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REVIEW ARTICLE

EFFICACY OF KNEE–ANKLE–FOOT ORTHOSIS ON FUNCTIONAL MOBILITY AND ACTIVITIES OF DAILY LIVING IN PATIENTS WITH STROKE: A SYSTEMATIC REVIEW OF CASE REPORTS

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Objective: **To synthesize available evidence from case reports regarding the efficacy of knee–ankle–foot orthosis (KAFO) on functional mobility and activities of daily living (ADL) in patients with stroke.**

Methods: **The following databases were searched, based on the Population Intervention Comparison Outcome (PICO) model: PubMed, CINAHL, Scopus, Cochrane Central Register of Controlled Trials, PEDro, Web of Science, and Igaku Chuo Zassi (in Japanese). Methodological quality was assessed using the CARE checklist.**

Results: **A total of 14 articles, including 15 cases, were selected. Clinically meaningful improvement in functional mobility was reported in 10 of 15 cases, measured using the Functional Ambulatory Category, Trunk Control Test, walking speed, and Berg Balance Scale. Clinically meaningful improvement in ADL was reported in 9 of 15 cases, measured using the Barthel Index and Functional Independent Measure. However, the methodological quality of the reviewed articles was low, with missing information on limitations of management, adverse events, and patient-reported outcomes.**

Conclusion: **This systematic review of case reports found a low level of evidence of the efficacy of KAFO in terms of improvement in functional mobility and ADL. Of value, this study revealed the optimal outcomes for measuring the efficacy of KAFO.**

Key words: stroke; knee–ankle–foot orthosis; KAFO; functional mobility; activities of daily living; systematic review; case report.

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LAY ABSTRACT

For many years, rehabilitation experts have considered knee–ankle–foot orthosis (KAFO) therapy to be effective for patients with stroke. However, evidence regarding the efficacy of KAFO is unclear, since there is a lack of published high-quality studies. Recently, some case reports have been published claiming the efficacy of KAFO therapy. A systematic review was performed, which reviewed 14 case reports involving 15 patients. Improvements of functional mobility and activities of daily living were shown in 10 and 9 of the 15 patients, respectively. However, the methodological quality of the reviewed case reports was low. These findings present the current evidence from case reports regarding KAFO therapy in patients with stroke; however, the findings are insufficient to draw clear conclusions about the efficacy of such therapy. Of value, the study revealed the optimal outcome measures for use in measuring the effect of KAFO therapy, which can be used to facilitate high-quality future studies.

Improving functional mobility and activities of daily living (ADL) in patients with stroke are important aims of rehabilitation (1). Functional mobility is the capacity of a person to move from one place to another in order to participate in ADL, which includes movements such as standing, walking, and transferring (2). Ankle–foot orthosis (AFO) (3, 4), functional electrical stimulation (FES) (5), trunk training (6), and physical fitness training (7) are considered useful interventions to improve functional mobility in patients with stroke.

Knee–ankle–foot orthosis (KAFO) is a treatment option for orthotic management in patients with stroke (8). KAFO is usually prescribed when bracing of an AFO or knee orthosis (KO) fails to control knee instability during standing or walking (9). When the optimal orthotic knee joint and ankle joints of orthoses are selected according to the prescription, KAFO provides adequate stability of the knee and foot during the stance phase of the gait cycle. In contrast, one of the biomechanical problems with KAFO is that it can lead to an abnormal gait pattern. For example, the locked knee

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joint of KAFO allows patients to stand or ambulate safely; however, it prevents floor clearance of the foot during the swing phase (10). Also, conventional types of KAFO, which comprise a metal orthosis attached with stirrups to the outside of the shoe, can be very heavy and make it difficult to switch shoes (10).

A few decades ago, a study reported the eligibility criteria for KAFO therapy in patients with stroke, who had severe flaccid motor paralysis, severe sensory loss, visuospatial apraxia, muscle weakness of the lower limb, joint deformities, or contractures (11). A few case-control studies have reported positive effects of KAFO therapy on walking ability in patients with stroke (12, 13). Recently, some Japanese physical therapy experts have proposed the use of KAFO in gait training for patients with stroke who are unable to walk (14) or in early training on regaining functional mobility for patients with acute-phase disease (15). However, the recent Japanese physical therapy guideline bulletin considers that the evidence of benefits from using KAFO therapy is unclear, since there is a lack of published high-quality research studies (16). Furthermore, clinical practice guidelines of the Academy of Neurologic Physical Therapy (ANPT) of the American Physical Therapy Association (APTA) (17) and the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie; KNGF) clinical practice guidelines for physical therapy in patients with stroke (18) do not mention the effectiveness of KAFO therapy. Therefore, the clinical decision-making process in KAFO therapy is dependent on the knowledge and experience of a few physical therapy experts.

A systematic review of case reports is considered useful when no other high-level evidence is available to inform decision-making processes (19). Hence, the aim of this study is to systematically review case reports and case series, in order to provide evidence regarding the efficacy of KAFO on functional mobility and ADL in patients with stroke.

METHODS

Study design

A systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement (20). The current study involved partial analysis of data obtained from a study protocol registered in the PROSPERO International Prospective Register of Systematic Reviews database (CRD42020219359).

Inclusion and exclusion criteria

Study design. Case reports or case series articles that examined the efficacy of KAFO on functional mobility or ADL in patients with stroke, published in English or Japanese, were included.

Participants. All disease stages of stroke and adults (18 years or older, with no upper limit of age) were included. Articles reporting participants other than patients with stroke (e.g. patients with cerebral palsy and neurodegenerative disorders) were excluded.

Interventions. The type of KAFO for inclusion was considered as follows: KAFO or KO with AFO. There were no restrictions on the design or materials used in the orthosis. There was no restriction on the type of ankle or knee joint, or whether there was an electronic component. Articles evaluating the effects of AFO, KO, FES, taping, or strapping were excluded.

Articles reporting on KAFO used in real-life settings were included. Articles in which the KAFO had been used solely within a laboratory or experimental setting were excluded.

Outcomes. The following outcomes were of interest: measurements of functional mobility (walking ability, or functional balance) or measurements of independence of ADL.

Study selection

The search strategy for PubMed is shown in Table I. The Population Intervention Comparison Outcome (PICO) framework used for this review was as follows: P, patients with stroke; I, KAFO; C, not specified; and O, functional mobility or ADL. The MeSH database in MEDLINE was used to search for synonyms. The study selection procedure was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Fig. 1). The following 7 databases were searched: PubMed, CINAHL, Scopus, Cochrane Central Register of Controlled Trials, PEDro, Web of Science, and Igaku Chuo Zassi (in Japanese). All relevant articles published between 1964 and October 2021 were included. A literature search was conducted by a researcher (EK). After using EndNote X9 software (Clarivate Analytics, Philadelphia, Pennsylvania, USA) to remove duplicates, the titles, abstracts, and full texts of the articles

Table I. PubMed search strategy

Search number	Query
5	(#1 OR #2 OR #3) AND #4
4	knee ankle foot orthosis OR knee ankle foot orthoses OR long leg brace OR orthotic device OR orthotic management OR orthotic*
3	hemiplegia OR hemiparesis OR paresis OR hemipleg* OR paretic*
2	brain* OR cerebral* OR cerebellum* OR intracranial* OR intracerebral* OR vertebrobasilar* OR hemorrhage* OR ischemic* OR infarct* OR hematoma* OR bleed*
1	stroke OR stroke* OR cva OR cvas OR poststroke OR apoplex* OR cerebrovascular disease OR cerebrovascular accident

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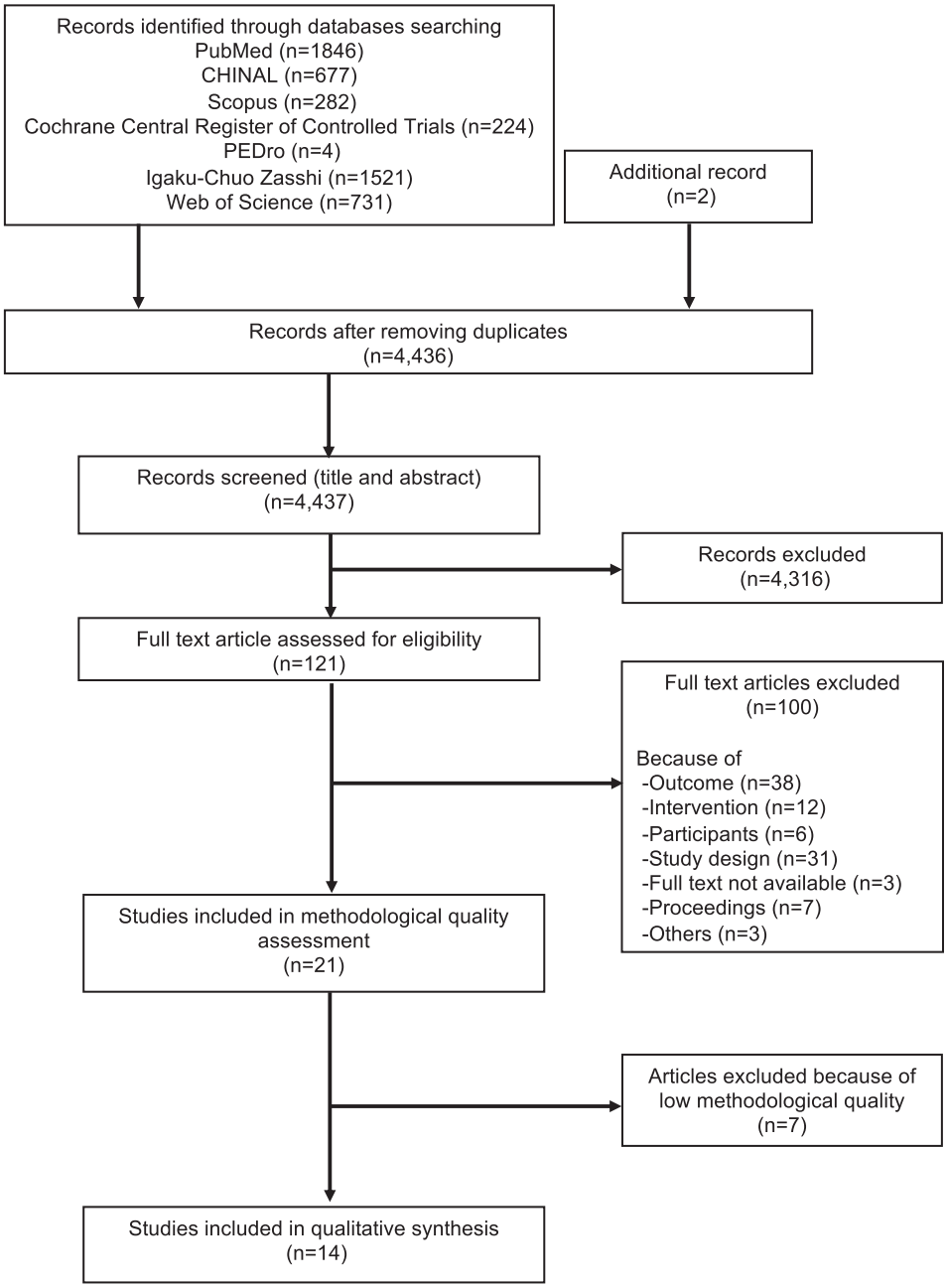

Fig. 1. PRISMA flow chart of article inclusion and exclusion

identified by the database searches were independently reviewed for eligibility criteria by 4 researchers (EK, KH, NK, HH). Disagreements were settled based on the opinion of another researcher (NH), who was not involved in the screening process.

Methodological quality

The quality of individual articles was assessed using the Japanese version of the CARE statement and checklist (21). This provides a framework for writing a quality case report, including 13 sections (title, keywords, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic interventions, follow-up and outcomes, discussion, patient perspective, informed consent), and 29 items to be completed in high-quality case reports, and endorsed by many medical journals (21). Some checklist items were modified by the authors to meet the aim of the current study. Thus, item 8b of "Diagnostic challenges" and item 8d of "Prognostic characteristics" were not scored; item 8a of "Diagnostic methods" was changed to item 8a of "Diagnostic methods, the reason for using KAFO was clearly stated"; and item 8c of "Diagnostic reasoning" was changed to item 8c of "Diagnostic

Table II. Participants' characteristics

Author, year (reference)	Age, years	Sex	Diagnosis	Time*** of KAFO initiation	Motor functions of paretic side	Superficial and deep sensory functions in paretic side	Consciousness, Higher brain functions	Functional mobility	ADL
Acute phase (<1 m)									
Murakami et al. 2018 (26)	60's	M	Thalamic haemorrhage	2 w	BRS1-1-1	Severe sensory loss	NS	NS**	NS
Fujimoto et al. 2018 (29)	64	M	Thalamic haemorrhage	12 d	MMT upper limb 2, (lower limb 2)	Severe sensory loss	USN, attention disorder, pusher syndrome	NS**	NS
Kubo et al. 2019 (24)	76	F	Putaminal haemorrhage	10 d	SIAS-M (1-0, 0-1-0)	NS	JCS I-1, USN	FAC 0, TCT 12	BI 0/20(0%)
Kamiishi et al. 2019 (23)	60's	M	Medial medullary infarction	23 d	BRS 3-1-3	Moderate sensory loss	NS	BBS 26	FIM 75 (FIM m 50, FIM c 25)
Harayama et al. 2020 (25)	70	M	Putaminal haemorrhage	10 d	BRS1-2-1, SIAS-M (0-0, 0-0-0)	Severe sensory loss	JCSII-10, USN, total aphasia, attention disorder, pusher syndrome	FAC 0, TCT 0	BI 0/100 (0%)
Satoh et al. 2020 (35)	60's	M	Pontine infarction (with cerebral infarction 3 years previously)	6 d	BRS5-3-3, MMT (A/S) (iliopsoas 2, hip extensor 1, quadriceps 2, tibialis anterior 0, gastrocnemius 1)	Moderate deep and superficial sensory loss in L/L of A/S	Attention disorder	FAC 3, walking speed 0.63 m/s, stride length 61cm	FIM 74
Kurita et al. 2021 (36)	30's	M	Putaminal haemorrhage	14 d	BRS1-1-1	NS	GCS 7 (E2V1M4)	TCT 0	FIM 18 (FIM m 13, FIM c 5)
Subacute phase (1-6 m)									
Tsujimoto et al. 2018 (31)	10's	M	Arteriovenous malformation (AVM)	34 d	SIAS-M (2-1A, 2-1-0), MMT (A/S) (iliopsoas 2, hip abductor 2, hip adductor 1, hip extensor 1, quadriceps 1, hamstrings 1, tibialis anterior 0, gastrocnemius 0)	Severe sensory loss	JCSII, USN, attention disorder	FAC 0 Difficult to measure walking speed	NS
Kadowaki et al. 2019 (33)	50's	F	Putaminal haemorrhage	36 d	BRS1-1-2, MMT (A/S) (iliopsoas 2, hip abductor 2, hip adductor 2, hip extensor 1, quadriceps 2, hamstrings 1, tibialis anterior 0, gastrocnemius 1)	Mild sensory loss	Aphasia (mild)	FAC 0, TCT 36, Difficult to measure walking speed and stride length	BI 40/100 (40%)
Chronic phase (6 m<)									
Kadowaki et al. 2019 (33)	10's	M	Vascular malformations (post-operation)	12 m	BRS5-5-5 MMT(A/S) (iliopsoas 4, hip abductor 4, hip adductor 4, hip extensor 4, quadriceps 5, hamstrings 4, tibialis anterior 4, gastrocnemius 4)	Mild sensory loss	Aphasia (mild)	FAC 5, TCT 100, Walking speed 1.33 m/s, Stride length 111.1 cm	BI 100/100 (100%)
Aoyagi et al. 2008 (34)	50	F	Putaminal haemorrhage	20 m	BRS 2-2-3	NS	USN, attention disorder	Stride length 34.5 cm	NS
Umeda et al. 2009 (27)	52	F	Putaminal haemorrhage	7 m	BRS 2-NS-3	NS	NS	Walking speed 0.12 m/s, Stride length 49 cm**	BI 85/100 (85%)
Minagawa et al. 2010 (28)	37	M	Putaminal haemorrhage	430 d	BRS 2-2-2	Severe sensory loss	JCS I-3, aphasia, apraxia, attention disorder	Difficult to measure TUG, FR and 6MWT	FIM 43 (FIM m 34, FIM c 9)
Nishizawa et al. 2016 (30)	30's	M	Subarachnoid haemorrhage	200 d	BRS 3-2-3	NS	JCS I to II	NS	FIM 49 (FIM m 32, FIM c 17)
Kadowaki et al. 2018 (32)	50's	F	Subarachnoid haemorrhage	20 m	BRS 2-2-2, MMT (A/S) (iliopsoas 2, hip abductor 1, hip adductor 1, hip extensor 1, quadriceps 2, hamstrings 1, tibialis anterior 1, gastrocnemius 1)	NS	USN, attention disorder	FAC 0, BBS 5	BI 45/100 (45%)

m: months; d: days; M; male; F: female; BRS: Brunnstrom recovery Stage (upper limb – finger – lower limb); MMT: Manual Muscle Testing; SIAS-M: Stroke Impairment Assessment Scale-Motor (upper limb, lower limb); USN: unilateral spatial neglect; JCS: Japan Coma Scale; GCS: Glasgow Coma Scale: eye opening (E), verbal responses (V), and motor responses (M); FAC: Functional Ambulatory Category; TCT: Trunk Control Test; BBS: Berg Balance Scale; TUG: Timed up & Go Test; FR: Functional Reach test; 6MWT: 6-Minute Walk test; ADL: activities of daily living; BI: Barthel index; FIM: Functional Independent Measure; FIM m: Functional Independent Measure (motor); FIM c: Functional Independent Measure (cognition); NS: not stated.

*The original data were 10-m walk time and steps. The recalculated data is shown in this table.

**Descriptively reported that the cases had difficulty walking.

***Time after stroke onset.

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reasoning, considering treatment options other than KAFO". Methodological quality was independently scored by 2 researchers (EK, KH). Each fulfilled item was scored as follows: "no", 0 points; "unable to determine", 0 points; or "yes", 1 point. Any disagreements in scoring were solved based on the opinion of another researcher (NH). In the current study, case reports with a score > 60% of all items were included, and those with a score of < 60% of all items were excluded, which were judged as low-quality case reports.

Data synthesis

A qualitative synthesis of the results was conducted in this study. The following data were collected: author's name, publication year, study design, participant characteristics (age, sex, diagnosis, time of KAFO therapy initiation, motor functions of the paretic side, superficial and deep sensory functions on the paretic side, consciousness, higher brain functions, functional mobility, and ADL), information on KAFO therapy intervention (practice, types of KAFO, custom or prefabricated KAFO, frequency and dose of practice, setting, time from KAFO therapy initiation to completion, duration of KAFO therapy, reason for KAFO therapy, and concomitant physical exercises), and outcomes (functional mobility, ADL, and adverse events). As described in a previous study (22), participants were divided into 3 groups: acute phase (those who participated < 1 month after stroke), subacute phase (those who participated 1–6 months after stroke), and chronic phase (those who participated > 6 months after stroke).

RESULTS

Study selection

A flow chart of the inclusion and exclusion criteria for this review is shown in Fig. 1. After removing duplicates, a total of 4,436 articles were screened at the title and abstract level, among which 121 were screened at the full-text level. Based on the eligibility criteria, 14 articles were selected for data synthesis (23–36). All of the selected 14 case reports, describing 15 cases, were in Japanese. All first authors were Japanese physical therapists. The publication years ranged from 2008 to 2021, with 11 of 14 articles published in 2018 or later (23–26, 29, 31–33, 35, 36).

Participants

Data regarding participant characteristics are shown in Table II. The age range was teen to 76 years. Notably, 12 of the 15 cases were hospitalized, and 3 were outpatients. Of 15 cases, 9 had cerebral haemorrhage (7 putaminal haemorrhage and 2 thalamic haemorrhage), 2 had subarachnoid haemorrhage, 1 had medial medullary infarction, 1 had pontine infarction, 1 had arteriovenous malformations (AVMs), and 1 had vascular malformations. Of 15 cases, KAFO therapy was initiated in the acute phase (< 1 month after stroke), subacute phase (1–6 months after stroke), and chronic phase (> 6 months after stroke) in 7, 2 and 5 participants, respectively.

Motor function was assessed in all 15 patients. Brunnstrom recovery stage (BRS) (37) was measured in 12 of 15 cases (23, 25–28, 30, 32–36), including 6 cases of severe disease with flaccid motor paresis (BRS I or II) (25, 26, 28, 32, 33, 36), 4 cases of moderate disease (BRS III) (23, 27, 30, 34), and 2 cases of mild disease (BRS V) (33, 35). Stroke Impairment Assessment Set-Motor (SIAS-M) (38) was measured in 3 of 15 cases (24, 25, 31), including 1 case with at least 1 subtest of the lower limb of SIAS-M that was < 2 points with severe disease (31) and 2 cases with at least 1 subtest of the lower limb of SIAS-M that was ≥ 2 points with moderate to mild disease (25, 31). Muscle strength in the paretic lower limb was measured using manual muscle testing (MMT) in 6 of 15 cases (29, 31–33, 35), including 6 cases of MMT < 3 (24, 29, 31–33, 35) and 1 case of MMT ≥ 3 (33). Crucially, of the 15 eligible cases, 7 had no severe disease with flaccid motor paralysis (23, 27, 30, 31, 33–35).

Superficial and deep sensory functions in the paretic lower limb were measured in 9 of 15 cases, including 5 cases of severe sensory loss (25, 26, 28, 29, 31), 2 cases of moderate sensory loss (23, 35), and 2 cases of mild sensory loss (32, 33). This means that, of the 15 eligible cases, 4 cases had no severe sensory loss in the paretic lower limb (23, 33, 35). Sensory functions were reported qualitatively in these 9 cases, none of articles reported them using the quantitative or standardized measures. Six cases had attention disorder (25, 29, 31, 32, 34, 35), 5 cases had unilateral spatial neglect (25, 29, 31, 32, 34), and 4 cases had aphasia (25, 28, 32, 33).

Functional mobility was measured in 12 of 15 cases (23–25, 27, 28, 31–36). Functional Ambulatory Category (FAC) (39) was measured in 7 cases (24, 25, 31–33, 35), including 5 cases of FAC 0 (24, 25, 31–33), 1 case of FAC 3 (35), and 1 case of FAC 5 (33). The Trunk Control Test (TCT) (40) was measured in 5 cases, with 0, 12, 36, and 100 points in the TCT (24, 25, 33, 36). Walking speed was measured in 5 cases, including 1 case reporting 37.8 m/min, 1 case reporting 76 m/min, 1 case reporting 80 m/min, and 2 cases in which measurement was difficult (27, 31, 33, 35). Stride length was measured in 4 cases, including 1 case reporting 34.5 cm, 1 case reporting 61 cm, 1 case reporting 111 cm, and 1 case in which measurement

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Table III. Intervention

Author, year (reference)	Practices	Types of KAFO (owner of orthosis)	Frequency, dose of practice	Setting	Time* from KAFO therapy initiation to completion	Duration of KAFO therapy	Reason for finishing KAFO	Concomitant physical exercises
Acute phase (<1 m)								
Murakami et al. 2018 (26)	Standing and walking	DK-KAFO (C)	NS	Hospital	2–10 w	8 w	Conversion for AFO	NS
Fujimoto at al. 2018 (29)	Standing and walking	DK-KAFO (C)	20~120 min/d, 7 d/w	Hospital	12–70 d	58 d	Conversion for AFO	NS
Kubo et al. 2019 (24)	Walking	OD-KAFO (NS)	15 min, 5/w	Hospital	10– 41 d	31 d	NS	Standing up
Kamiishi et al. 2019 (23)	Walking	OD-KAFO (PF)	65 min/d, 2/w	Hospital	23–37 d	14 d	Conversion for AFO	NS
Harayama et al. 2020 (25)	Standing	DK-KAFO (NS)	10 min × 2/d	Hospital	10–43 d	33 d	Discharge	Visual feedback exercise
Satoh et al. 2020 (35)	Standing and walking	OD-KAFO (C)	40–60/min, 7 d/w	Hospital	6–24 d	18 d	Conversion for AFO	Standing up, walking with AFO
Kurita et al. 2021 (36)	Standing and walking, Toileting behaviour	OD-KAFO (C)	40 min/d	Hospital	14–44 d	30 d	Discharge	NS
Subacute phase (1–6 m)								
Tsujimoto et al. 2018 (31)	Walking	OD-KAFO (NS)	50 min/d	Hospital	34–100 d	51 d	Conversion for AFO	Strength training, standing up, semi-KAFO
Kadowaki et al. 2019 (33)	Walking	OD-KAFO (C)	30 min/d, 5/w	Hospital	36–126 d	90 d	Conversion for AFO	Strength training, walking with AFO
Chronic phase (6 m <)								
Kadowaki et al. 2019 (33)	Walking	OD-AFO+knee brace (NS)	30 min/d, 5/w	Outpatient	NS	21 d	Improvement in gait	Strength training
Aoyagi et al. 2008 (34)	Walking	P-KAFO (C)	4/w	Hospital	12–12 M + 81 d	81 d	Conversion for AFO	NS
Umeda et al. 2009 (27)	Walking	P-KAFO (C)	4 h/d, 6–7/w	Outpatient	20–20 M + 26 d	26 d	Discharge	Neuro developmental approaches
Minagawa et al. 2010 (28)	Standing and walking	DK-KAFO (NS)	7/week (including practice by family)	Hospital	7–7 M + 4 w	4 w	Discharge	Providing care instructions to family members
Nishizawa et al. 2016 (30)	Standing	NS (NS)	1/w, 20–40 min/day	Outpatient	430–479 d	49 d	Conversion for AFO	Strength training
Kadowaki et al. 2018 (32)	Standing and walking	OD-KAFO (C)	30 min/d, 5/w	Hospital	200–411 d	211 d	Conversion for AFO	Strength training, standing up, walking with AFO

min: minutes; d: days; w: weeks; M: months; KAFO: knee–ankle–foot orthosis; DK-KAFO: knee–ankle–foot orthosis with double Klenzak ankle joint; OD-KAFO: knee–ankle–foot orthosis with oil dumper ankle joint; P-KAFO: plastic knee–ankle–foot orthosis; AFO: ankle–foot orthosis; NS: not stated; C: custom; PF: prefabricated.

*Time after stroke onset.

was difficult (33–35). The Berg Balance Scale (BBS) (41) scores were measured in 2 cases, each reporting 5 and 26 points (23, 32). In contrast, in 3 of 15 cases, walking and moving were described without using any outcome measures (26, 29, 30).

ADL was measured in 11 of 15 cases (23–25, 27, 28, 30, 32, 33, 35, 36). Barthel Index (BI) (42) was measured in 6 cases, each reporting 0, 0, 40, 45, 85 and 100 points (24, 25, 27, 32, 33). Functional Independent Measure (FIM) (43) was measured in 5 cases, each reporting 18, 43, 49, 74 and 75 points (23, 28, 30, 35, 36).

Interventions

The data representing the details of the intervention are shown in Table III. Using the KAFO therapy, standing and walking exercises were performed in 13 of 15 cases, walking exercises were performed in 6 of 15 cases, and exercise in toileting behaviour was performed in 1 of 15 cases. The types of KAFO were KAFO with an oil damper ankle joint (OD-KAFO) in 7 of 15 cases (18, 19, 26–28, 35, 36), KAFO with double Klenzak ankle joints (DK-KAFO) in 4 of 15 cases (25, 26, 28, 29), plastic KAFO (P-KAFO) in 2 of 15 cases (27, 34), and AFO with an oil damper ankle joint (OD-AFO) and knee brace in 1 of 15 cases (33); however, no detailed information was reported in 1 of 15 cases (26). Custom orthoses were used in 8 of 15 cases (26, 27, 29, 32–36), while prefabricated orthoses were used in 1of 15 cases (23). The reasons for terminating KAFO therapy were as follows: a conversion to AFO in 9 of 15 cases (23, 26, 29–35), discharge from hospital in 5 of 15 cases (24, 25, 27, 28, 36), and improvement in gait in 1 of 15 cases (33). Typical frequencies and doses of KAFO therapy were 5–7 times/week and 40–60 min/day, respectively. The

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Table IV. Outcomes

Author, year (reference)	Functional mobility	ADL	Adverse events
Acute phase (<1 m)			
Murakami et al. 2018 (26)	NS	NS	NS
Fujimoto at al. 2018 (29)	NS	FIM 74	NS
Kubo et al. 2019 (24)	FAC 2, TCT 87	BI 10/20 (50%)	NS
Kamiishi et al. 2019 (23)	BBS 53	FIM 109 (FIM m 79, FIM c 30)	NS
Harayama et al. 2020 (25)	FAC 1, TCT 24	BI 10/100 (10%)	Worsening standing balance (during KAFO therapy without visual feedback therapy)
Satoh et al. 2020 (35)	FAC5, Walking speed 0.57 m/s Stride length 77 cm, BBS 41	FIM 117	NS
Kurita et al. 2021 (36)	TCT 62	FIM 58 (FIM m 32, FIM c 26)	NS
Subacute phase (1–6 m)			
Tsujimoto et al. 2018 (31)	FAC 3	NS	NS
Kadowaki et al. 2019 (33)	FAC 5, TCT 87,	BI 85/100 (85%)	NS
Chronic phase (6 m <)			
Kadowaki et al. 2019 (33)	FAC 5, TCT 100, Walking speed 1.92 m/min Stride length 153.8 cm	BI 100/100 (100%)	NS
Aoyagi et al. 2008 (34)	Stride length 54.5 cm	NS	NS
Umeda et al. 2009 (27)	Walking speed 0.69 m/s, Stride length 90 cm*	BI 95/100 (95/%)	NS
Minagawa et al. 2010 (28)	TUG 42 s, FR 30 cm, 6MWT 128 m, RMI 6	FIM 75 (FIM m 60, FIM c 15)	NS
Nishizawa et al. 2016 (30)	NS	FIM 65 (FIM m 45, FIM c 20)	NS
Kadowaki et al. 2018 (32)	FAC 3, BBS 39 Walking speed 0.23 m/s Stride length 64.5cm	BI 70/100 (70%)	NS

BRS: Brunnstrom recovery stage; FAC: Functional Ambulatory Category; TCT: Trunk Control Test; BBS: Berg Balance Scale; TUG: Timed up & Go Test; FR: Functional Reach test; 6MWT: 6-Minute Walk Test; m/s: metre per second; sec: second: M: meter; RMI: Rivermead Mobility Index; ADL: activities of daily living; BI: Barthel Index; FIM: Functional Independent Measure; FIM m: Functional Independent Measure (motor); FIM c: Functional Independent Measure (cognition); NS: not stated.

*Original data were 10-m walk time and steps. The recalculated data are shown in this table.

duration of KAFO therapy was 18–211 days (mean 53.1±49.1 days).

Outcomes

The data representing details about outcomes are shown in Table IV and Fig. 2. The minimum clinically important differences (MCID) of each outcome measurement was considered to be as follows: 0.16 m/s in walking speed (44), 5 points in the BBS (45), 9.25% (1.85/20 points) in the BI (46), and 22 points in the FIM (47). In addition, changes in the TCT above the cut-off score of 40 was considered clinically meaningful (40), and an improvement of at least 1 point in the FAC was considered to be clinically meaningful (45). Based on the above considerations, the improvements in each outcome were as follows: those in functional mobility were reported in 10 of 15 cases, with improvements in the FAC in 6 cases (Fig. 2a) (24, 25, 31–33, 35), the TCT in 3 cases (Fig. 2b) (24, 33, 36), walking speed in 2 cases (Fig. 2c) (27, 33), and the BBS score in 3 cases (Fig. 2d) (23, 32, 35). Improvements in ADL were reported in 9 of 15 cases, with those in the BI in 5 cases (Fig. 2e) (24, 25, 27, 32, 33) and FIM in 4 cases (Fig. 2f) (23, 28, 35, 36). Improvements in the FAC was reported in all disease phases (24, 25, 31–33, 35). Improvements in walking speed were reported only in chronic phase cases (27, 33). In contrast, those in the TCT were reported in 3 cases in the acute or subacute phase (24, 33, 36).

Methodological quality

The methodological quality of the 14 articles is shown in Table V. In the section on "Follow-up and Outcomes", 0 of 14 articles fulfilled item 10b of "Clinician and patient-reported outcomes", 1 of 14 articles fulfilled item 10d of "Adverse and unanticipated events" (24), and 7 of 14 articles fulfilled item 10c of "Important follow-up test result (positive and negative)" (23, 25, 26, 31, 32, 35, 36). In the "Discussion" section, 5 of 14 articles fulfilled item 11a of "Strength and limitations of the management of this case" (23, 25, 33–35). Nonetheless, 4 of 14 articles fulfilled item 12 in the "Patient perspectives" section (30, 34–36).

Adherence to KAFO therapy

Four articles reported patient adherence to KAFO therapy, including that the clinicians incorporated the patient's wishes, which were to walk independently (30, 34, 35) and perform toilet behaviour independently (36), into the plan of orthotic therapy. None of the articles in this study included reported the non-adherence to KAFO therapy.

Adverse events and limitations of KAFO therapy

None of the included articles reported adverse events while using KAFO. Limitations of KAFO therapy were reported in the following 4 articles. Harayama et al. reported a case in which standing balance did not

Table V. Methodological quality assessment

Section	Title	Key word	Abstract			Introduction		Patient information		Clinical findings	Time-line	Diagnostic assessment				Therapeutic intervention			Follow-up and outcomes				Discussion			Patient perspective	Informed consent
Item number	1	2	3a	3b	3c	3d	4	5a	5b	5c	6	7	8a	8b	8c	8d	9a	9b	9c	10a	10b	10c	10d	11a	11b	11c	11d	12	13
Acute phase (<1 m)																													
Murakami et al. 2018 (26)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	NA	N	NA	Y	Y	N	Y	N	Y	N	N	Y	Y	Y	N	N
Fujimoto at al. 2018 (29)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	NA	Y	Y	Y	Y	N	N	N	N	N	N	Y	N	N
Kubo et al. 2019 (24)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	NA	N	NA	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	N	N
Kamiishi et al. 2019 (23)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	NA	N	NA	Y	Y	Y	Y	N	Y	N	Y	N	Y	Y	N	Y
Harayama et al. 2020 (25)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	NA	Y	NA	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y
Satoh et al. 2020 (35)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y		Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y
Kurita et al. 2021 (36)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y		Y		Y	Y	N	Y	N	Y	N	N	Y	Y	Y	Y	Y
Subacute phase (1–6 m)																													
Tsujimoto et al. 2018 (31)	N	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	NA	Y	NA	Y	Y	Y	Y	N	Y	N	N	Y	Y	Y	N	Y
Kadowaki et al. 2019 (33)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	NA	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	N	Y
Chronic phase (6m <)																													
Aoyagi et al. 2008 (34)	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	NA	Y	Y	N	Y	N	N	N	Y	N	N	Y	Y	N
Umeda et al. 2009 (27)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	NA	N	NA	Y	Y	Y	Y	N	N	N	N	Y	Y	Y	N	Y
Minagawa et al. 2010 (28)	N	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	NA	Y	NA	Y	Y	Y	Y	Y	N	N	N	Y	Y	Y	N	N
Nishizawa et al. 2016 (30)	N	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y	NA	Y	NA	Y	Y	Y	Y	N	N	N	N	N	N	Y	Y	Y
Kadowaki et al. 2018 (32)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	NA	Y	NA	Y	Y	Y	Y	N	Y	N	N	Y	Y	Y	N	Y

Y: yes (included specific information items in CARE checklist); N: no (not included specific information items in CARE checklist); m: months; NA: not available.

improve after performing KAFO therapy when it was not combined with visual feedback therapy (25). Kamiishi et al. and Aoyagi et al. reported a few cases in which independent ambulation was not regained after KAFO therapy (23, 34). Kadowaki et al. reported a case of deterioration in walking ability 1 year after completion of KAFO therapy (33).

DISCUSSION

This systematic review of case reports provides a low level of evidence regarding efficacy of KAFO therapy for patients with stroke. Improvements of functional mobility and ADL by KAFO therapy are reported in 10 and 9 of 15 cases of the reviewed articles, respectively. The review elucidated the optimal application of each outcome measure for efficacy of KAFO therapy. The methodological quality of the reviewed articles was poor due to a lack of information on limitations of management, adverse events, and patient-reported outcomes. Therefore, evidence regarding the efficacy of KAFO therapy is limited and insufficient to draw a more definite conclusion.

Efficacy of KAFO on functional mobility

Due to the limited number of articles reviewed, the evidence regarding the efficacy of KAFO therapy for improving functional mobility in patients with stroke was unclear. However, the focus on functional mobility as an outcome of interest in KAFO therapy is the originality of this review, since the previous review study reported walking ability in an experimental setting, using a motion capture system or electromyography, as an outcome of KAFO therapy (8). Functional mobility is important for patients, to enable participation in ADL in the real-life setting by addressing orthotic therapy (2, 8).

In addition, this review elucidates the selection of optimal outcomes measures for the efficacy of KAFO therapy regarding functional mobility according to the disease phase of stroke. Choosing an appropriate outcome measure is an important first step in facilitating high-quality quantitative studies (50). Since no other high-level evidence is available in the efficacy of KAFO therapy, this finding is relevant in terms of identifying optimal outcome measures to facilitate future studies. The FAC, the most frequently reported outcome measuring functional mobility, would be applicable in all disease phases. The FAC is a simple and valid functional walking test that evaluates ambulation status with a 6-point scale by determining how much human support the patient requires when walking (39, 48). The simplicity of the tests could be useful for clinicians to measure the outcomes of KAFO therapy.

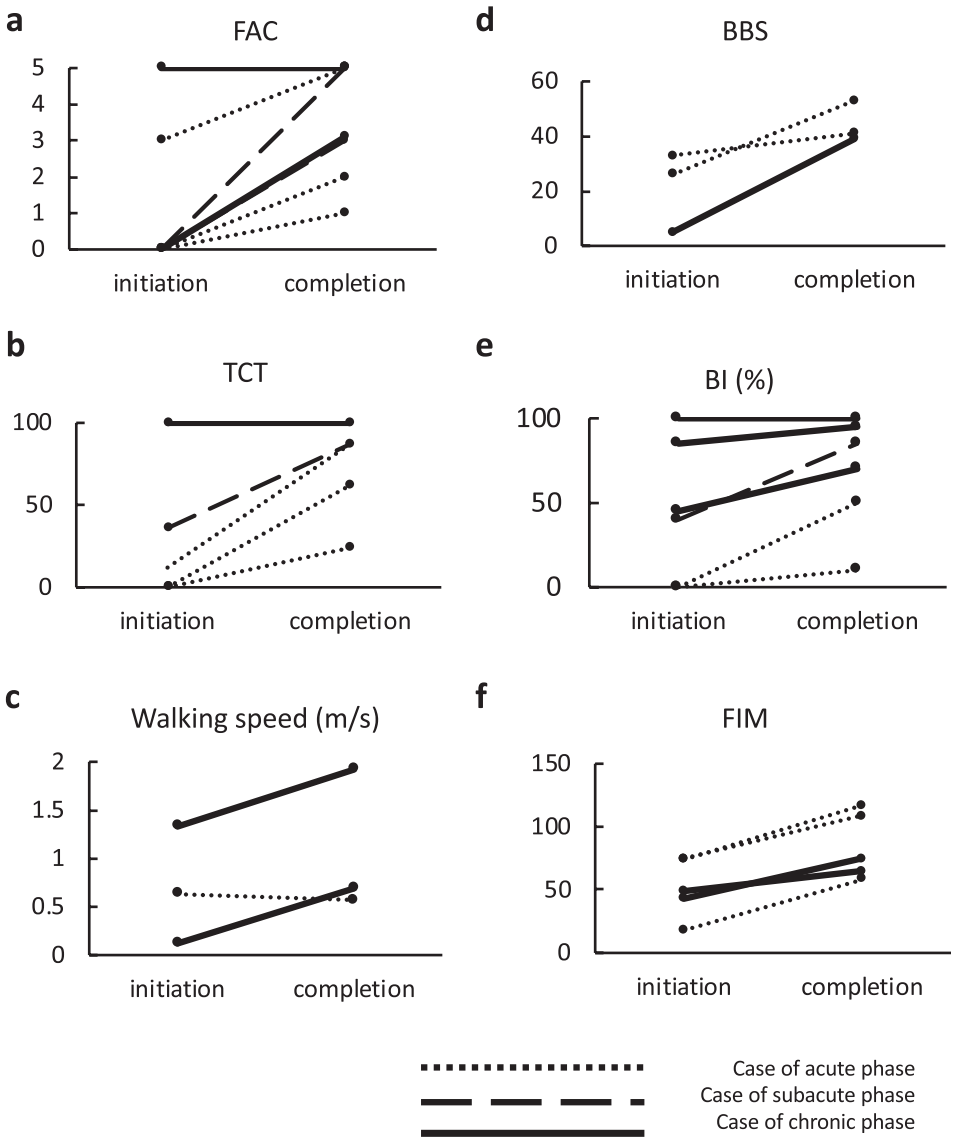

Fig. 2. (a-f). Changes in outcome measures on functional mobility and activities of daily living in each case due to knee-ankle-foot orthosis therapy.

*Abbreviations: FAC = Functional Ambulatory Category, TCT = Trunk Control Test, BBS = Berg balance Scale, BI = Barthel Index, FIM = Functional Independent Measure.

Walking speed measurements are suitable for use in the chronic phase. Most of the patients had difficulty walking before therapy initiation in the acute and subacute phases, wherein 4 of them had FAC 0 (24, 25, 31, 33) and 2 were descriptively reported as having difficulty walking (26, 29). In contrast, the TCT would be applicable in the acute or subacute disease phase. The TCT is a reliable and valuable tool in assessing trunk movements in patients with strokes (49). KAFO therapy can be performed on patients in the acute or subacute phase with the expectation of improving trunk movement.

Efficacy of KAFO on ADL

Improvement in ADL is an important purpose of rehabilitation in patients with stroke (51). The application of efficient KAFO therapy in improving ADL is expected to improve ambulation (4). However, in this systematic review, the evidence regarding the efficacy of KAFO therapy for improving ADL, which was assessed using the BI and FIM, was unclear. The BI rates the amount of assistance required to complete 10 items of ADL (feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation, and stair climbing) (42). Nevertheless, only a total BI score was reported in 4 of these cases, whereas none of these cases reported changes in each item were. Similarly, only the scores of the motor and cognitive components of the FIM were reported; therefore, the changes in each FIM item were unknown (23, 28, 30, 36). Future studies are needed to investigate the efficacy of KAFO therapy in improving ADL by indicating which ADL items are affected by KAFO therapy.

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Patients eligible for KAFO therapy

Inconsistent with the previous criteria reported by Ishigami et al. (11), the current study revealed that patients without severe disease and without severe sensory loss were both eligible for KAFO therapy. The results of this study suggest an extension of the current indications for KAFO therapy.

Methodological quality of included case reports

The methodological quality of the reviewed articles was relatively low. Therefore, evidence regarding the efficacy of KAFO therapy is limited. None of the articles included in this study reported patient-reported outcomes, which was consistent with the previous study (8). There are some advantages of using patient-reported outcomes in orthotic therapy, such as satisfaction with orthosis or usage of devices; however, their use has often been limited (8).

Adherence to KAFO therapy

In this review, some articles reported patient adherence to treatment; none of them reported non-adherence. Adherence is a key determinant of healthcare interventions (53). Various reasons for non-adherence to orthotic therapy include: the patients found it unnecessary, usage difficulties, pressure sensation, not making life easier, and lack of a suitable environment (55). Clarifying the reasons for non-compliance with orthotic therapy may mean that the orthotic therapy plan could be modified based on patient perspectives so that the intervention would be more acceptable to patients or more effective (53). Future studies, including information about non-adherence, would have particular value.

Adverse events and limitations of the management of KAFO therapy

Skin trauma, falls, discomfort, and inconvenience are typical adverse events associated with using lower limb orthoses (52, 53); clinicians should aim to minimize these risks. Nevertheless, in this review, none of the articles reported adverse events associated with KAFO therapy. Describing unknown adverse events of existing treatment is an important role of case reports (19). Therefore, future studies should investigate the effect of KAFO therapy.

For lower limb orthosis, there are some disadvantages in terms of the effect on movement, such as the requirement for high energy during ambulation, slow walking speed, not feeling safe, and usage difficulty (54). Clinicians need to consider carefully the benefit-risk balance of KAFO therapy. In this review, disadvantages and limitations of KAFO therapy in real-life settings have been reported as the inability to achieve independent walking (23, 34), limited long-term effects after 1 year of KAFO therapy (33), and the need to combine sensory feedback therapy (25). Hence, the efficacy of KAFO therapy may be enhanced if it is used in a controlled environment, such as a hospital, rather than in the patient's home.

Future study

There is a large gap in evidence regarding the efficacy of KAFO and AFO in patients with stroke. Although the efficacy of AFO, which is a commonly used orthosis, on functional mobility has already been investigated in several systematic reviews and meta-analyses (3, 4), there is no high-quality study examining the efficacy of KAFO therapy. Future studies are required to address optimal outcome measures that are appropriate for the disease phase of stroke, or patient-reported instruments. In addition, in terms of expanded indications, it is necessary to investigate carefully which characteristics of patients will benefit from KAFO therapy. Considering the disadvantages of KAFO, such as being heavy, difficulty in use, or leading to abnormal gait patterns (10), more information about adverse events or limitations in management is required.

Study limitations

This review study aimed to collect all the available articles on the efficacy of KAFO therapy in patients with stroke. Nevertheless, the current review included case reports, which are at the lowest level of medical evidence and are subject to limitations, such as publication bias and inability to establish cause–effect relationships. Since the evidence in each report was reported exclusively using case report methodology, it was not possible to compare outcomes among patients who were exposed and not exposed to KAFO therapy (19). The CARE checklist was used to assess methodological quality, but the cut-off score, which indicates whether a case report is valid, was not specified (21); thus, we endeavoured to define our own criteria in the current study.

CONCLUSION

The effectiveness of KAFO therapy in patients with stroke has been debated for many years; however, it has not been scientifically investigated. This systematic review of case reports provides a low level of evidence regarding the effectiveness of KAFO therapy in improving functional mobility and ADL. However, due to the limited number of published case reports and the existence of unavoidable publication bias, no clear conclusion can be drawn. Of value, this study identifies

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outcome measures that should be selected in future quantitative studies in order to build more scientific evidence of the effectiveness of KAFO therapy. With the expansion of the current indications for KAFO therapy, there is a need to clarify the characteristics of patients who benefit from such therapy.

All of the reviewed case reports were in Japanese, indicating the emphasis placed on KAFO therapy in treatment of patients with strokes in Japan. Crucially, there is limited evidence regarding the efficacy of KAFO therapy, because of the poor methodological quality of each case report, along with missing information on patient-reported outcomes, adverse events, and limitations of management. Future studies with high-quality case reports are needed to address this lack of evidence.

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