



Consensus and Recommendations on the lower limb orthotic management of stroke patients

Current situation in lower limb orthotics

VHS medical center

Department of Rehabilitation Medicine

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Gait after stroke

- **Flaccid paralysis**

Swing : Foot drop

Stance : Knee collapse



- **Spastic paralysis**

Eequinovarus

Genu recurvatum

When to consider orthosis

- Different needs according to the phase
- Early orthotic intervention is required in some cases
- Close monitor the change of muscle tone, development of spasticity
- DO NOT HURRY

· 다리 보조기

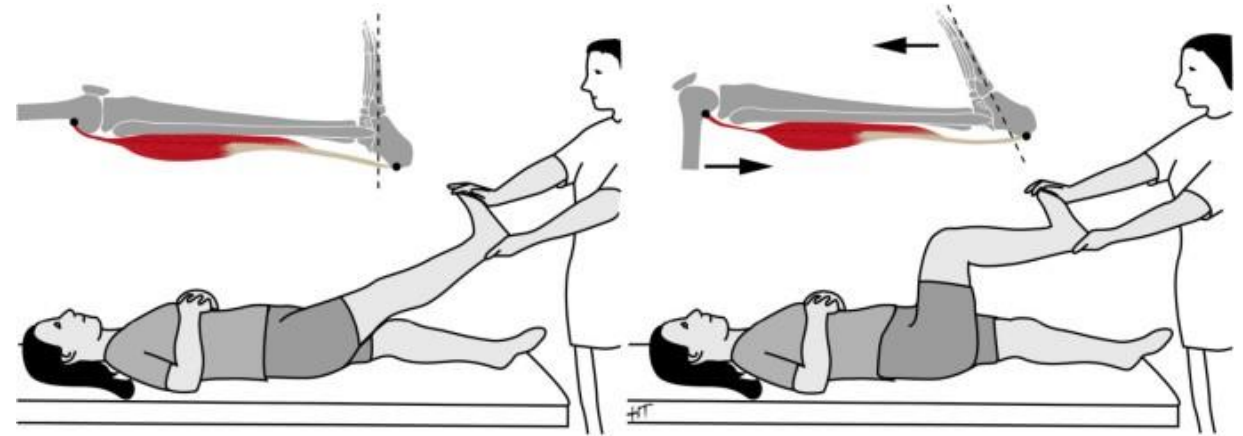
유형	용도	구분	기준액(원)	내구연한(년)
1) 엉덩-무릎-발목-발 보조기	엉덩이관절을 포함하여 무릎 및 발목의 관절운동을 제한하거나 고정하는 경우 사용	한쪽	540,000	3
		양쪽	790,000	3
2) 무릎-발목-발 보조기	엉덩이관절을 제외한 무릎 및 발목의 관절운동을 제한하거나 고정하는 경우 사용		410,000	3
3) 무릎 보조기	무릎관절 또는 넓적다리 무릎뼈관절의 운동을 견고하게 제한하거나 고정하는 경우 사용	관절운동 제한 장치 부착형	190,000	3
	무릎인대 손상 시 무릎관절 축 회전운동을 방지하기 위한 경우 사용	레녹스힐	160,000	3
	무릎 안쪽 및 바깥쪽 결인대 손상 및 앞 십자인대 손상 시 무릎관절축의 회전운동을 방지하기 위하여 경증 환자에게 사용하는 보조기	인대 손상용	80,000	3
4) 발목-발 보조기	플라스틱형 테두리(brim)를 사용한 체중부하장치가 포함된 보조기로 종아리 및 발뼈 또는 발목관절의 안정과 보호를 위한 경우 사용	체중부하식	370,000	3
	발목관절의 발등 굽힘 근육과 발바닥 굽힘 근육의 안정 또는 발목의 관절운동 제한을 위한 경우 사용	일체형 (플라스틱)	120,000	3
		90도 고정형 (플라스틱)	310,000	3
		90도 고정형 (금속형)	300,000	3
	스프링이 들어있는 금속 발목관절인 크렌자크 발목관절장치를 사용한 보조기로 근력이 약한 발목관절을 보조하는 경우 사용	크렌자크식 (플라스틱)	360,000	3
		크렌자크식 (금속형)	350,000	3

Assessment

- MMT
- Spasticity, tone, reflex
- ROM (active and passive)

*Gastrocnemius shortening

- ankle dorsiflexor passive ROM : knee extension < knee flexion
- dorsiflexion angle of orthosis : dictated by GCM length
- inappropriate dorsiflexion setting (greater than actual GCM length)
 - midfoot collapse, gait deviations



- Gait analysis

Lower limb orthosis after stroke

- Review (2021)
- 14 trials, 282 patients
- Increase of ankle dorsiflexion angle during walking
- Improved walking speed
- No effect on fall frequency, QOL, ADL

Review > PM R. 2021 Aug 9. doi: 10.1002/pmrj.12687. Online ahead of print.

The effect of ankle-foot orthosis on ankle kinematics in individuals after stroke: A systematic review and meta-analysis

Yoshitaka Wada ¹, Yohei Otaka ², Masahiko Mukaino ², Yasushi Tsujimoto ^{3 4 5}, Akihiro Shiroshita ^{5 6}, Nobuyuki Kawate ¹, Shunsuke Taito ^{5 7}

Affiliations + expand

PMID: 34369101 DOI: 10.1002/pmrj.12687

Abstract

Objective: To evaluate whether ankle-foot orthosis (AFO) has a beneficial effect on dorsiflexion angle increase during the swing phase among individuals with stroke and patient-important outcomes in individuals with stroke.

Literature survey: Randomized controlled trials (RCTs), randomized crossover trials, and cluster RCTs until May 2020 were researched through CENTRAL, MEDLINE, EMBASE, PEDro, CINAHL, and REHABDATA databases. Studies reporting on AFO use to improve walking, functional mobility, quality of life, and activity limitations and reports of adverse events in individuals with stroke were included.

Methodology: Two independent reviewers extracted the data and assessed the risk of bias. The certainty of evidence was assessed using the Grading of Recommendations, Assessment, Development and Evaluations approach.

Synthesis: Fourteen trials that enrolled 282 individuals with stroke and compared AFO with no AFO were included. Compared with no AFO, AFO could increase the dorsiflexion angle of ankle joints during walking (mean difference [MD, 3.7°]; 95% confidence interval [CI], 2.0-5.3; low certainty of evidence). Furthermore, AFO could improve walking ability (walking speed) (MD, 0.09 [m/s]; 95% CI, 0.06-0.12; low certainty of evidence). No study had reported the effects of AFO on quality of life, adverse events, fall frequency, and activities of daily life.

Conclusions: Our findings suggest that AFO improved ankle kinematics and walking ability in the short term; nonetheless, the evidence was characterized by a low degree of certainty.

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Lower limb orthosis after stroke

- Review (2021)
 - 19 studies, 434 patients
 - AFO improved gait speed, cadence, step length, and stride length
 - Improve in sagittal plane angle of the ankle, knee, and hip
- ankle dorsiflexor weakness or hyper plantarflexion problems can benefit

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OPEN

Effectiveness of an ankle–foot orthosis on walking in patients with stroke: a systematic review and meta-analysis

Yoo Jin Choo¹ & Min Cheol Chang^{2,3}✉

We conducted a meta-analysis to investigate the effectiveness of ankle–foot orthosis (AFO) use in improving gait biomechanical parameters such as walking speed, mobility, and kinematics in patients with stroke with gait disturbance. We searched the MEDLINE (Medical Literature Analysis and Retrieval System Online), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane, Embase, and Scopus databases and retrieved studies published until June 2021. Experimental and prospective studies were included that evaluated biomechanics or kinematic parameters with or without AFO in patients with stroke. We analyzed gait biomechanical parameters, including walking speed, mobility, balance, and kinematic variables, in studies involving patients with and without AFO use. The criteria of the Cochrane Handbook for Systematic Reviews of Interventions were used to evaluate the methodological quality of the studies, and the level of evidence was evaluated using the Research Pyramid model. Funnel plot analysis and Egger's test were performed to confirm publication bias. A total of 19 studies including 434 participants that reported on the immediate or short-term effectiveness of AFO use were included in the analysis. Significant improvements in walking speed (standardized mean difference [SMD], 0.50; 95% CI 0.34–0.66; $P < 0.00001$; I^2 , 0%), cadence (SMD, 0.42; 95% CI 0.22–0.62; $P < 0.0001$; I^2 , 0%), step length (SMD, 0.41; 95% CI 0.18–0.63; $P = 0.0003$; I^2 , 2%), stride length (SMD, 0.43; 95% CI 0.15–0.71; $P = 0.003$; I^2 , 7%), Timed up-and-go test (SMD, –0.30; 95% CI –0.54 to –0.07; $P = 0.01$; I^2 , 0%), functional ambulation category (FAC) score (SMD, 1.61; 95% CI 1.19–2.02; $P < 0.00001$; I^2 , 0%), ankle sagittal plane angle at initial contact (SMD, 0.66; 95% CI 0.34–0.98; $P < 0.0001$; I^2 , 0%), and knee sagittal plane angle at toe-off (SMD, 0.39; 95% CI 0.04–0.73; $P = 0.03$; I^2 , 46%) were observed when the patients wore AFOs. Stride time, body sway, and hip sagittal plane angle at toe-off were not significantly improved ($p = 0.74$, $p = 0.07$, $p = 0.07$, respectively). Among these results, the FAC score showed the most significant improvement, and stride time showed the lowest improvement. AFO improves walking speed, cadence, step length, and stride length, particularly in patients with stroke. AFO is considered beneficial in enhancing gait stability and ambulatory ability.

Selection of orthosis according to clinical features

foot drop

knee collapse

equinovarus + genu recurvatum

Foot drop

- Ankle dorsiflexor weakness



Foot drop in swing

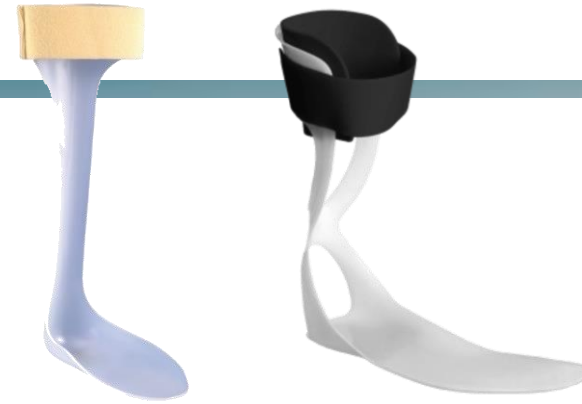
Initial contact with forefoot

Foot-flat as foot dorsiflexed by weight

- Compensatory strategies : hip hike, vaulting, circumduction, steppage gait

one-piece AFO

- Posterior leaf spring AFO
 - Traditional
- (Dynamic) AFO
 - DynaAnkle® : control rotation
 - AFO Dynamic®, WalkOn® : carbon
- Material : Carbon
 - strong, lightweight, energy-storing
- Shape : medial or lateral strut / anterior shell
 - less visible in shoe, fit inside any shoe



- TurboMed®



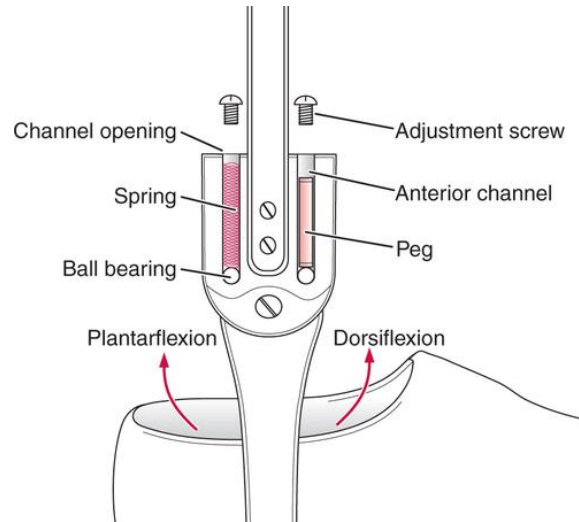
- Foot-up®

- Foot-wrap



articulated AFO with double adjustable ankle joint

- Plantarflexion resisting spring or stop/block at appropriate angle (typically 90°)



FES (functional electrical stimulation)

- Worn around calf, stimulate peroneal nerve
- Control : instrumented foot plate, accelerometer, or microprocessor
- Advantages : greater option for shoe wear, cosmesis, improve muscle strength
- but. Control only swing phase



■ FES vs AFO

- Review (2018)
- 8 papers
- FES = AFO

: walking speed after 4-6 weeks' use

J Rehabil Med 2018; 50: 129-139
REVIEW ARTICLE
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JRM
Journal of Rehabilitation Medicine
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FUNCTIONAL ELECTRICAL STIMULATION AND ANKLE FOOT ORTHOSES PROVIDE EQUIVALENT THERAPEUTIC EFFECTS ON FOOT DROP: A META-ANALYSIS PROVIDING DIRECTION FOR FUTURE RESEARCH*

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Objective: To compare the randomized controlled trial evidence for therapeutic effects on walking of functional electrical stimulation and ankle foot orthoses for foot drop caused by central nervous system conditions.

Data sources: MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, REHABDATA, PEDro, NIHR Centre for Reviews and Dissemination, Scopus and clinicaltrials.gov.

Study selection: One reviewer screened titles/abstracts. Two independent reviewers then screened the full articles.

Data extraction: One reviewer extracted data, another screened for accuracy. Risk of bias was assessed by 2 independent reviewers using the Cochrane Risk of Bias Tool.

Data synthesis: Eight papers were eligible; 7 involving participants with stroke and 1 involving participants with cerebral palsy. Two papers reporting different measures from the same trial were grouped, resulting in 7 synthesized randomized controlled trials ($n=464$). Meta-analysis of walking speed at final assessment ($p=0.46$), for stroke participants ($p=0.54$) and after 4-6 weeks' use ($p=0.49$) showed equal improvement for both devices.

Conclusion: Functional electrical stimulation and ankle foot orthoses have an equally positive therapeutic effect on walking speed in non-progressive central nervous system diagnoses. The current randomized controlled trial evidence base does not show whether this improvement translates into the user's own environment or reveal the mechanisms that achieve that change. Future studies should focus on measuring activity, muscle activity and gait kinematics. They should also report specific device details, capture sustained therapeutic effects and involve a variety of central nervous system diagnoses.

Key words: electric stimulation therapy; foot orthoses; walking; foot drop; central nervous system; therapeutic effects; systematic review; meta-analysis.

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J Rehabil Med 2018; 50: 129-139

*Some of this material was presented as a poster on 25-29 June 2017 at the International Society of Posture & Gait Research (ISPGR) World Congress in Fort Lauderdale, FL, USA.

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Foot drop is a common motor impairment associated with many central nervous system (CNS) conditions (1). An estimated 20-30% of stroke survivors experience foot drop; thus approximately 240,000-360,000 people might be living with it in the UK alone (2). Foot drop is an abnormal activation of the musculature of the lower limb, resulting in inefficient foot clearance during swing (3) and reduced stability in stance (4). These impairments negatively impact the function of walking, which may restrict participation in many aspects of life.

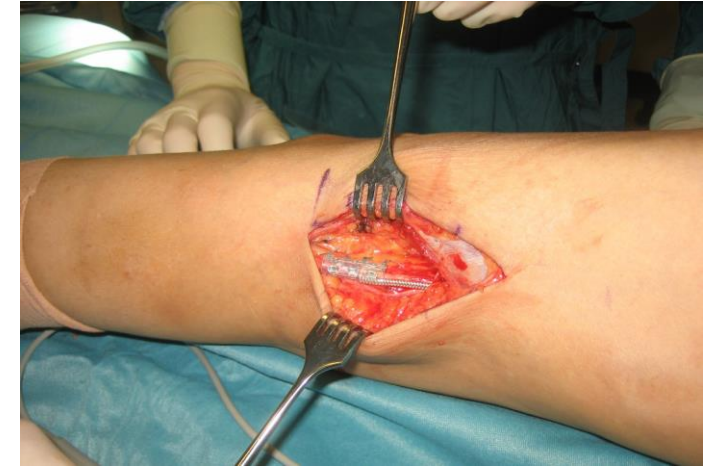
There are 2 demonstrably effective orthotic interventions for foot drop: ankle-foot orthoses (AFO) (5-9) and functional electrical stimulation (FES) devices (10). AFOs address foot drop by changing the effective stiffness and neutral point of the ankle joint (11). FES devices stimulate lower motor neurones, in this case the common peroneal nerve, to assist muscle contraction over appropriate phases in the gait cycle (12).

Recent randomized controlled trials (RCT) have sought to compare the direct effects of using each device on various walking behaviours (13, 14). These comparisons have been made both with and without the devices being worn, at the point of provision and at various time-points after a period of use (15). Clinically the devices are commonly prescribed as orthotics for long-term use (16); the difference between walking behaviours without the device at baseline and walking with the device being worn after a period of use is called the combined-orthotic effects (14). RCTs (14, 17-19) reporting these effects have found that both devices achieve the same improvement at various time-points up to 12 months (18). The combined results of individual RCTs, demonstrating equal combined-orthotic effects of AFO and FES, have also been confirmed in a recent meta-analysis (15). However, given the clinical importance of attempting to achieve therapeutic benefits (20, 21) (i.e. improvement in measured walking behaviours without a device being worn relative to baseline, called the therapeutic effects (13)), further work is required to establish whether there are differences in the therapeutic effects of the 2 devices.

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doi: 10.2340/16501977-2289

Implanted FES (ActiGait®)

- Cuff electrode : 4-channel stimulation for the peroneal nerve
- External control unit with antenna : on/off, stimulation intensity
- Heel switch : control the timing of the stimulation



- One-year follow up
 - increased dorsiflexion angle at initial contact without stimulation
 - no improvement in gait speed



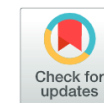
RESEARCH ARTICLE

The long-term effects of an implantable drop foot stimulator on gait in hemiparetic patients

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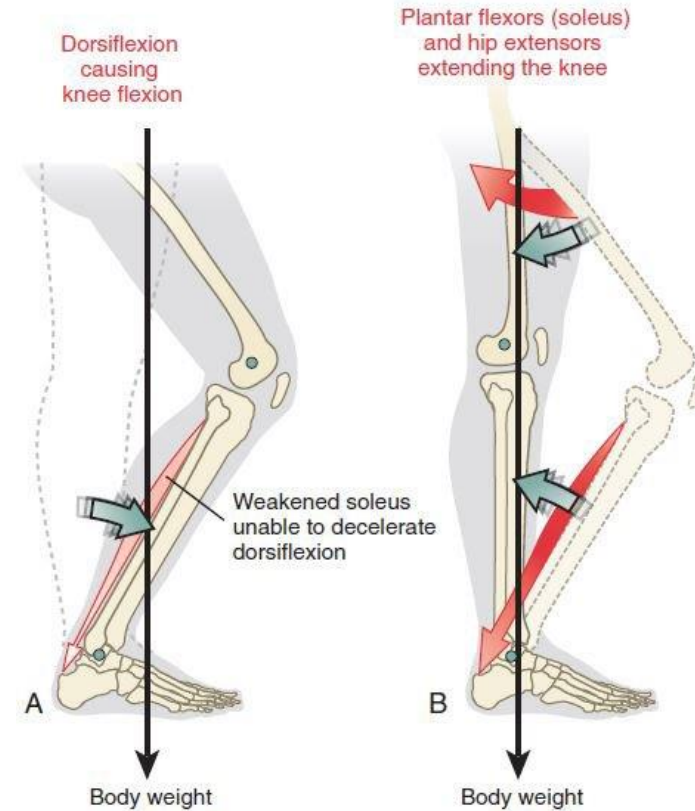
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Knee collapse

- At stance phase
- Ankle plantarflexor weakness
- Quadriceps weakness
- or Both



→ Orthosis to block dorsiflexion (block tibial progression)

AFO

Articulated AFO with dorsiflexion stop

- double-adjustable ankle joint : allow fine tuning of ankle alignment

Rigid plastic AFO

- thickness, stiff plastic, corrugation, carbon composite inserts or carbon laminate

Hinged AFO

- lock hinge → unlock with plantarflexor motor recovery

Ground reaction AFO

- block dorsiflexion-GRF in front of knee center-create extension moment-prevent knee collapse
- original ground reaction AFO : designed in plantarflexion. difficulty with tibial progression
- modern ground reaction AFO : 5° dorsiflexion to help tibial progression

KAFO

- Improve **postural alignment** and enable better **weight bearing** in early stage of rehab
- KAFO → AFO : by removing knee upright

- Article
 - participants - mean post-stroke interval 26.8day
 - unstable knee and ankle joint
 - insufficient with AFO
 - stand as long as possible in various condition
(step base width, tandem stance, eye open/close)
 - within one week after providing KAFO
(spring assisted extension knee joint & Klenzak ankle joint)

→ improved static standing balance

J. Phys. Ther. Sci. 31: 127-131, 2019

The Journal of Physical Therapy Science



Original Article

Early effects of a knee-ankle-foot orthosis on static standing balance in people with subacute stroke

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Abstract. [Purpose] The purpose of this study was to evaluate the early effects of a knee-ankle-foot orthosis on static standing balance in people with subacute stroke. [Participants and Methods] Timed static standing balance in four standing conditions (feet apart with eyes open, feet apart with eyes closed, feet together with eyes open, and tandem stance with eyes open) was assessed in 29 inpatients (mean age: 67.3 ± 13.3 years) with subacute stroke with and without a knee-ankle-foot orthosis on the paretic lower limb. [Results] In the group of participants who were unable to stand without a knee-ankle-foot orthosis, the proportion of participants who were able to stand with a knee-ankle-foot orthosis was significantly increased in the following conditions: feet apart with eyes open and feet apart with eyes closed. In the group of participants who were able to stand without a knee-ankle-foot orthosis, the mean duration of time for which the participants with a knee-ankle-foot orthosis were able to stand was significantly longer than that for those without a knee-ankle-foot orthosis for all standing conditions. [Conclusion] A knee-ankle-foot orthosis may be a useful assistive device to support static standing balance for people with subacute stroke.

Key words: Stroke, Knee-ankle-foot orthosis, Static standing balance

(This article was submitted Sep. 13, 2018, and was accepted Nov. 2, 2018)

KAFO

- Locking knee
 - maximum stability
- Extension assist knee
 - assist knee extension during swing phase
 - not prevent knee flexion

- SPEX[®] knee
- GX-knee[®]
- Levitation[®] knee brace



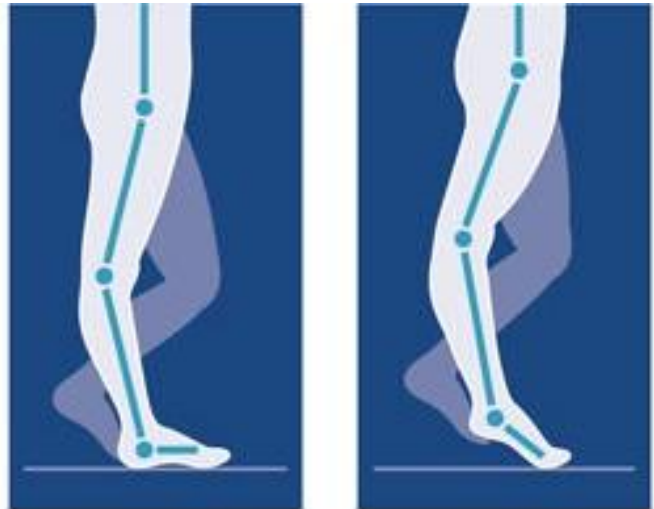
KAFO

- Stance control mechanism
 - **Ankle activated**
 - terminal swing full extension-lock the knee for stance
 - terminal stance ankle dorsiflexion-unlock the knee for swing
 - **Weight activated**
 - instrumented footplate
 - **Gait activated**
 - pendulum, accelerometer, inclinometer
 - SP2 system®, FreeWalk®
 - E-mag®, C-brace® : with microprocessor



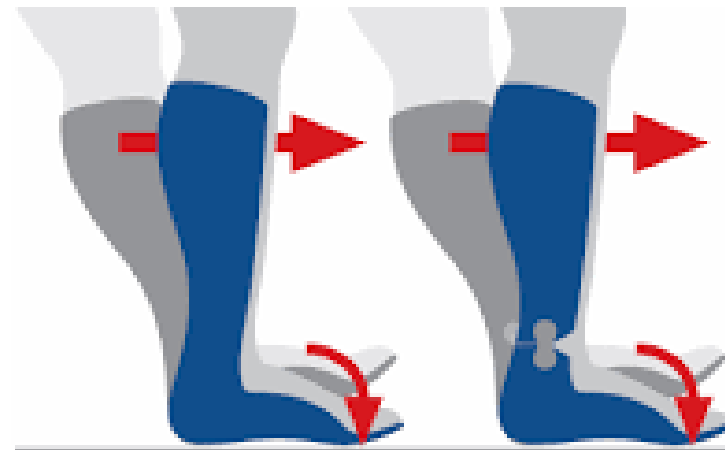
Hypertonic ankle plantarflexor + Knee hyperextension

- a.k.a. Spastic gait pattern
- Common gait pattern in chronic phase of stroke
- Increased plantarflexor tone
 - difficulties on both swing and stance phase
 - foot remain plantarflexed during stance
 - full contact only at persistent knee extension, hyperextension or midfoot collapse



Knee hyperextension

- **Direct control (X)**
 - Knee orthosis
 - KAFO
 - **Indirect control (O)**
 - Prevent plantarflexion with AFO – control knee hyperextension
 - Angle of dorsiflexion : 5~10°
 - Angle of dorsiflexion < Angle of inclination of the tibia
- Rigid plastic AFO
- Articulated AFO with plantarflexion stop



Rigid plastic AFO

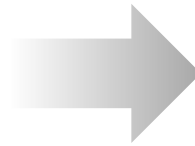
To overcome high plantarflexion moment

- **Adequate stiffness**
 - stiff plastic (such as polypropylene)
 - anterior trim lines
 - corrugation
 - reinforcements of carbon composite material
- **Ankle strap** : required to maintain foot position
- **Extending foot plate** to end of toes : in presence of tonic toe flexion reflex
- **If AFO must be made in plantarflexion (contracture, sustained ankle clonus)**
 - : angle of tibial inclination can be achieved by varying heel height or heel wedge
 - : heel lift on the contralateral shoe



Articulated AFO with plantarflexion stop

- **Allow dorsiflexion**
 - Benefit only with adequate dorsiflexion range (GCM length)
 - Dorsiflexion with short GCM : knee go early and excessive stance phase flexion
 - To stretch GCM
 - GCM cannot be lengthened with dorsiflexion allowing AFO
 - use **extension of knee in late stance** - orthosis should be designed to block dorsiflexion



- Review (2018)
- Articulated vs Non-articulated
- Total 27 article
 - 20 - chronic phase of stroke patient (> 6 months)
 - 5 - subacute phase (3~6 months)
 - 2 - acute phase (< 3 months)
- All types of AFOs : positive effects on ankle kinematic in loading response and swing phases, but not on knee in swing phase
- Articulated AFO : better effects on preventing ankle plantarflexion by providing dorsiflexion assisting force
- Assessed immediate or short-term effects only



-
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 - Advances in manufacturing technology
 - New materials and shapes
 - High technology such as microprocessor
 - **The more you know, the better you can choose**