Effect of early compensation of distal motor deficiency by the Chignon ankle–foot orthosis on gait in hemiplegic patients: A randomized pilot study

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Conclusion: Early compensation of distal motor deficiency by the Chignon ankle-foot orthosis improves the immediate gait of hemiplegics more than the standard ankle-foot orthosis and seems to modify motor recovery processes in the legs after stroke.

Key Words: Orthotic devices, Stroke; Rehabilitation.

INTRODUCTION

Recovery after stroke is variable, but many studies on hemiplegic gait have shown that at least 80% of the patients recover gait capacities in the first six months after stroke, with or without technical assistance [1-5]. Nevertheless, this new gait is often tiring, dysfunctional, unaesthetic and costly in energy expenditure and leads to more numerous falls compared with able-bodied persons [6, 7]. The observation of a lack of dorsiflexion linked to weakness of the tibialis anterior muscle usually leads to the prescription of a standard ankle-foot orthosis, which usually increases the quality of gait [8].

The effect of ankle-foot orthoses was recently reported by Leung and Moseley in a systematic review of the literature that confirmed the efficacy of ankle-foot orthoses to improve temporo-spatial gait parameters (gait speed, stride length) and kinematics (better gait pattern and particularly reduction of plantar flexion during swing phase) and to decrease the energy expenditure of walking [9]. Muscle activity remains a controversial issue but studies have shown that plantar flexor activity varies with the use of an ankle-foot orthosis and with the change in the biomechanical features of the ankle-foot orthoses, like flexibility, rigidity or initial ankle angle [10-14]. Many types of ankle-foot orthoses have been developed to address these problems. Hesse *et al*. suggested that a rigid ankle-foot orthosis may reduce the tricipital stretch imposed during the step phase and lead to a decrease in the premature contraction in gait and to limiting the development of spasticity [15]. Furthermore, patients may also present a weakness of the triceps surae muscle, which is not compensated by the standard ankle-foot orthosis. Lehmann *et al.* showed the value of a plantar flexion-assisted ankle-foot orthosis in order to replace the triceps surae muscle concentric contraction, which in turn improved propulsion and gait quality [16, 17]. The Dual carbon fiber spring ankle foot orthosis was recently developed and a dynamic effect on gait with propulsion assistance was reported with it [18].

On the basis of these data, the Chignon dynamic ankle-foot orthosis, which was first developed to offset peripheral deficits, was proposed to hemiplegic patients since it combines all the mechanical properties required of an ankle-foot orthosis for hemiplegic patients [11]. The purpose of the present study was to compare the effect on gait of the Chignon ankle-foot orthosis in early rehabilitation programs for hemiplegic patients versus a standard ankle-foot orthosis.

METHODS

This was a multicenter randomized controlled study conducted in seven French rehabilitation centers. We included 28 patients. According to the Helsinki protocol for clinical trials, the study protocol was approved by the local ethics committee. All patients provided written informed consent.

Patients admitted to a rehabilitation department with hemiparesis after unilateral supra-tentorial, ischemic or hemorrhagic stroke lasting less than 6 months were recruited. Exclusion criteria were: impossibility to stand for 10 seconds; ankle passive dorsi-flexion < 5 degrees with knee flexed to 90 degrees; triceps spasticity $\geq$ 3/4 on the Ashworth modified scale (19); motor or cardiovascular disease that might impair locomotion or other cognitive, visual or general state alteration that might impair active participation in the study.

Eligible patients were randomized to the Chignon group or the control group. Randomization was performed by phoning the coordinator of the study, who attributed the group treatment by consulting a randomization list. Afterwards, patients were given a standard ankle-foot orthosis or Chignon ankle-foot orthosis which was manufactured by an orthoprosthetist. Orthosis wearing time was not stipulated. There were no constraints regarding associated treatments or rehabilitation time, but the investigators had to note the treatments that the patients were taking at each follow-up time.

The standard ankle-foot orthosis was a classic off-the-shelf polypropylene orthosis. The Chignon ankle-foot orthosis is an articulated double-stopped custom-made orthosis with elastic straps to assist dorsiflexion. It is composed of two rigid polyolefin-molded pieces (calf and foot segments). The foot segment has lateral walls in the posterior part and covers the length of the foot (partly padded with foam for greater comfort). The two segments are joined by a steel articulation at the rear and anterior elastic straps on each side (medial and lateral strips). The articulation, which enables adjustment of the dorsal stop in the sagittal plane, is linked by composite straps with strong elastic properties. The Chignon orthosis can in fact be partially likened to a limited dorsiflexion orthosis, but which also generates a dorsiflexion assist moment and allows movement in the lateral plane (i.e., exo/endorotation of the foot). Adjustment in the frontal plane (varus or valgus of the ankle) is performed by the lateral elastic straps). For example, a more powerful traction on the lateral side on the lateral side on the lateral side of the ankle helps compensate for varus. If significant dorsiflexion force is exerted by the two elastic straps, plantar-ankle flexion is highly limited and the orthosis helps slimit knee extension when the heel strikes. In contrast, if less stiff elastic straps are used, the plantar flexion is not greatly limited. This system has the advantage of being adjustable over time in accordance with the patient's condition (Figure 1).

Standardized assessments were performed at initial wearing time and at 30 and 90 days of follow-up. Motor functional evaluations were performed with and without the orthosis they were allocated in each group and at each time of follow-up. Primary outcome measure was the gain ratio at day 30 calculated with the 10-meter test with and without at maximal gait speed, i.e.: time on 10-meter test without orthosis – time on 10-meter test with orthosis / time on 10-meter test without orthosis. Secondary measures evaluated on days 0, 30 and 90 were gait speed on the 10-meter test, tricipital and quadricipital spasticity on the Ashworth modified scale, range of ankle motion measured with a goniometer, motricity index (MI) (20),

the Functional ambulation classification (FAC) (21), the Postural assessment structural scale (PASS) (22), the Functional independence measure (FIM) (23), subjective quantification of dropped foot by the therapist, knee recurvatum and foot varus, associated treatments, pain evaluation on an analogical visual scale, time of orthosis-wearing per day, and patient's tolerance on an analogical visual scale.

Statistical analysis

Quantitative data are represented as mean ± standard deviation in tables/text. Qualitative data are presented as number or as percentage. The Student T test or the non-parametric Kruskall-Wallis test was performed to analyze possible differences between quantitative values, and Fisher's test was used for qualitative ones. A repeated measures ANOVA test was used to compare repeated measures in similar conditions. A p value of $p < 0.05$ was considered to be significant.

RESULTS

Twenty-eight patients with vascular hemiplegia were enrolled in seven study centers in France. Thirteen patients wore the Chignon device and 15 control subjects used a standard ankle-foot orthosis.

Patient characteristics at baseline were similar in both groups except for time since onset and gender. Other clinical data did not differ between groups (Table 1).

The decreasing time on the 10-meter test between the conditions with and without their allocated orthosis was significantly greater in the Chignon group than in the control one at days 30 and 90 (Table 2).

The flow diagram (figure 2) shows that four patients in the control group wore their orthosis only partially during the follow up while everyone in the Chignon group did so (26.6% in the control group versus 0% in the Chignon group, $p<0.05$).

In the condition without orthosis, the time on the 10-metes test performed at maximal walking speed tended to be lower in the control group at day 90 (p=0.09, Table 2). In the condition with orthosis, it tended to be lower in the Chignon group at initial wearing time (p=0.09,Table 2).

At day 90, in the without orthosis condition, the Functional Ambulatory classification score was higher in the control group (Table 3).

With the allocated orthosis, dropped foot was better corrected in the Chignon group than in the control group at days 0 (p= 0.003), 30 (p= 0.01) and 90 (p= 0.02). However, at day 90 the percentage of dropped foot without orthosis was significantly higher (p=0.01). Corrections of knee recurvatum and foot varus by the allocated orthosis were observed significantly more often in the Chignon group than in the control one, but the effect disappeared when it was removed (Table 3).

Maximal ankle dorsiflexion with knee in extension or flexed at 90 degrees was significantly different between both groups at D90 (12.5± 9.4 for the Chignon group vs 6± 7.7 for the control group in the knee-flexed condition, p= 0.04, and 9.1± 5.5 for the Chignon group vs 2± 8 for the control group in the knee-extension condition, p=0.01).

No significant difference between the both groups was found regarding spasticity scores (Table 4).

The percentage of patients taking an oral antispastic treatment (baclofen or dantrolene) (Table 4) was similar in both groups at baseline. The percentage of patients receiving baclofen was higher in the control group than in the Chignon group at day 30 (p=0.03) and day 90 (p=0.01). No patient had botulinum toxin A injection in the triceps surae at baseline. At day 30 and 90, the percentage of patients who had received a botulinum toxin A injection was significantly higher in the control group (p=0.01 and p=0.03, respectively).

Daily wearing time was not statistically different between the two groups at days 30 (8.64 ± 3.96 hours in the Chignon group vs 9.00 ± 4.68 hours in the control group; p=0.7) and 90 (9.48 ± 3.72 in the Chignon group vs 6.96 ± 5.52 in the control group ; p=0.06).

There was no significant difference in tolerance as assessed on the visual analogical scale between the groups at day 30 (mean visual analogic scale tolerance was 82±33 in the control group versus 86±16 in the Chignon group, p>0.05), but there was a difference at day 90 ((mean Vas tolerance was 70±46 in the control group versus 96±5 in the Chignon group, p=0.01).

DISCUSSION

These results demonstrate an immediate improvement when wearing an orthosis (effect of orthosis as technical aid) that was greater with the Chignon ankle-foot orthosis for walking speed (table 2), dropped foot, foot varus, and knee recurvatum correction (table 3). On the other hand, regularly wearing the Chignon ankle-foot orthosis had a detrimental effect on recovery of active drop foot correction (when walking without ankle-foot orthosis) and on functional gait recovery in a more general sense (Table 3). Thus, it seems that the Chignon device improves immediate and subsequent quality of gait, but induces dependence. A much longer study is necessary to verify this point.

The kinematic parameters with the best correction from day 0 to day 90 with the Chignon ankle-foot orthosis were dropped foot, foot varus and knee recurvatum. The difference with the standard ankle-foot orthosis was immediate and lasting. These findings are consistent with previous findings that ankle-foot orthoses with resistance to plantar flexion improve the posture and kinematic parameters of walking [24-26].

From a methodological point of view, our prospective multicenter controlled randomized study would have benefited from a quantified movement analysis, but this was

unfortunately difficult to organize because of its multicenter nature. Thus, we used subjective assessments in despite of their debatable reproducibility. Nevertheless, these findings corroborate the results of Bleyenheuft *et al*. regarding the improvement of maximal walking speed, the decrease in dropped foot and foot varus [27]. Bleyenheuft *et al*. did not find the efficacy of the Chignon ankle-foot orthosis for knee *recurvatum* correction that we observed. Nevertheless, differences in the populations studied might explain these contrasting results. Only 15% of their patients presented a knee *recurvatum* at baseline, while 80% of our patients did.

Since the Chignon orthosis offers good early stabilization to the whole lower limb, we think it could be used for early gait training with body weight support [28]. Indeed, in the authors' experience, fewer staff are needed for body weight support training when patients wear a Chignon [29].

This study has two main limitations. First, the two groups differed at baseline regarding onset time and gender distribution. We have no methodological explanation for the latter difference. A limitation of the Chignon ankle-foot orthosis is the waiting time before delivery, which is about two weeks minimum but is often much longer, while the standard ankle-foot orthosis is immediately available. This might explain the significant difference at baseline between both groups for the time since onset, which was longer in the Chignon group. For this reason, spasticity and gait parameters might have been worse in the Chignon group, although no difference was noted.

Another limitation is that manufacture and adjustment of the Chignon ankle-foot orthosis need the skills of an experimented orthoprosthetist. Furthermore, the price of the Chignon device is about 10 times that of the standard ankle-foot orthosis. Since the present study showed a decreased consumption of anti-spastic treatment, the price of the Chignon

device should be offset against the cost of treating spasticity in hemiplegic patients, which usually combines systemic and focal treatments and is often expensive [30-32].

The effect on spasticity is another issue concerning the Chignon ankle-foot orthosis. Consumption of anti-spastic treatment, which was freely available during the study and was prescribed when considered necessary, was lower in the Chignon group than in the control group both for oral anti-spastic treatment and botulinum toxin A injection, with a significant difference for both treatments. We hypothesize that this effect is linked with the biomechanical characteristics of the Chignon ankle-foot orthosis, which associates dorsiflexion assistance when ankle dorsiflexion is less than 5 degrees thanks to the elastic straps, and plantar flexion assistance when dorsiflexion is greater than 5 degrees thanks to the straps. This seems to prevent the development of tricipital and quadricipital spasticity by limiting quick muscular stretch during stride. These results are in accordance with the hypothesis of a reorganization of the central nervous system stimulated by proprioceptive afferences that are induced by functional electrical stimulation or repetitive controlled movements [33-38].

Since analytic motricity in both groups was equal and functional walking without orthosis was less improved in the Chignon group than in the control group, we think that the Chignon ankle-foot orthosis offers strong distal contention and reduces spasticity but also induces a distal functional motor inhibition that disturbs spontaneous functional recovery. From a practical point of view, these results suggest that the Chignon ankle-foot orthosis limits the development of the spasticity and improves gait earlier during stroke rehabilitation.

In conclusion, this study demonstrates the benefits of gait retraining after stroke with the Chignon ankle-foot orthosis i.e. superiority of the device compared to the classical one with regard to the immediate effects on gait pattern and speed in hemiplegic patients and by

reducing spasticity during the early rehabilitation phase. Nevertheless, the contrary seemed to be the case for motor re-learning and natural recovery. Further research is needed to investigate its physio-pathological effects on spasticity and spontaneous recovery as well as to evaluate the cost-effectiveness of such a device.

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Legends:

Figure 1: Lateral view of Chignon ankle-foot orthosis

Figure 2: Flow diagram

Table 1: Demographic and baseline characteristics of subjects

	Chignon group N = 13	Control group N = 15	P values
Age, years	56.4 (8)	53 (13)	>0.05
Gender, male / female	11 / 2	7 / 8	<0.05*
Etiology, ischemic / hemorrhage	9 / 4	13 / 2	>0.05
Side of paresis, right/left	7 / 6	8 / 7	>0.05
Onset time, days	104.7 (39)	56 (19)	< 0.05*
10-meter test without orthosis, sec	94.3 (94)	78.4 (73)	>0.05
FAC (/5)	1.9 (1.3)	1.5 (1)	>0.05
PASS (/33)	28.7 (4.4)	25.1 (7.3)	>0.05
FIM (/126)	86.4 (28.7)	81.4 (26.6)	>0.05
MI (/100)	32.8 (16)	32.5 (19.9)	>0.05
Dropped foot	11	12	>0.05

Knee recurvatum	12	10	>0.05
Foot varus	8	6	>0.05
Quadricipital spasticity/4 (mean, SD)	0.9 (1.1)	1.0 (1.1)	>0.05
Sural spasticity /4 (mean, SD)	1.3 (1.2)	1.7 (0.1)	>0.05
Oral antispastic treatment	3	8	>0.05
Botulinum toxin A injection	0	0	>0.05

Legends: FAC: functional ambulatory classification; PASS: postural assessment structural scale; FIM: functional independence measure; MI: motor index; * Significant result.

Table 2: Ten-meter test, difference and gain ratio

	Day 0			Day 30			Day 90		
	Chignon	Control	P	Chignon	Control	P	Chignon	Control	P
Time with orthosis (sec)	39.5 (36)	70.1 (63)	0.09	39.0 (35)	59.4 (63)	0.16	32.9 (37)	45.1 (32)	0.2
Time without orthosis (sec)	94.3 (94)	78.4 (73)	0.33	75.6 (93)	51.5 (34)	0.20	98.4 (110)	49.4 (31)	0.09
Mean of Time difference (sec)	54.8 (95)	4 (10)	0.056	40.8 (67)	4.5 (7)	0.020	65.5 (91)	8.8 (16)	0.01
Gain ratio (%)	27.2 (36)	0.8 (17)	0.006	39.9 (19)	7.5 (17)	0.0004	44.6 (27)	17.1 (0.3)	0.04

Legends: P value of the T student's test or the non parametric Kruskall-Wallis test, between chignon group and control group at each evaluation Gain ratio is : (time on 10 meter test without orthosis - time with orthosis)/10m without orthosis) x 100

Table 3: Functional and kinematic walking and postural evolution with and without orthosis

Test	Condition	**Day 0**			**Day 30**			**Day 90**		
		Chignon N=13	Control N=15	P	Chignon N=13	Control N=15	P	Chignon N=12	Control N=11	P
FAC (/5)	Without orthosis	1.9 (1.3)	1.5 (1)	>0.05	2.4 (1.6)	2.7 (1.2)	>0.05	2.3 (1.7)	3.5 (1.2)	<0.05
	With orthosis	2.5 (1.8)	1.6 (1.3)	>0.05	3.3 (1.2)	3.2 (1.1)	>0.05	3.5 (1.4)	3.9 (1.2)	>0.05
PASS (/33)	Without Orthosis	28.7 (4)	25.1 (7)	>0.05	29.4 (4)	29.2 (4)	>0.05	29.5 (4)	31.9 (2)	>0.05
	With orthosis	29.7 (4)	25.6 (7)	<0.05	30.1 (5)	29.5 (4)	>0.05	30.5 (4)	31.7 (2)	>0.05
Dropped foot	Without orthosis	11	12	>0.05	13	8	>0.05	9	4	<0.05

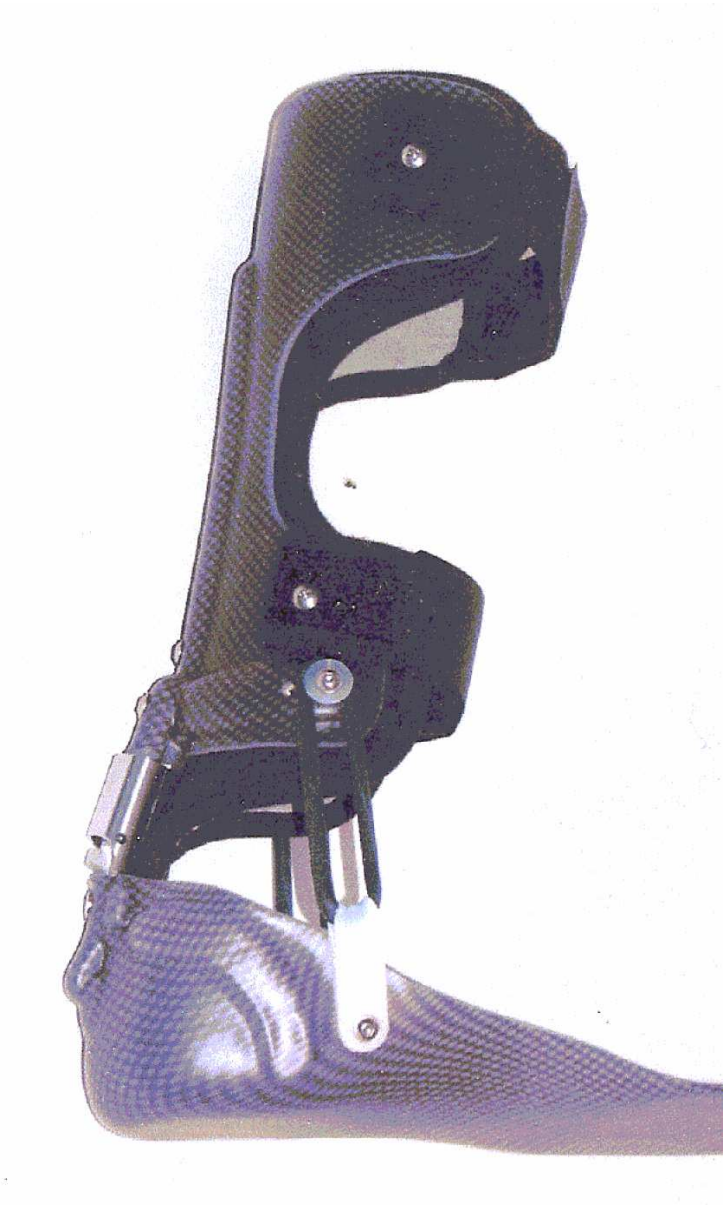
Knee recurvatum	With orthosis	1	8	<0.05	1	5	<0.05	1	3	<0.05
	Without orthosis	12	10	>0.05	10	6/	>0.05	8	5	>0.05
Foot varus (%)	With orthosis	2	10	<0.05	0	5	<0.05	1	4	<0.05
	Without orthosis	8	6	>0.05	9	4	>0.05	7	4	>0.05
	With orthosis	0	5	<0.05	1	3	>0.05	0	3	<0.05
FIM		86.4 (28)	81.4 (26)	>0.05	97.5± (21)	101 (17)	>0.05	104 (22)	104 (15)	>0.05

Legends: P value of T test or Fisher test between Chignon group and control group at each evaluation.

FAC: functional ambulatory classification; PASS: postural assessment structural scale; FIM: functional independence measure.

Table 4: Motor spastic and treatment evolution

	Day 0			Day 30			Day 90		
	Chignon	Control	P	Chignon	Control	P	Chignon	Control	P
Motor index (/100)	32.8 (16)	32.5 (19)	>0.05	40 (16)	39.3 (19)	>0.05	42 (20)	44.7 (17)	>0.05
Quadricipital spasticity (/4)	0.9 (1.1)	1.0 (1.1)	0.8	1.1 (1.3)	0.9 (1.1)	0.7	0.7 (0.8)	1.4 (1.2)	0.09
Sural spasticity (/4)	1.3 (1.2)	2 (0.79)	0.4	1.5 (1.05)	2.1 (1.1)	0.2	0.9 (0.9)	1.7 (1.5)	0.15
Oral antispastic treatment	3/13	8/15	>0.05	4/13	10/15	<0.05	4/13	10/15	<0.05
Botulinum toxin A injection (%)	0/13	0/13	>0.05	0/13	4/15	<0.05	1/13	7/15	<0.05



Legends: Figure 1: Lateral view of the Chignon AFO
215x351mm (100 x 100 DPI)