

## Key Points

- **The total number of stroke victims is expected to increase by 20% in 2010 and more than double by 2050.**
- **Stroke is a leading cause of serious, long-term disability in the United States.**
- **AFOs should be considered in the management of stroke and they should be individually fitted by a certified orthotist.**
- **Clinical studies suggest that AFOs improve walking.**
- **Well conducted cross-over studies should be considered when reviewing the clinical effectiveness of AFOs.**

## Health Technology Description

An orthosis is defined by the International Standards Organization as “an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system.”<sup>[1]</sup> Ankle Foot Orthoses (AFOs) are orthoses that encompass the ankle joint and the whole or part of the foot<sup>[2]</sup>. AFOs are intended to control motion, correct deformity and/or compensate for weakness<sup>[3]</sup>. AFOs can be designed with sufficient mechanical lever arms to control the ankle complex directly and to influence the knee joint indirectly<sup>[3]</sup>. AFOs are presently the most widely used orthoses in the United States (US), accounting for 26% of clinical practice by certified orthotists, double that of any other type of orthosis<sup>[4]</sup>. There are many types of AFOs, which may vary in their biomechanical design (including desired mechanical force systems, any joint or articulation, alignment and range of motion), materials and components<sup>[5]</sup>. AFOs can be rationally prescribed based on their biomechanical function. The design of the AFO should be considered and best practice points have been recommended for different AFO designs used in the management of stroke<sup>[5]</sup>.

## Epidemiology

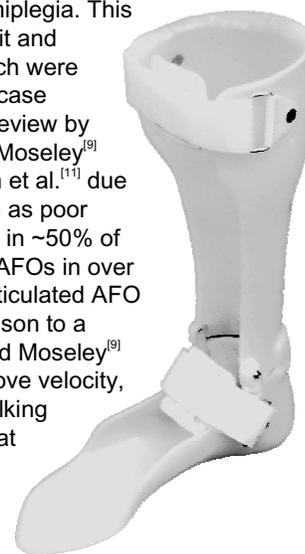
A stroke occurs when the blood supply to part of the brain is suddenly interrupted or when a blood vessel in the brain bursts. Brain cells die when they no longer receive oxygen and nutrients from the blood or there is sudden bleeding into or around the brain. According to data compiled by the American Heart Association<sup>[6]</sup> the prevalence of stroke in the US among persons 18 and older is between 2.4% and 5.1% depending on race, and increases with age beginning at 55 years. Although stroke afflicts persons of all ages, it is largely a disease of the elderly, and the number of Americans aged

65 and over is increasing<sup>[7]</sup>. This growth in the number of elderly people means that the total number of stroke is expected to increase by 20% in 2010 and more than double by 2050<sup>[8]</sup>. Each year about 500,000 people experience a first stroke and 200,000 have a recurrent attack. Stroke accounted for about 1 of every 16 deaths in the US in 2004 and is a leading cause of serious, long-term disability in the US. The length of time to recover from a stroke depends on its severity, but 15-30% of stroke survivors are permanently disabled, and 20% require institutional care at three months after onset. In 1999, more than 1.1 million American adults reported difficulty with functional activities and activities of daily living resulting from stroke. Among stroke survivors who were at least 65 years of age, 50% had some hemiparesis, 30% were unable to walk without some assistance and 26% were dependent in activities of daily living six months after stroke.

## Clinical Effectiveness

Two systematic reviews regarding the effect of AFOs on the management of persons with stroke were identified<sup>[9, 10]</sup>. Van Peppen et al.<sup>[10]</sup> reviewed the impact of physical therapy on functional outcomes after stroke, including the application of AFOs. This review was limited to randomized controlled or controlled clinical trials. Only one randomized control trial (RCT) that investigated the effect of an AFO on walking ability and gait speed was identified and reviewed<sup>[11]</sup>. Based on this RCT, Van Peppen et al.<sup>[10]</sup> concluded that there was no evidence for increased gait speed when an AFO was provided after stroke. However, many clinical studies indicate that walking speed<sup>[11-37]</sup> and step/stride length increase<sup>[16, 17, 19-21, 24, 25, 35, 36, 38-41]</sup> with an AFO.

Using broader criteria for study selection, Leung and Moseley<sup>[9]</sup> reviewed the impact of AFOs on gait and lower limb muscle activity in adults with hemiplegia. This review included 13 studies on gait and four on muscle activity, all of which were either cross-over (n=9) or single case studies (n=4). In contrast to the review by Van Peppen et al.<sup>[10]</sup>, Leung and Moseley<sup>[9]</sup> excluded the RCT by Beckerman et al.<sup>[11]</sup> due to methodological problems such as poor compliance with orthotic regimen in ~50% of patients, problems with fit of the AFOs in over 67% of patients and use of an articulated AFO as a placebo rather than comparison to a without AFO condition. Leung and Moseley<sup>[9]</sup> concluded that AFOs might improve velocity, stride length, gait pattern and walking for people with hemiplegia but that the effect of AFOs on paretic lower limb muscle activity was inconclusive.



Generally, clinical studies indicate that symmetry of gait<sup>[13, 16, 19-21, 24, 41, 42]</sup> improves with use of AFOs compared to walking without orthoses. Studies also suggest that non-articulated AFOs increase weight bearing through the affected limb during walking and standing<sup>[13, 18, 20, 32, 36, 40, 42-44]</sup>. AFOs with resistance to plantarflexion whether articulated or non-articulated improve the ankle angle at initial contact and mid swing<sup>[11, 20-22, 26, 30, 34, 35, 38, 45-47]</sup>. There is some indication that non-articulated or plantar flexion stop AFOs can control knee recurvatum and reduce the external knee extension moment during stance, especially if set in dorsiflexion or anterior tibial inclination<sup>[16, 22, 30, 34, 35, 40, 48]</sup>. There is also some suggestion that non-articulated AFOs may control supination of the foot<sup>[11, 20, 35, 38, 45]</sup>. Few studies report the effect of AFOs on the hip<sup>[14, 30, 40, 47]</sup> or standing balance<sup>[42, 44, 49, 50]</sup>. A few studies have demonstrated that non-articulated AFOs decrease the energy cost of gait compared to walking without orthoses<sup>[15, 27, 29, 31, 51, 52]</sup>. Generally subjects report that AFOs improve their walking and are comfortable<sup>[21, 24, 25, 28, 32, 34, 47, 53, 54]</sup>.

A comprehensive review of the orthotic management of stroke was undertaken by the International Society for Prosthetics and Orthotics (ISPO) in 2003 as part of a multidisciplinary consensus conference<sup>[5]</sup>. Specific to AFOs, Campbell<sup>[55]</sup> reviewed 21 articles, Bowers<sup>[56]</sup> reviewed 21 articles related specifically to non-articulated AFOs, and Hoy and Reinthal<sup>[57]</sup> reviewed 18 articles related specifically to articulated AFOs. A number of “best practice” points were identified with regard to the use of AFOs in the management of persons with stroke, with the evidentiary strength of the recommendations indicated based on a grading scale of strong (A), medium (B), and weak (C)<sup>[5, 58]</sup>. There was Grade C evidence for some aspects of the effects of AFOs on gait in persons with hemiplegia, but due to the limited number of unbiased clinical studies regarding the effectiveness of orthotic intervention for stroke<sup>[59]</sup> most of the recommendations were based upon the clinical experience of the guideline development group<sup>[5]</sup>.

A number of other organizations have made recommendations regarding orthotic management of stroke, in particular the use of AFOs<sup>[9, 11, 60-63]</sup>. The general consensus of these organizations is that AFOs should be considered for people with foot drop and that they should be individually fitted, particularly once long-term need is established.

### Safety

It has been recommended that qualified orthotists should be included as part of the stroke rehabilitation team, contributing to the assessment<sup>[61]</sup> and prescription of orthoses and specifically responsible for manufacture and delivery of

orthotic devices<sup>[6]</sup>. An orthotist is an allied health professional who is specifically trained and educated to provide or manage the provision of a custom-designed, fabricated, modified and fitted external orthosis to a patient<sup>[64]</sup>. Practitioners who successfully complete the education, experience and examination requirements prescribed by an accrediting body become certified orthotists. Certification indicates that the orthotist has met established standards and has the qualifications required to render orthotic services. A certified orthotist is the best person to ensure safe provision and use of an AFO.

### Economic Implications

According to data compiled by the American Heart Association<sup>[6]</sup> the estimated direct and indirect cost of stroke for 2007 was \$62.7 billion. The mean lifetime cost of ischemic stroke in the US was estimated at \$140,000 per patient in 1999 dollars and included inpatient care, rehabilitation, and follow-up care necessary for lasting deficits. Inpatient hospital costs for an acute stroke event account for 70% of first-year post-stroke costs. A large portion of the costs of stroke are due to length of stay in hospital, which is five to six times longer than that of average medical patients<sup>[6]</sup>. It is expected that the total costs of stroke care will rise in real terms by 20% in the next 20 years<sup>[6]</sup>. When placed in context, the cost of orthotic management is very low. A review of Medicare payment data for the years 2001 to 2006 shows that the base cost of an AFO (ranging from \$500-\$700)<sup>[65]</sup> represents only a small fraction of the estimated \$140,000 per patient lifetime cost that can be attributed to ischemic stroke.

### Ongoing Research

A Cochrane protocol for a systematic review of orthotic devices for abnormal limb posture after stroke has been proposed<sup>[66]</sup>. The aim of this review is to determine the effectiveness of the use of orthotic devices in upper and lower limbs following stroke and non progressive causes of spasticity, particularly in managing those problems arising from spasticity, improving function, and preventing complications. The review will include both randomized control and cross-over trials. The ISPO consensus conference also made recommendations for further research in the orthotic management of stroke patients, suggesting that there needs to be agreed upon standards of terminology and definitions; clearly defined biomechanical design, materials and components; well-controlled, multidisciplinary, multicenter research; and that the “good practice points” proposed should be used as a basis for research priorities<sup>[5]</sup>.

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