

Impact of Specialist Assessment versus Paper-Based Prescription on the Suitability of Ankle-Foot Orthoses in Patients with Chronic Stroke: A Comparative Study Using a Prescription Algorithm

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Abstract

Introduction: In orthosis prescription for patients with chronic-phase stroke, balancing high-quality specialist assessment with geographical accessibility remains a global challenge. In Japan, two models currently coexist: one in which a specialized multidisciplinary team conducts face-to-face assessments (direct judgment) and another in which non-specialist physicians prescribe orthoses based solely on written documentation (document-based judgment). Concern exists that the latter may lead to prescriptions that deviate from algorithm-recommended physiological standards. This study aimed to compare the rate of agreement with a physiologically based evaluation algorithm between these two prescription models as a measure of potential suitability. **Materials and Methods:** Participants were 42 patients with cerebrovascular disease who could use an ankle-foot orthosis (AFO): 26 and 16 in the face-to-face assessment and document-based prescription groups, respectively. Using a five-item physical function assessment algorithm with previously established validity, we determined the “orthosis recommended based on physical status”. The primary outcome was the agreement rate between the algorithm-recommended device and the orthosis actually prescribed, which served as a benchmark for evaluating the prescription’s alignment with the patient’s physical status. Sta-

tistical analysis was performed using the chi-square test. **Results:** The agreement rate between the algorithm-recommended and actually prescribed orthoses was higher in the face-to-face assessment group (61.5%) than in the document-based prescription group (25.0%). Among cases in which the same orthosis was re-prescribed without modification, the agreement rate in the document-based prescription group was only 16.7%, indicating that changes in physical function were often overlooked. **Conclusions:** Document-based AFO prescription by non-specialists carries a high risk of mismatch with the patient's physical condition. Even in settings with limited access to specialists, introducing an objective decision-support tool—such as the present algorithm—into clinical practice may help ensure orthosis prescription quality.

Keywords

Ankle Foot Orthosis, Chronic Phase, Stroke, Orthosis Prescription, Algorithm

1. Introduction

Cerebrovascular disease (CVD) is a major health problem in Japan, with the number of affected individuals estimated at approximately 1.975 million [1]. Following the onset of CVD, unilateral paralysis of the upper and lower extremities frequently occurs, markedly affecting activities of daily living and walking ability [2] [3]. Therefore, depending on the stage of rehabilitation, lower-limb orthoses, particularly ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs), are often required to support gait training and activities of daily living [4]. Recent systematic reviews have confirmed that AFOs significantly improve functional outcomes, including balance and walking speed, in stroke survivors [5]. Furthermore, clinical practice guidelines emphasize that since recovery and physical changes can occur at any stage, regular reassessment of AFOs is essential throughout the chronic phase to maintain these benefits [6].

During the acute and subacute (recovery) phases, patients with severe paralysis typically begin gait training using a KAFO, with transition to an AFO recommended as physical functions such as muscle strength and balance improve [3]. In contrast, this study focuses on the chronic phase, defined as the period starting six months after the onset of stroke, during which time patients have typically been discharged to the community [7] [8]. During this phase, some patients show improvements in walking ability due to neural recovery and increased muscle strength and balance on the non-paretic side [7] [8]. However, many patients walk with knee hyperextension on the paretic side or develop progressive equinovarus deformity of the ankle, which may lead to long-term failure of knee extension control mechanisms and foot deformities [9]-[12]. In addition, gait instability increases are associated with age-related declines in muscle strength [13] [14].

To address changes in physical function after discharge, the appropriate selection of lower-limb orthoses based on lower-extremity function remains important, even

in the chronic phase, and regular assessment and adjustment are necessary. However, globally, patients in the chronic phase often face challenges in accessing specialized prosthetics and orthotics clinics on a regular basis because of geographical and economic constraints.

In Japan, under the public funding system for daily-life orthoses (assistive devices), two contrasting prescription models have emerged, reflecting the tension between “specialization” and “access.” The first model, known as “direct judgment,” involves a face-to-face evaluation at a Rehabilitation Consultation Center for Persons with Disabilities. A specialized team—including a physician certified in prosthetic and orthotic assessment, prosthetist/orthotist, and physical therapist—evaluates the patient’s overall function and usage environment and may use trial orthoses when necessary to determine the most appropriate device on site [15]. This model represents a “specialist face-to-face assessment.”

The second model, known as “document judgment,” is applied when “direct judgment” at the consultation center is difficult because of geographical conditions or transportation limitations. In this model, a physician at a nearby hospital or clinic conducts the evaluation, prepares an orthosis prescription in written form, and submits it to the consultation center, which then makes its decision based on the documents alone [15]. This corresponds to a “non-specialist, paper-based prescription” by primary care physicians or non-specialists and can be considered an access-prioritized model.

In the “document judgment” model, many prescribing physicians are not rehabilitation specialists and often lack sufficient specialized knowledge and practical experience with prosthetics and orthotics. Based on internal data from Kyoto Prefecture, 20% of cases are evaluated via direct judgment, whereas 80% are managed through document judgment; among these, only 14% are prescribed by rehabilitation physicians. Furthermore, 90% of physicians prescribe orthoses in only one or two cases per year. Prosthetists and orthotists have noted that the same type of therapeutic orthosis used during hospitalization is often prescribed again. Under the document judgment model, many orthoses do not match the current physical condition of the patient. In fact, in 20% of document judgment cases, the prescribed orthosis is identical to the one previously used.

There is a certain level of evidence regarding methods of orthosis selection during the acute and recovery phases [4]. However, reports on orthosis selection in the chronic phase remain limited [6]. Against this background, we hypothesized that orthoses selected through specialist face-to-face assessment (direct judgment) would be well matched to the physical status of patients, whereas paper-based prescriptions by largely non-specialist physicians (document judgment) would more likely overlook changes in physical function and, thus, carry a higher risk of inappropriate orthosis prescription.

We have previously developed an algorithm—which evaluates physical status using six items and determines the optimal orthosis—for patients with CVD in the chronic phase and reported its effectiveness. Using this algorithm, we con-

firmed that an orthosis appropriate to physical status could be proposed for 90% of patients [14]. However, when actual prescription outcomes—considering environmental and psychological factors—were examined, 25% of patients preferred an orthosis that did not match their current physical condition because of factors such as insufficient rehabilitation environments or reluctance to change to a new orthosis. Consequently, only 65% of patients received an orthosis that matched their physical status [14]. In other words, the use of this algorithm may enable even facilities with little experience in orthosis prescription to select orthoses that match the physical conditions of patients.

This study aimed to compare the rate of agreement with a physiologically based evaluation algorithm between these two prescription models as a measure of potential suitability, and to objectively clarify both the importance of specialist involvement and challenges associated with the current prescription system.

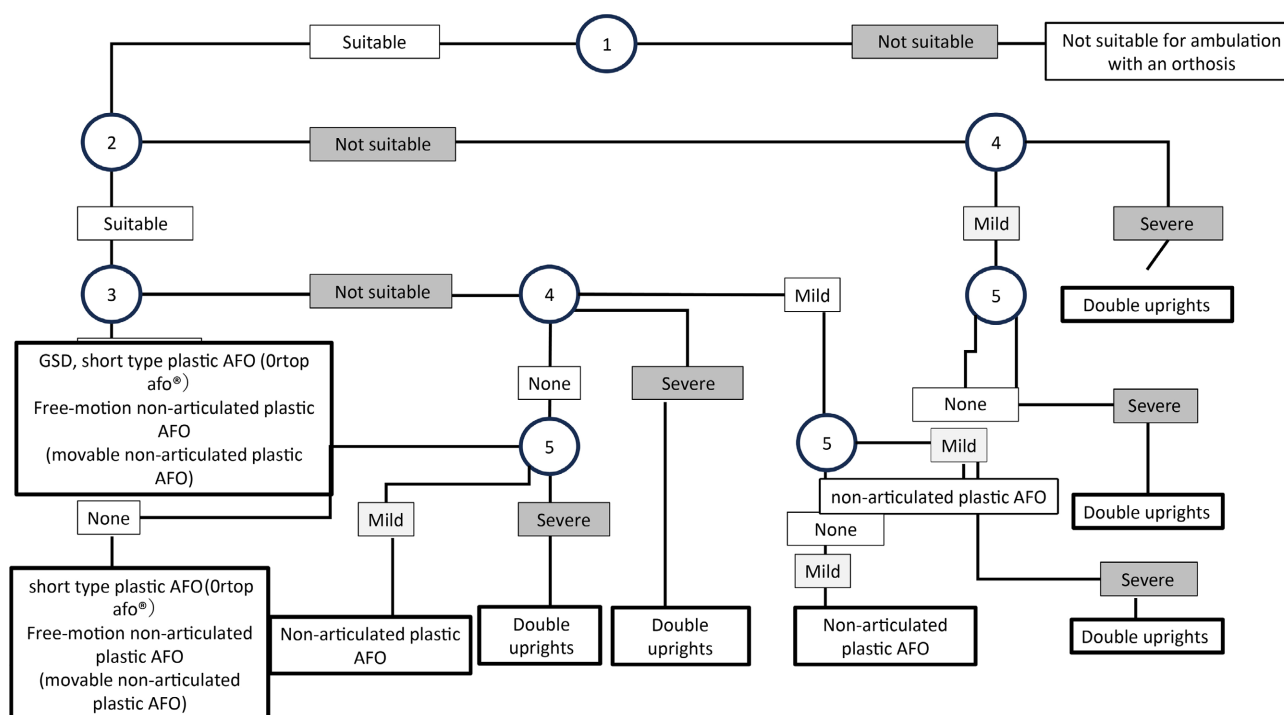
2. Subjects and Methods

This study included patients with CVD who visited the Kyoto Prefectural Rehabilitation Consultation Center for Persons with Disabilities and received an orthosis through specialist face-to-face assessment (direct judgment), or were prescribed an orthosis at other facilities through paper-based prescription by non-specialist physicians (document judgment) between April 2024 and October 2025. All eligible cases during this recruitment period were enrolled consecutively. Eligible cases were those able to walk using an AFO. This study was approved in advance by the Ethics Committee of the Rehabilitation Hospital attached to the Kyoto Prefectural Center for Welfare of Persons with Physical and Mental Disabilities (approval number: RBMR 202201). All patients were informed about the study and provided written informed consent prior to participation. The sample size was determined based on a significance level of $\alpha = 0.05$ and statistical power of 80% ($\beta = 0.2$), calculated using pilot survey results. The number of cases required to compare the primary outcome was 34 in total: 24 in the direct judgment group and 10 in the document judgment group.

Patient information collected included age, sex, paretic side, type of CVD, date of onset, type of orthosis previously used, and walking ability.

To determine whether an AFO appropriate to the physical status of the patient had been prescribed, we used the algorithm we previously developed [16]. The algorithm consists of five questions, and based on the responses, the appropriate orthosis can be determined (Figure 1). Our previous study reported that the algorithm can identify an orthosis that matches physical status in 90% of patients, and its validity has been confirmed [16]. However, in 25% of cases, an orthosis different from that recommended by the algorithm is prescribed because of external factors, such as a patient's preference to continue using a previously prescribed orthosis. In other words, by using this algorithm, an orthosis that matches physical status can be prescribed in 65% of patients [16].

In the face-to-face assessment group (direct judgment), the algorithm was



Flowchart developed to determine the optimal ankle-foot orthosis based on the physiological and physical functions of patients with cerebrovascular disease. The algorithm incorporates the clinical assessments such as “single-leg stance on the paretic side with the knee in flexion” and “heel contact during gait,” and is designed to enable standardized orthosis selection, including use by non-specialist physicians. Adapted from Imai *et al.* [16].

Figure 1. Ankle-foot orthosis selection algorithm.

actively utilized during the evaluation process to determine the orthosis most appropriate for the patient’s current physical status. If the result matched the orthosis the patient had been using, the same device was continued. If the orthosis recommended based on physical status differed from the one currently in use, several orthoses—centered on the recommended type—were trialed. In the direct judgment group, after the specialized team’s evaluation and the algorithm-guided selection, a demonstration was conducted using the candidate orthosis. During this process, we collected the patient’s subjective feedback on “ease of walking” to ensure the prescription’s clinical feasibility. In contrast, for the document judgment group, this subjective assessment of walking ease through demonstration was not performed, as the prescription was based solely on written documentation.

In the paper-based prescription group (document judgment), the prescribing physician ordered the orthosis deemed appropriate, which was then fabricated based on the prescription of the physician. At the time of casting for the orthosis, the prosthetist/orthotist evaluated the five items listed on the questionnaire form (Table 1). In contrast, in the paper-based prescription group (document judgment), neither the prescribing physicians nor the prosthetists/orthotists were provided with the algorithm during the prescription process, ensuring that their decisions were made based on standard clinical practice without the influence of the tool. This design allowed for a comparative analysis between an algorithm-guided

specialist assessment and a non-specialist, paper-based model that operates independently of the algorithm.

Table 1. Assessment items used for orthosis determination. Adapted from Imai *et al.* [17].

1	Ability to ambulate (able/unable)
2	Ability to perform single-leg stance on the paretic side with the knee in flexion (able/unable) Use of an orthosis is permitted; performance is considered possible in the absence of giving way
3	Presence of rocker function at initial contact (present/absent)
4	Degree of knee hyperextension during gait (none/mild/severe) *If braking cannot be achieved with the non-articulated plastic AFO, classify as severe
5	Degree of equinovarus deformity (none/mild/severe) *If the entire plantar surface cannot make contact with the ground during weight-bearing in standing without an orthosis, classify as severe.

Based on the questionnaire data obtained in the document judgment group, we applied the algorithm to determine the orthosis appropriate to the physical status of the patients and compared this with the orthosis actually prescribed to calculate the agreement rate. We also examined whether the current orthosis differed from the previous one, and whether this change was associated with appropriate prescription.

Statistical analysis for the primary outcome was performed using the chi-square test to compare the agreement rates between the two groups. To compare baseline characteristics, Student's t-test was used for age and time since onset, the chi-square test for stroke subtypes, and the Mann-Whitney U test for the types of orthoses previously used. Effect size for the agreement rate was evaluated using Cramér's V, with associations interpreted as strong (0.5 - 1.0), moderate (0.25 - 0.5), or weak (0.1 - 0.25). The level of statistical significance was set at $p < 0.05$.

3. Results

During the study enrollment period, cases that met the eligibility criteria were included. Consequently, the final analysis comprised 42 cases: 26 in the direct judgment group and 16 in the document judgment group. This sample size exceeded the initially calculated requirement, indicating that sufficient statistical power was achieved to evaluate the validity of the study results.

Regarding baseline characteristics, there were no significant differences between the direct judgment and document-based prescription groups in terms of age (65.1 ± 12.6 vs. 62.0 ± 15.1 years), time since onset (12.6 ± 10.9 vs. 16.4 ± 16.0 years), or stroke subtype ($p = ns$). Furthermore, the types of orthoses previously used did not differ significantly between the two groups (**Table 2**). These results indicate that the baseline functional and demographic backgrounds were com-

parable, minimizing the potential for these factors to confound the subsequent group comparisons.

Table 2. Patient characteristics.

		Direct assessment	Document- based assessment	p value
age		65.1 ± 12.6	62.0 ± 15.1	ns
time since onset		12.6 ± 10.9	16.4 ± 16.0	ns
stroke subtype	cerebral infarction	19	11	ns
	cerebral hemorrhage	7	4	
	unknown	0	1	
previous orthosis use	GSD	3	1	ns
	short type plastic AFO	3	3	
	Free-motion non-articulated plastic AFO	4	2	
	Non-articulated plastic AFO	12	9	
	Double uprights	5	1	

Values are expressed as mean ± SD or number of patients. ns: not significant ($p > 0.05$ by chi-square test or Student's t-test).

In the direct judgment group, 24 of 26 patients (92.3%) subjectively reported that the orthosis was “easy to walk with” when it matched the algorithm at the time of assessment. Regarding patient-reported outcomes in the direct judgment group, the demonstration and subsequent feedback collection revealed that all patients who transitioned to the algorithm-recommended orthosis reported it was “easy to walk with.” Note that this subjective assessment was specific to the direct judgment group and was not evaluated in the document judgment group. Therefore, this result is presented as supplemental evidence of patient satisfaction within the face-to-face assessment model. The agreement rate between the actually prescribed orthosis (including the influence of external factors) and the orthosis determined by the algorithm was 61.5% in the direct judgment group and 25.0% in the document judgment group, showing a significant difference between the two groups ($p = 0.02$). The effect size, assessed using Cramér's V , was 0.36, indicating a moderate association (**Table 3**).

The orthosis change rate was 23.1% in the direct judgment group and 25.0% in the document judgment group. Among cases in which the orthosis was changed, the proportion in which the prescribed orthosis matched physical status according to the algorithm was 66.7% and 50.0% in the direct and document judgment groups, respectively (**Table 4**). In the direct judgment group, two cases in which the algorithm-recommended orthosis based on physical status matched were observed; however, the actually prescribed orthosis was judged as mismatched. In one of these

cases, gait ability had been improving with rehabilitation, and it was predicted that walking with a lighter orthosis would become possible in the future; therefore, an orthosis different from that recommended by the algorithm was selected.

Table 3. Agreement rate between algorithm-based determination and actual prescription in the direct and document judgment groups.

	Match	Mismatch	Agreement rate	External factors (mismatch)
Direct assessment	16	10	61.5%	8
Document-based assessment	4	12	25.0%	

$p = 0.0213083$; Cramér's $V = 0.35528$ middle.

Table 4. Agreement rate in cases where the orthosis was changed.

			Match → Match	Match → Mismatch	Mismatch → Match	Mismatch → Mismatch
Direct assessment	Change	6	0	2	4	0
	No change	20	12	0	0	8
Document- based assessment	Change	4	0	2	2	0
	No change	12	2	0	0	10

In contrast, among cases in which the orthosis was not changed, the agreement rate was 60.0% and 16.7% in the direct and document judgment groups, respectively, showing a significant difference between the two groups ($p = 0.02$) (Table 5). When examining the eight “no change-mismatch” cases in the direct judgment group, seven cases were due to the reluctance of the patient to change because of long-term familiarity with the existing orthosis. The remaining case involved a patient with marked equinovarus deformity who, although indicated for a double-upright AFO, selected a non-articulated plastic AFO because of challenges with independent donning and doffing. Among the ten “no change-mismatch” cases in the document judgment group, six were prescribed orthoses intended for more severe cases than those recommended by the algorithm based on physical status. In the remaining four cases, orthoses intended for milder cases than those recommended by the algorithm were selected.

Table 5. Agreement rate in cases where the orthosis was not changed.

	Match	Mismatch
Direct assessment	12	8
Document based assessment	2	10

$p = 0.0167465$; Cramér's $V = 0.42289$ middle.

4. Discussion

This study aimed to use an algorithm to clarify how accurately AFOs appropriate to the physical status of patients with CVD are prescribed under the paper-based prescription (document judgment) model, which is often implemented in facilities with limited experience in orthosis prescription.

The analysis demonstrated that the agreement rate between the algorithm-recommended orthosis and the orthosis actually prescribed was significantly higher in the face-to-face assessment group (direct judgment: 61.5%) than in the paper-based prescription group (document judgment: 25.0%). While it must be acknowledged that the direct judgment group's use of the algorithm during the assessment phase inherently predisposes that group to a higher agreement rate, the results still highlight a significant discrepancy. This result supports the hypothesis that paper-based prescriptions by non-specialists are more likely to diverge from the standards established by the evaluation algorithm, and suggests that in facilities with limited prescription experience, discrepancies from these algorithm-based recommendations may have become routine.

The most important finding of this study is the objective demonstration that many orthoses prescribed under the paper-based model do not match the current physical conditions of patients. Notably, among cases in which the orthosis was not changed from a previous prescription, the agreement rate in the document judgment group was only 16.7%. This indicates that, in 10 of 12 such cases, patients may have continued using an orthosis that no longer matched their current physical status.

This phenomenon may be explained by “clinical inertia,” in which clinicians continue previous prescriptions without sufficient re-evaluation. These findings are consistent with internal surveys from Kyoto Prefecture showing that many prescriptions under the document judgment model are made by physicians who are not rehabilitation specialists, and many institutions have experience with only one or two orthosis prescriptions per year. The results also support reports from prosthetists/orthotists noting cases in which they question the appropriateness of the prescribed orthosis.

Although AFOs can improve gait and balance even in the chronic phase [17]-[21]. This is particularly important because the appropriate type of AFO can optimize energy expenditure during walking; conversely, an unsuitable match may increase the metabolic cost of gait and limit the patient's activity levels [22]. Post-stroke gait exhibits considerable individual variability, and in milder cases, orthoses may even worsen walking ability [21]. Therefore, selecting an orthosis that accounts for individual physical ability is essential. Despite the fact that physical function in patients with CVD continues to change not only during the recovery phase but also in the chronic phase [6]-[8], our results suggest that physicians with limited prescription experience may not adequately evaluate these changes and may routinely re-prescribe the same orthosis.

In contrast, the “specialist face-to-face assessment (direct judgment)” conducted at the consultation center showed a significantly higher agreement rate.

This highlights the effectiveness of a system in which physicians specialized in prosthetic and orthotic assessment can accurately evaluate knee control and ankle condition and select appropriate orthoses on site [16]. While this subjective measure cannot be directly compared with the document judgment group—where no demonstration or subjective feedback was recorded—it suggests that face-to-face specialist assessment, supported by the algorithm, can effectively incorporate patient preferences into the final prescription, as evidenced by the high rate of patients reporting improved ease of walking during trials [16]. However, even in the direct judgment group, the final agreement rate was only 61.5%. Of the 10 mismatched cases, eight were attributable to “external factors,” such as the reluctance of patients to change from an orthosis they had been using for a long time. Sato *et al.* reported that patients tend to prioritize ease of donning and doffing and lightness, whereas healthcare professionals focus on gait and standing stability [23]. Thus, the “mismatches” in the direct judgment group can be interpreted as the result of shared decision making, in which specialist recommendations are balanced with patient preferences. In contrast, the “mismatches” in the document judgment group are likely due to prescriptions made without adequate medical evaluation and are qualitatively different in nature.

The results of this study demonstrate the clinical validity and usefulness of the algorithm we developed. By using an objective “decision support tool” such as this algorithm in paper-based prescription, prescribing physicians and prosthetists/orthotists may be able to select orthoses that better match the physical status of patients, regardless of their level of prescription experience. For example, if prosthetists/orthotists were to attach an evaluation sheet based on this algorithm when submitting a paper-based prescription, physicians could make decisions based on objective information, thereby reducing inappropriate prescriptions. This approach could provide a concrete solution to improve prescription quality while maintaining the geographical convenience of the access-prioritized, paper-based prescription system.

This study had some limitations. First, the sample size was relatively small, and the data were limited to Kyoto Prefecture; therefore, caution is required when generalizing the results. Second, we did not conduct a detailed analysis of background factors that could influence prescription quality, such as the specialty or years of clinical experience of the prescribing physicians in the document judgment group. Future directions include large-scale, multicenter collaborative studies to examine the generalizability of these findings, as well as interventional studies in which the algorithm is actually provided to prescribing physicians at the time of prescription to determine whether agreement rates improve. In addition, investigating effective approaches, such as providing sufficient trial periods and counseling, is essential to reduce the psychological resistance of patients and promote acceptance of the most appropriate orthosis.

4. Conclusion

This study showed that, under Japan’s paper-based prescription system for pa-

tients with CVD in the chronic phase—namely, non-specialist, document-based prescription—orthoses that do not align with the algorithm-recommended standards may likely be prescribed. In particular, the risk of overlooking changes in physical function and continuing the use of unsuitable orthoses was evident. These findings suggest that evaluations by physicians with limited prescription experience are more likely to diverge from the actual needs of patients compared with specialist face-to-face assessment. To achieve more accurate and appropriate orthosis prescription, direct evaluation by specialists should be ensured, while also integrating objective assessment tools, such as algorithms, should be integrated to support non-specialist physicians in achieving better alignment with physiological needs. In the future, implementing concrete measures to improve the quality of the paper-based prescription system and establishing support systems to help patients access the most appropriate orthosis will be necessary.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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