ORIGINAL ARTICLE

Neutral Functional Realignment Orthosis Prevents Hand Pain in Patients With Subacute Stroke: A Randomized Trial

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ABSTRACT. Bürge E, Kupper D, Finckh A, Ryerson S, Schnider A, Leemann B. Neutral functional realignment orthosis prevents hand pain in patients with subacute stroke: a randomized trial. Arch Phys Med Rehabil 2008;89:1857-62.

Objective: To quantify the preventive effect of a neutral functional realignment orthosis on pain, mobility, and edema of the hand in subacute hemiparetic poststroke patients with severe motor deficits.

Design: Randomized trial.

Setting: Rehabilitation center.

Participants: Poststroke patients (N=30) with subacute hemiparesis and severe deficits of the upper limb were enrolled. Fifteen patients were randomized to a standard rehabilitation program without orthosis and 15 patients received an experimental orthosis in addition to their standard rehabilitation program.

Intervention: The orthosis group wore the neutral functional realignment orthosis for at least 6 hours daily.

Main Outcome Measures: Hand pain at rest (visual analog scale), wrist range of motion (Fugl-Meyer Assessment subscale), and edema of hand and wrist (circumferences). Outcome measures were assessed at time of randomization and after 13 weeks between groups.

Results: At baseline, 2 patients in each group complained about a painful hand. After 13 weeks, 8 subjects in the control group and 1 subject in the orthosis group complained of hand pain (P=.004). Mobility and edema evolved similarly in both groups.

Conclusions: Neutral functional realignment orthoses have a preventive effect on poststroke hand pain, but not on mobility and edema in the subacute phase of recovery.

Key Words: Biomechanics; Hand; Occupational therapy; Physical therapy techniques; Rehabilitation; Stroke.

IN THE REHABILITATION of the upper extremity in subacute hemiparetic patients, therapists are often confronted with the problem of malpositioning of paretic wrists and hands. Atypical positions of hand and wrist can be a source of pain, edema, and loss of ROM. Incidence of pain, edema, and loss of ROM in subacute hemiparetic patients are rarely described in the scientific literature except for edema[1] and pain in the context of complex regional pain syndrome.[2] All these can impact on individual well-being and quality of life and may interfere with the rehabilitation of functional hand usage. Therapists use various types of hand orthoses in order to favor motor and functional recovery.[3-5] Indications for hand orthoses may include decreasing spasticity, pain or edema, improving function, or preventing contracture.[6-9] Two opposing theoretical rationales for the use of hand orthosis currently exist. Therapists who apply a biomechanic rationale[3,6,9,10] use orthoses to prevent and manage length-associated changes in muscles and related modifications (stiffness and/or contracture) of the connective tissue. Therapists who favor a neurophysiologic reasoning[6,9] use the orthosis to inhibit reflexive contraction (spasticity) of muscles.

As a result, principles that guide the fabrication of upper-extremity orthoses (dorsal or palmar) are often conflicting and their effectiveness remains controversial.[5,11-13] In 2003, a systematic review of the literature by Lannin and Herbert[14] did not show any efficacy of the examined splints. The majority of papers reviewed were of low methodologic quality and many were case series. Study populations included small cohorts of chronic stroke patients and primary outcomes were not consistent. Impairments measured were disparate and included measures of pain, edema, function of the hand, joint ROM, and muscle tone. Increased muscle tone seems to be an inappropriate outcome to measure the efficacy of orthoses, because of its weak relationship with functional capacity.[14] A randomized trial investigating the efficacy of no splinting, low-range palmar splinting (10°–15°) with finger platform, or extreme-range palmar-finger platform splinting (45°) reported no significant difference between groups.[15]

The purpose of this trial was to evaluate the preventive effect of a neutral functional realignment hand and wrist orthosis on pain, ROM, and edema in the subacute rehabilitation recovery phase after stroke. The splint used in this study differed from those of previous studies. It followed a biomechanic, functional theory of hand splinting. The design stressed the importance of anatomic alignment, considered the plasticity of muscles, and the deleterious effects of prolonged immobilization.[16-18] The patients wore the study splint exclusively during the day, not at night.

List of Abbreviations

FMA	Fugl-Meyer Assessment
MAS	Modified Ashworth Scale
ROM	range of motion
VAS	visual analog scale

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It supported the wrist in neutral position (sagittal and frontal planes) and gave support to the carpal arches, yet was designed to allow the hand and fingers to be used for manipulating objects.[3] We hypothesized that these orthoses would result in decreased secondary impairments of pain, loss of ROM, and edema as compared with the control group with no orthosis.

METHODS

Between June 2004 and December 2005, all patients with poststroke paresis involving the distal upper limb, in the subacute recovery phase, who were consecutively admitted to the inpatient rehabilitation unit at the University Hospitals of Geneva were asked to participate (N=44). Patients who agreed to participate (n=39) and met inclusion criteria (n=31) signed an informed consent form. They were randomly allocated either to the orthosis group receiving standard rehabilitation care (n=16) and a wrist neutral functional realignment orthosis (figs 1, 2), or to the control group receiving only standard rehabilitation care (n=15). The allocation schedule was computer generated and concealed in opaque, consecutively numbered sealed envelopes by a person not otherwise involved in the study. Inclusion criteria included: hospitalization for intensive rehabilitation, no previous stroke, and severe paresis of the upper limb (FMA upper-extremity motor score $\leq$45 points). Exclusion criteria were: traumatic injuries, rheumatic comorbidities, a lesion of the peripheral nervous system, other lesions of the central nervous system, or lymphedema. A speech therapist tested patients with aphasia in order to select candidates with sufficient comprehension to participate in the trial.

An independent blinded assessor performed clinical assessments at baseline and after 13 weeks. However, complete blinding of the assessor to the group assignment proved to be difficult in practice because some patients would spontaneously comment on their splint type. The study received approval by the local ethics committee.

Fig 1. Bird's-eye view from a wrist neutral functional realignment orthosis.

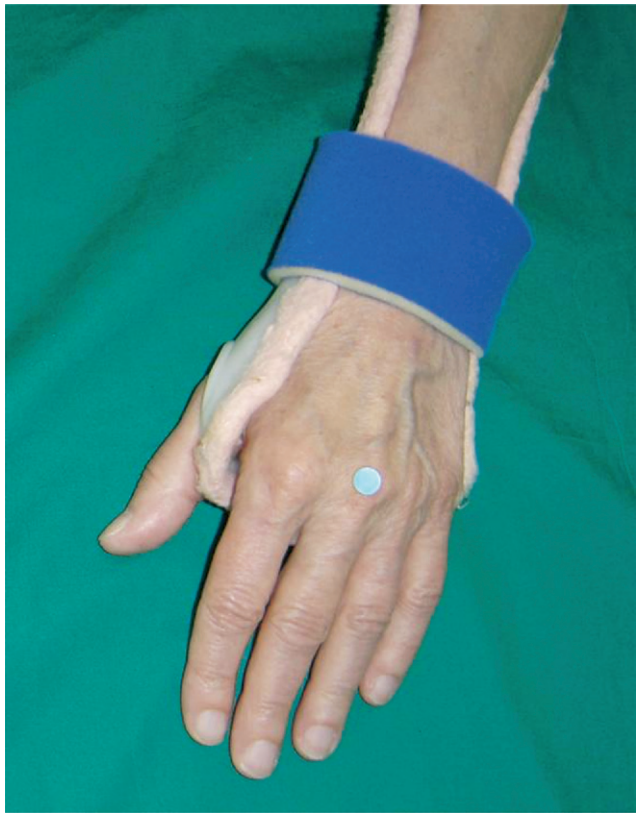

Fig 2. Alignment of hand and forearm on wrist neutral functional realignment orthosis.

Participants' Flowchart and Descriptive Characteristics

The flow of participants through the study with recruitment, withdrawals, and missing data details is presented in figure 3. In the orthosis group, 1 patient abandoned the study due to a psychologic disorder before the final evaluation; in the control group, 2 participants died during the trial. Descriptive characteristics are presented in table 1.

We used the arm motor section of the FMA (scores range, 0–66) to evaluate severity of motor impairment in the paretic upper extremity. The FMA is considered to be a good comprehensive quantitative measure of motor impairment after stroke and has particular value in clinical trials.[19] The arm motor section includes items measuring movement, coordination, and reflex action of the shoulder, elbow, forearm, wrist, and hand. The interrater reliability is good (.97).[20] The FMA upper-extremity motor subscore is moderately correlated with the Barthel Index at 5 weeks (r=.82)[20] and correlated with the self-care scores of the FIM instrument (r=.61).[20]

Evaluators used the MAS to assess muscle tone of the wrist and finger flexors.[21-23] This 6-point scoring system measures resistance to passive stretch. The inter- and intrarater agreement for the measurement of muscle tone in wrist (flexors − extensors) was good to very good: (weighted κ range, .84–.89; weighted κ range, .80–.88).[24]

Interventions

The standard care consisted of 2 sessions of physical therapy a day, 1 session of occupational therapy once a day, and, if indicated, neuropsychologic and speech therapy. Patients who

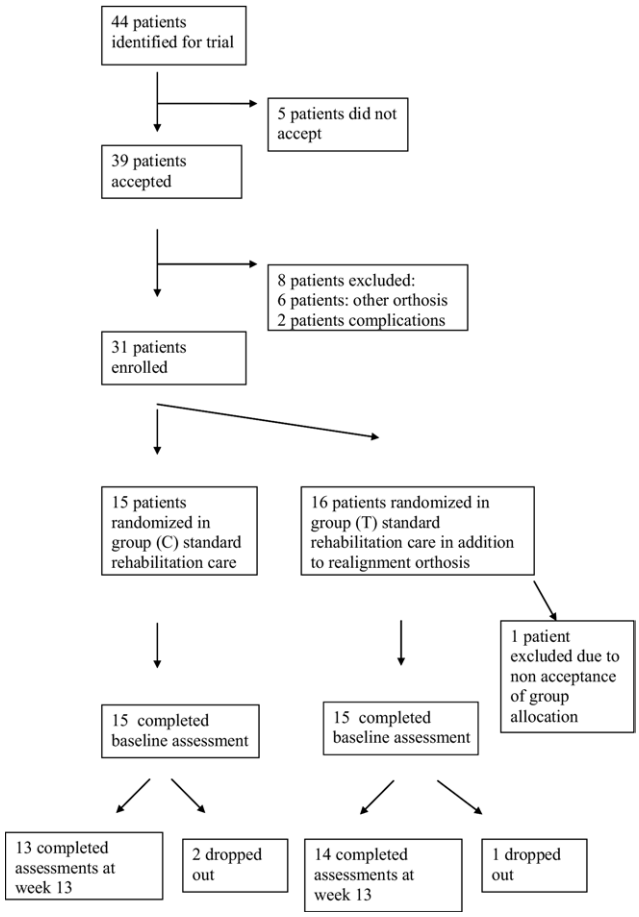

Fig 3. Flowchart of subjects through the trial.

were not able to walk independently had a wheelchair equipped with a molded, elevated armrest.

Specialized occupational therapists fabricated the experimental orthoses the day after the first evaluation with the following biomechanic and reeducation principles[25]: (1) alignment of forearm and hand (third finger aligned with the longitudinal axis of the forearm), (2) maintenance of wrist in neutral position (0° extension, 0° radial, ulnar deviation), (3) support of longitudinal and oblique hand arches, and (4) low carpal trimlines to allow holding or manipulation of objects. During a previous pilot study,[26] the investigators developed a quality scale permitting verification that the orthoses conformed to biomechanic principles. The treating therapists asked patients to wear the orthoses at least 6 hours a day. The wearing of the orthosis was discontinued when the patient was able to stabilize the wrist when trying to use the hand for functional tasks. The therapists encouraged patients in both groups to use their more affected upper extremity. The patients with the neutral functional realignment orthosis learned how to use their more affected hand while wearing the orthosis.

Outcome Measures

Outcome measures included a VAS for hand pain at rest, the FMA subtest for passive ROM of forearm, wrist and fingers, and circumferential measures to quantify hand edema.[27,28] The VAS is a generally accepted and validated instrument to measure pain and other subjective feelings.[29,30] The lowest position on the scale corresponded to absence of pain (0 for the assessor); the highest possible position of the cursor stood for unsupportable pain (10 for the assessor). If the patient was not able to manage the cursor, the assessor moved the cursor and the patient indicated which position corresponded best to the perceived pain intensity. The precise wording was: "Is your hand painful?" If the answer was no, we considered that pain was absent. If the patient affirmed and scores on the VAS were greater than or equal to 1, we considered that pain was actually present.

The FMA joint ROM subtest was used to assess passive wrist ROM. This subscale consists of 24 points. The reliability coefficient for this subscale is .85.[20] We defined the wrist joint as limited if its range was reduced by more than two thirds compared with the less affected hand. We considered wrist mobility to be impaired if FMA passive ROM scores were less than 2.

The evaluation of hand edema was performed according to Leibovitz et al.[31] We used a tape measure to record circumference at the proximal phalange of the index finger, the mid-metacarpal line, and the wrist proximal to the carpometacarpal joint crease. The measurements were performed on both hands. As proposed by Leibovitz,[31] the presence of edema was affirmed if the difference at 3 sites (circumferential measures of metacarpophalangeal, midhand, and wrist) was greater than or equal to 2 SDs of the mean difference between dominant and nondominant hand. This decision is based on values observed in the healthy population. To determine the SD, we performed a total of 60 measurements on these defined sites in 10 non-neurologically impaired people. The non-neurologically impaired group consisted of people presenting no musculoskeletal condition on their wrists or hands. In our healthy population, 2 SDs of the mean difference between dominant and nondomi-

Table 1: Baseline Characteristics of Study Subjects

Characteristics	Orthosis Group (n=15)	Control Group (n=15)	$P(\chi^2)$
Age (y)*	68±12 (45–84)	64±14 (36–84)	
Sex, n (%)			
Men/women	6 (40)/9 (60)	5 (33)/10 (67)	
Side of hemiplegia, n (%)			
Right side/left side	5 (33)/10 (67)	7 (47)/8 (53)	
No. of days poststroke at baseline*	29±15.7 (15–74)	30±12.1 (12–57)	
No. of patients with perceptual problems, n (%)	12 (75)	10 (66)	
Upper-limb FMA total median motor score (range)	9 (0–30)	11 (0–45)	0.513 (NS)
Median MAS scores, finger flexors (range)	0 (0–1)	0 (0–1.5)	0.152 (NS)

Abbreviation: NS, not significant.
*Values are mean ± SD (ranges, unless otherwise noted.).

nant hand corresponded to 0.6. To define the presence of edema, we calculated the mean difference in circumference (paretic vs nonparetic hand) at each measurement site. We considered edema present if the difference was greater than or equal to 0.6.

We evaluated patient satisfaction and compliance with the orthosis. Patient satisfaction was measured subjectively by asking each patient of the orthosis group about the comfort of the orthosis.[26] In addition to the clinical outcome measures, the treating therapists reported compliance with the splint-wearing schedule on a weekly basis. They asked the patients about the number of hours a day they wore the orthosis. We compared this answer with the hours recorded by the nurse in charge.

Data Analysis

We analyzed data on an intention to treat and per protocol basis. Baseline characteristics and compliance data were analyzed using conventional descriptive statistics. To investigate the efficacy of the study intervention, we compared the change in the 3 primary outcome measures in both groups between baseline and 13 weeks using Fisher exact test for dichotomous data. For the statistical analysis, we used the statistical software SPSS[a] for Windows. All analyses were performed at an α error level of .05 using 2-sided hypothesis testing.

RESULTS

Outcomes and Estimation

Six patients wore the orthosis for 16 or more hours a day, 6 patients between 7 and 12 hours a day, 1 patient was noncompliant, and 1 patient achieved sufficient wrist control to stop wearing the orthosis at week 4.

In the orthosis group, the number of patients who perceived hand pain at rest decreased from 2 patients (13%) to 1 patient (7%) at the final evaluation after 13 weeks. In the control group, the number of patients complaining of a painful hand was also 2 at baseline, but after 13 weeks, 8 patients reported a painful hand (Fisher exact test, $P=.004$).

The number of patients presenting a loss of wrist mobility increased in the control group (1 patient at baseline, 8 patients after 13 weeks), whereas it remained stable in the orthosis group (Fisher exact test, $P=.128$).

Hand and wrist edema was uncommon in our study population. At baseline, only 1 patient in each group presented with edema. At the final evaluation 1 patient of the orthosis group and 2 in the control group still presented edema (Fisher exact test, $P=.481$) (table 2).

Motor recovery was similar in both groups. The median FMA upper-extremity motor scores were 28 in the orthosis group and 27 in the control group. After 13 weeks, the majority of patients still showed a severe upper-limb paresis. Muscle tone in the wrist and finger flexors measured by the MAS slightly increased in both groups. The median MAS scores were 0 in both groups, with a maximum of 1 in the orthosis group and 1.5 in the control group. The results did not differ when an intention-to-treat analysis was performed with the assumption that scores remained unchanged.

At 13 weeks, the majority of the patients in the orthosis group (n=12) judged the orthosis comfortable.

Table 2: Absolute, Relative Frequencies, and Statistical Significance Occurrence of Hand Pain, Edema, and Impaired Passive ROM of the Wrist at Baseline and After 13 Weeks

	No. of Patients (%)		
	Orthosis Group	Control Group	*P* (Fisher exact test)
Pain			
Baseline	2 (13)	2 (13)	1.000 (NS)
After 13 weeks	1 (7)	8 (53)	0.004*
Limited passive			
Baseline	4 (27)	1 (7)	0.329 (NS)
After 13 weeks	4 (29)	8 (62)	0.128 (NS)
Edema			
Baseline	1 (7)	1 (7)	1.000 (NS)
After 13 weeks	1 (7)	2 (15)	0.596 (NS)

Abbreviation: NS, not significant.
*Significant results.

DISCUSSION

Wrist neutral functional realignment orthoses prevent the development of hand pain in subacute stroke patients. The effect of this orthosis on pain could be due to the neutral alignment of the wrist and the support of the arches of the hand. The positive effect of the orthosis could also be influenced by the fact that the majority of the patients appreciated the orthosis and found it comfortable. Or, it could be that the creation of muscular and joint alignment enhances appropriate postural responses in the hand and wrist. In addition, the orthosis might have had a protective role and the rehabilitation and nursing staff might have paid more attention to the hand. Furthermore, the orthosis permitted the active use of the hand for functional activities.

The between-group effect of the neutral functional realignment orthosis on passive mobility was not statistically significant. The scores of the FMA subscale for passive ROM might not have been sensitive enough for changes in ROM. Angle measurements with a goniometer would document these changes more precisely. Our results were similar to those of studies by Lannin[15] and Pizzi[32] and colleagues, who investigated the effect of static volar splints. In these splints, the patient's wrist was positioned in varying degrees of extension with the thumb in abduction and opposition. Metacarpal and proximal interphalangeal joints of the fingers were immobilized in 45° of flexion. While Pizzi[32] reported a positive effect on pain in a subacute population with stroke and observed a significant improved ROM of the wrist, Lannin[15] reported no difference between low and high degrees of wrist immobilization on ROM. These results suggest that neutral functional realignment orthoses do not lead to decreased ROM. Decreased ROM might result in a less favorable prognosis for hand function.[33]

The frequency of edema was surprisingly low in our study population (2/30 patients). Boomkamp-Koppen et al[1] diagnosed hand edema in 33% of 88 subacute patients with stroke. However, in Boomkamp-Koppen's study, patients with hypertonia of wrist and finger flexors had greater edema. The findings of their study revealed that hypertonia was the only significant predictor of edema. Increased wrist and finger flexor muscle tone as measured by the MAS was not common in our study population. This might explain the low prevalence of edema. Alternatively, the difference in edema could be due to the fact that Boomkamp-Koppen's stroke population was in a more acute recovery phase than ours (6d vs 30d poststroke). Furthermore, the positioning of the upper limb appears to be different. In our clinic, wheelchairs were equipped with a molded and elevated armrest, whereas in the cited study, patients seem to have used a table to support the arm.

Our results show that several patients wore the orthosis more than the required time, even though they could independently

remove the orthosis. A subgroup analysis showed that the patients who wore the orthosis 6 hours daily as prescribed had similar results to those who wore it 10 or more hours daily. However, this study was not designed to answer the question of optimal duration of orthosis therapy. There is no agreement in the literature about the optimal wearing schedules. In both the Lannin et al[15] and the Langlois et al[6] studies, patients wore splints overnight averaging 9 to 12 hours, for 4 weeks, whereas in the Pizzi et al[32] study, patients wore an immobilizing hand splint for only 90 minutes daily for 3 months. This aspect warrants further investigation.

Study Limitations

We have to address several limiting factors. Although the VAS is frequently used and validated,[34,35] we encountered 1 assessment difficulty. A few patients described the presence of pain, but their manipulation of the cursor did not appear to match their answer. Price et al[36] described a similar discrepancy between verbal answers and scale responses when investigating pressure application at different sites of the upper extremity. They found that the answer yes or no was systematically correct, but the answer concerning the intensity of the pressure was inconsistent. Other researchers reported similar problems when applying a VAS.[37-39] We confronted difficulties interpreting information on pain intensity. But in agreement with the findings of Snels[40] and Benaim[41] and colleagues, patients were clear in their assessment of whether pain was present or not. For pain assessment, the use of the Face Pain Scale as proposed by Benaim[41] might be more objective. However, to our knowledge, the Face Pain Scale has not been validated in the subacute recovery phase poststroke.

The wearing schedule of the orthosis was derived from the patients' weekly reports because the nurses did not systematically record this information. Consequently, a recall bias cannot be excluded. In a future trial, we suggest that wearing compliance should be monitored on a daily basis.

The sample size (n=30), while limited, was sufficient to show a significant effect on pain. We cannot exclude the fact that a larger sample size might not have shown a significant effect of wrist neutral functional realignment orthosis on mobility or edema. The lack of blinding of patients and outcome assessors was a further limitation. Further multicenter trials are warranted to establish whether these orthoses provide a benefit to patients in a less intensive reeducation program or stroke patients in the chronic recovery phase.

CONCLUSIONS

Results from this trial show that wrist neutral functional realignment orthoses have a preventive effect on pain in a subacute stroke population treated in a rehabilitation center. We found no beneficial effect of realignment orthoses on mobility or hand edema.

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Supplier

a. Version 11.0; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.