFO; $P=0.0023$ for the dynamic AFO).

Table VII reports mean and SD of kinematic indicators for ankle, knee and hip. The solid as well as the dynamic AFO led to a statistically significant

TABLE VI.—*Spatio-temporal data in hemiparetic patients.*

| Parameter | | Shoes | Solid AFO | Dynamic AFO |
|---|---|---|---|---|
| Cadence [step/min] | | 56.68 ± 9.08 | 58.38 ± 15.77 | 57.51 ± 13.51 |
| Stride time [s] | A | 2.03 ± 0.48 | 1.95 ± 0.61 | 2.05 ± 0.66 |
| | U | 2.08 ± 0.41 | 1.96 ± 0.57 | 2.16 ± 0.68 |
| Step length [m] | A | 0.28 ± 0.08 | 0.30 ± 0.10 | 0.28 ± 0.08 |
| | U | 0.28 ± 0.11 | 0.26 ± 0.01 | 0.23 ± 0.10 |
| Stride length [%] | A | 0.57 ± 0.16 | 0.60 ± 0.21 | 0.55 ± 0.21 |
| | U | 0.59 ± 0.20 | 0.58 ± 0.19 | 0.58 ± 0.20 |
| percentage of the swing phase [%] | A | 31.37 ± 7.90[1c] | 32.57 ± 7.90 [c] | 31.67 ± 10.10 [c] |
| | U | 21.12 ± 5.00 | 19.30 ± 6.70 | 22.02 ± 8.10 |
| percentage of the double support phase [%] | A | 18.88 ± 7.30[c] | 17.58 ± 5.50 [c] | 17.07 ± 5.50 [c] |
| | U | 26.76 ± 7.50 | 26.87 ± 10.8 | 29.26 ± 11.60 |

Data are mean±SD. A: affected limb; U: unaffected limb.
a) Mean of this condition differed significantly from mean of Shoes condition; b) Mean of solid AFO differed significantly from mean of dynamic AFO; c) Mean of controlateral differed significantly from mean of paretic limb.

TABLE VII.—*Kinematic data in hemiparetic patients.*

| Parameter [°] | | Shoes | Solid AFO | Dynamic AFO |
|---|---|---|---|---|
| Ankle: | | | | |
| angle at initial contact (sagittal plane) | A | -1.63 ± 6.3[c] | 3.98 ± 3.8[a] | 3.64 ± 3.9 |
| | U | 5.33 ± 3.6 | 6.33 ± 5.0 | 7.08 ± 3.9 |
| dorsi-plantar flexion RoM during the stance phase | A | 16.41 ± 6.4 | 11.11 ± 3.1[a, c] | 10.02 ± 1.9 [a, c] |
| | U | 19.21 ± 5.6 | 18.76 ± 5.5 | 18.16 ± 6.5 |
| dorsi-plantar flexion RoM during the swing phase | A | 6.56 ± 5.6 | 4.60 ± 2.6[c] | 3.92 ± 3.9[c] |
| | U | 7.50 ± 3.4 | 9.67 ± 5.0 | 9.43 ± 6.4 |
| dorsi flexion peak during the swing phase | A | 1.09 ± 9.2[c] | 5.71 ± 5.9[c] | 2.57 ± 9.2 |
| | U | 9.12 ± 3.7 | 11.57 ± 4.4 | 9.79 ± 2.7 |
| Knee: | | | | |
| flexion RoM during the stance phase | A | 11.88 ± 5.8 | 13.58 ± 6.5 | 10.81 ± 3.9 |
| | U | 10.31 ± 4.3. | 9.69 ± 4.3 | 8.12 ± 2.3 |
| flexion peak during the swing phase | A | 31.72 ± 12.0[c] | 28.44 ± 8.4[c, b] | 20.76 ± 13.0 [c, a] |
| | U | 55.16 ± 8.4 | 54.58 ± 8.5 | 52.54 ± 12.9 |
| Hip: | | | | |
| flexion/extension RoM during the stance phase | A | 23.07[c] ± 9.1 | 23.69 ± 10.1[c] | 19.52 ± 8.8[c] |
| | U | 33.44 ± 7.3 | 31.66 ± 7.7 | 31.16 ± 7.8 |
| flexion/extension RoM during the swing phase | A | 15.26 ± 8.6 | 18.01 ± 4.0 | 15.60 ± 7.4 |
| | U | 19.10 ± 7.9 | 21.14 ± 10.7 | 18.58 ± 8.6 |
| flexion peak during the swing phase | A | 32.49[c] ± 13.9 | 33.57 ± 11.4 | 30.20 ± 17.7[c, a] |
| | U | 40.66 ± 15.1 | 39.44 ± 13.5 | 37.61 ± 17.3 |
| ad/abduction RoM during the swing phase | A | 5.57 ± 3.9 | 4.88 ± 1.7 | 4.41 ± 1.6 |
| | U | 4.60 ± 1.5 | 4.59 ± 2.3 | 4.97 ± 3.1 |
| pelvic tilt RoM during the stance phase | A | 7.59 ± 4.2 | 7.38 ± 3.2 | 6.78 ± 3.0 |
| | U | 8.42 ± 4.2 | 7.90 ± 3.8 | 7.93 ± 4.1[c] |
| pelvic tilt RoM during the swing phase | A | 6.82 ± 4.4[c] | 6.72 ± 4.0 [c] | 6.21 ± 4.6[c] |
| | U | 2.74 ± 1.9 | 2.93 ± 2.7 | 3.02 ± 1.7 |

Data are mean±SD. A: affected limb; U: unaffected limb
a) Mean of this condition differed significantly from mean of Shoes condition; b) Mean of solid AFO differed significantly from mean of dynamic AFO; c) Mean of controlateral differed significantly from mean of paretic limb.

reduction of the ROM of the dorsi-plantar-flexion of the affected ankle during stance with respect to the ambulation without AFO (solid AFO: P=0.008, dynamic AFO: P=0.011). The angle between the floor and the foot at initial contact changed towards positive values for both orthoses. The variation was significant only for the solid AFO (P=0.008). The other examined kinematic parameters did not show statistically significant changes in the use of AFOs compared to the walking without AFO.

On the other hand, data on the affected and unaffected limbs pointed out that both AFOs have the

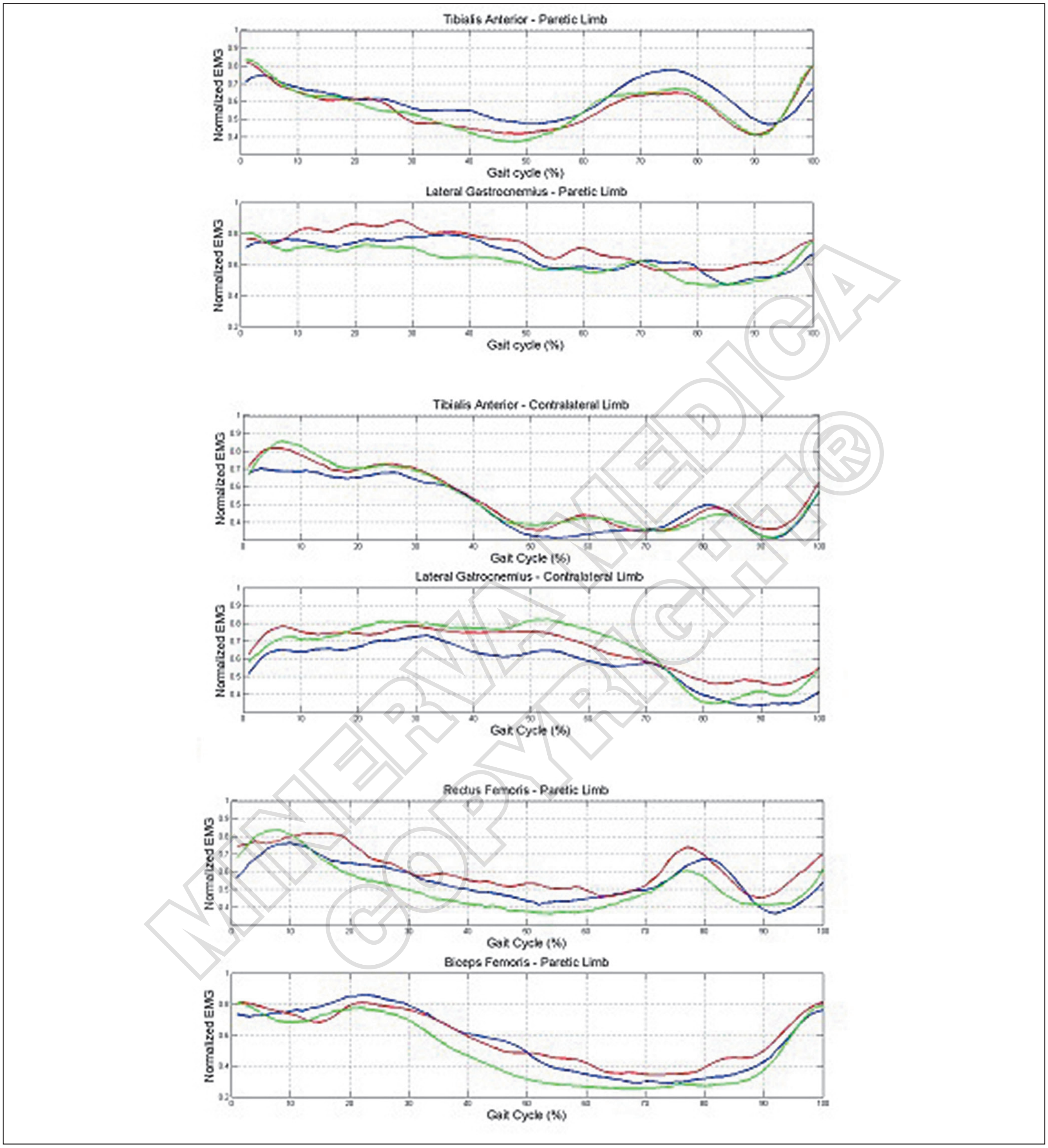


Figure 4.—EMG Mean Envelope for the couples of muscles A) *tibialis anterior-gastrocnemius* of the paretic limb; B) *tibialis anterior-gastrocnemius* of the contralateral limb; C) *rectus femoris-biceps femoris* of the paretic limb (black: without AFO; red: solid AFO; green: dynamic AFO).

effect of reducing the asymmetry between the two limbs in terms of ankle angle at initial contact and hip flexion peak (the difference between affected and unaffected limbs is not significant).

The mean value of EMG activity over all the subjects is drawn in Figure 4 for the two muscular couples of *tibialis anterior-lateral gastrocnemius* and *rectus femoris-biceps femoris*. Quantitative indicators extracted from EMG signals are reported in Tables VIII-IX. Significant results were retrieved only for the co-activation index.

Consider first the couple of muscles *tibialis anterior-lateral gastrocnemius* in Table VIII. For the paretic limb, in each stance sub-phase except for the pre-swing, CI values related to the solid AFO were higher than ones for the dynamic AFO. This difference however was not statistically significant. On the contralateral limb, during mid-stance and terminal stance CI values obtained with Toe-Off and without orthosis were higher than values obtained for the paretic limb (P=0.050 and P=0.036 without orthosis; P=0.036 and P=0.017 with the dynamic AFO).

TABLE VIII.—*Coactivation Index in hemiparetic patients.*

| Parameter | | Shoes | Solid AFO | Dynamic AFO |
|---|---|---|---|---|
| *Tibialis anterior-gastrocnemius* | | | | |
| Co-activation index | | | | |
| *During mid-stance* | | | | |
| | A | 0.401 ± 0.194[c] | 0.533 ± 0.249 | 0.460 ± 0.223[c] |
| | U | 0.632 ± 0.177 | 0.595 ± 0.202 | 0.644 ± 0.171 |
| *During terminal stance* | | | | |
| | A | 0.303 ± 0.136[c] | 0.382 ± 0.206 | 0.304 ± 0.137[c,] |
| | U | 0.520 ± 0.151 | 0.410 ± 0.130 | 0.445 ± 0.114 |
| *During initial swing* | | | | |
| | A | 0.455 ± 0.273 | 0.478 ± 0.253[c] | 0.443 ± 0.164[c] |
| | U | 0.250 ± 0.125 | 0.214 ± 0.070 | 0.224 ± 0.108 |
| *During mid-swing* | | | | |
| | A | 0.413 ± 0.203[c] | 0.396 ± 0.181[c] | 0.340 ± 0.162 |
| | U | 0.247 ± 0.127 | 0.263 ± 0.157 | 0.226 ± 0.096 |
| *During terminal swing* | | | | |
| | A | 0.409 ± 0.214 | 0.583 ± 0.101 [c] | 0.554 ± 0.180[c] |
| | U | 0.297 ± 0.113 | 0.336 ± 0.166 | 0.337 ± 0.153 |
| *Rectus femoris-biceps femoris* | | | | |
| Co-activation index | | | | |
| *During loading response* | | | | |
| | A | 0.639 ± 0.239 | 0.703 ± 0.222 | 0.685 ± 0.186 |
| | U | 0.622 ± 0.160 | 0.563 ± 0.215 | 0.527 ± 0.202 |
| *During mid-stance* | | | | |
| | A | 0.533 ± 0.227 | 0.688 ± 0.117[c] | 0.533 ± 0.209 |
| | U | 0.562 ± 0.176 | 0.488 ± 0.118 | 0.410 ± 0.151 [a,] |
| *During terminal stance* | | | | |
| | A | 0.348 ± 0.124 [c] | 0.416 ± 0.198 | 0.269 ± 0.115 |
| | U | 0.553 ± 0.211 | 0.442 ± 0.204[a] | 0.409 ± 0.165[a] |
| *During pre-swing* | | | | |
| | A | 0.229 ± 0.154 | 0.263 ± 0.226 | 0.150 ± 0.087[, c] |
| | U | 0.404 ± 0.233 | 0.325 ± 0.169 | 0.306 ± 0.155 |
| *During initial swing* | | | | |
| | A | 0.207 ± 0.174 | 0.283 ± 0.283 | 0.209 ± 0.208 |
| | U | 0.252 ± 0.121 | 0.190 ± 0.136 | 0.187 ± 0.116 |
| *During mid swing* | | | | |
| | A | 0.290 ± 0.170[c] | 0.338 ± 0.203[c] | 0.249 ± 0.130 |
| | U | 0.220 ± 0.125 | 0.227 ± 0.137 | 0.207 ± 0.092 |
| *During terminal swing* | | | | |
| | A | 0.436 ± 0.101 | 0.537 ± 0.176 | 0.418 ± 0.110 |
| | U | 0.469 ± 0.191 | 0.398 ± 0.187 | 0.422 ± 0.151 |

Data are mean±SD
A: affected limb; U: unaffected limb.

TABLE IX.—*Electromyographic data in hemiparetic patients.*

| Parameter | | Shoes | Solid AFO | Dynamic AFO |
|---|---|---|---|---|
| Tibial Anterior Activation Index | A | 0.41 ± 0.13 | 0.47 ± 0.11 | 0.43 ± 0.16 |
| | U | 0.21 ± 0.07 | 0.28 ± 0.10 | 0.27 ± 0.09 |
| Premature Calf Activation Index | A | 0.24 ± 0.10 | 0.23 ± 0.06 | 0.23 ± 0.02 |
| | U | 0.20 ± 0.05 | 0.22 ± 0.06 | 0.21 ± 0.02 |
| Push-off Index | A | 0.24 ± 0.05 | 0.21 ± 0.07 | 0.21 ± 0.03 |
| | U | 0.24 ± 0.06 | 0.24 ± 0.04 | 0.24 ± 0.03 |

Data are mean±SD
A: affected limb; U: unaffected limb.

As regards the swing phase, in both limbs during the initial swing there were not significant differences with and without orthosis. For the paretic side, in the terminal swing both AFOs caused an increase of CI, although significance was not reached. For the contralateral limb, during initial swing and terminal swing CI values were lower than CI values obtained for the paretic limb with both solid (P=0.017 and P=0.012) and dynamic AFO (P=0.012 and P=0.036). In the mid-swing, the difference between CI values in the contralateral and paretic limbs was significant only for the solid AFO (P=0.025) and without orthosis (P=0.025).

Consider now the couple of muscles *rectus femoris-biceps femoris*. For the paretic side, all along the stance phase the Codivilla spring made the CI increase with respect to the Toe-Off and the absence of orthosis. However, this behaviour did not produce significant variations. During the terminal stance and the subsequent pre-swing, the Toe-Off induced a notable CI reduction with respect to the absence of AFO; because of the Bonferroni correction, the variation was not significant but close to the threshold (P=0.025). For the contralateral limb, there were no statistically significant changes in the performed multiple analysis.

Along the swing phase, the Codivilla spring generally provided higher CI values than the Toe-Off, although the difference was not significant. In the mid-swing, the difference between CI values in the contralateral and paretic limbs was significant only for the solid AFO (P=0.017) and without orthosis (P=0.025).

## Discussion

This paper presented a clinical study of the effects of two different commercial AFOs typically used in the clinical practice (solid versus dynamic AFO) on walking capabilities of 10 chronic hemiparetic patients with foot drop syndrome. No other types of ankle foot anomalies were present in the enrolled patients. Three walking sessions (without AFO, with an anterior dynamic AFO and with a posterior solid AFO), randomly ordered, were carried out for each patient. A biomechanical gait analysis based on the Davis protocol was carried out through a stereo-photogrammetric system (BTS Smart D). Spatio-temporal, kinematic and electromyographic changes in patients ambulation patterns were measured through quantitative indices.

The results showed that both AFOs can reduce the ROM of the dorsi-plantar-flexion angle of the ankle, thus proving that the use of the AFO is effective in correcting the foot drop syndrome, independently on the specific type of orthosis. No relevant difference was retrieved in the spatio-temporal parameters probably because of the short time the patient used the orthoses. Furthermore, both devices showed a balancing effect between the two limbs, with different co-activation patterns of the involved muscles (Table VIII).

In detail, for the couple of muscles *tibialis anterior-gastrocnemius*, it was observed a clear increase of the CI on the paretic side during mid-stance with both AFOs (with respect to the absence of AFO). It was probably caused by the proprioceptive stimulus related to the presence of the external device. Lower CI could be observed for the Toe-Off (although not statistically significant), probably because of its elastic structure.

CI values obtained without orthosis and with Toe-Off on the contralateral limb during mid-stance were similar and higher than values obtained for the paretic limb. This may be due to the longer time duration of the stance phase and to the major effort for the ankle stabilization. Additionally, the combined effect of the elastic features and the anterior leaf of the Toe-Off caused a reduction of the tibialis anterior activity of the paretic limb (Figure 4A) and, consequently, a lower CI value in mid-stance and terminal stance phases with respect to the contralateral limb. In the terminal stance, both orthoses reduced the CI on the contralateral limb with respect to the absence of AFO because of the "push" effect of the orthoses during pre-swing. The expected consequence is the positive effect on the contralateral side of reducing co-contraction. This is confirmed by the increased activity of the gastrocnemius for both AFOs compared to the absence of orthosis (Figure 4B), while tibialis anterior activity is similar.

During the initial swing, the use of orthoses (independently on the specific type) did not entail significant CI differences in the two limbs with respect to the ambulation without orthosis. Both orthoses enabled a more effective clearance of the paretic limb (confirmed by the lower activity of the tibialis anterior in presence of AFOs [Figure 4A]). The effect was more evident in the Toe-Off that, because of the elastic material, allowed storing energy in the stance phase and releasing it in the swing phase. This behaviour was sharpened in the subsequent mid-swing. Furthermore, in the mid-swing CI values were significantly higher on the paretic side than on the contralateral side for the solid AFO and the absence of AFO (Table VIII). Correspondingly, Figure 4A points out that the absence of orthosis caused higher tibialis anterior activity. With the Toe-Off the gastrocnemius was less active than with the Codivilla spring, thus getting the behaviour of the paretic limb closer to the contralateral limb.

On the other hand, for the couple of muscles *rectus femoris-biceps femoris*, CI values for the Codivilla spring were higher than the other two cases all along the stance phase. The solid AFO caused the reduction of the ankle ROM with respect to the ambulation without orthosis and, due to the mechanical stiffness of the material, caused the major involvement of the knee in the trunk weight-bearing. Correspondingly, the rectus femoris was more activated also because of the posterior leaf. This behaviour is particularly evident in the mid-stance (Figure 4C). During the terminal stance and the pre-swing, the Toe-Off induced a large (close to significance) CI reduction with respect to the absence of AFO; this was due to its mechanical elasticity, and consequent energy release.

All along the swing phase, the Codivilla spring provided higher CI values than the Toe-Off. The elastic properties of the Toe-Off coupled to the anterior leaf contributed to generate an extensor torque on the knee that reduced the rectus femoris activity and correspondingly the CI (Figure 4C).

Despite the limited number of subjects, the obtained results were encouraging because they showed that: wearing an AFO did not lead to drawbacks on patient ambulation and provided a corrective action on the typical deficit of dorsi-flexion of patients with foot drop, as expected. Moreover, AFOs played an important role in recovering the balance between the two limbs. Finally, in terms of muscular activation, the anterior dynamic AFO was more beneficial than the posterior solid AFO because of the lower co-contraction of the couple of muscles involved in gait.

Future efforts will be addressed to: a) increase the number of patients, in order to strengthen the statistical significance of the reported results; b) add force data and kinetic indices, which are expected to point out more relevant differences between the two devices; c) define clinical guidelines for the prescription of the two devices.

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