Development of a Dynamic Response Rehabilitation Gait Orthosis for Improving Stability and Gait in Patients with Neurological Disorders

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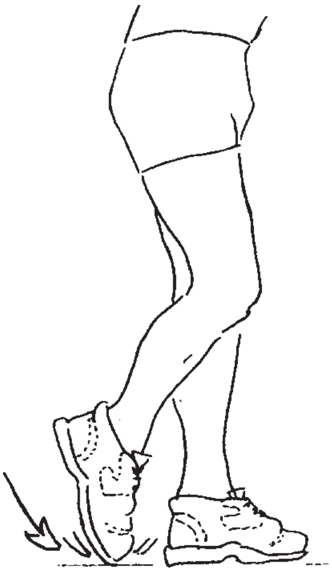
Background

There are available a variety of orthoses for stabilizing the ankle and foot. A frequent indication is peroneal nerve palsy or other neurologic deficit which causes 'drop foot', a condition often seen in various types of neurologic disorders but perhaps most frequently in the post-C.V.A. patient. The forefoot "drops" as the patient walks, making walking a challenge and normal gait impossible. It is logical that for all neurologic injuries or insults, speed of rehabilitation may be proportionately expedited to the speed of mobilizing the patient into as normal gait as possible. This is particularly true in the case of the C.V.A. patient, where it is so crucial to retrain, through repetitive 'normal' movements, the neurologic system to respond appropriately.



Up to this time, orthotic management of drop foot has been limited to conventional AFOs. Historically, these have included spring assisted metal uprights added or built into shoes, but plastics technology has produced a variety of custom or prefabricated plastic (most commonly polypropylene) AFOs. The primary goal and function of these devices has been to "brace" the foot to prevent the "dropping". The toe off of the forefoot is not dynamic and the stance and swing of the foot are rigid. When wearing the orthosis, you may see some decrease in "dragging" of the foot, but you will not see significant gait improvement and the patient will not be able to significantly increase his/her walking distance, which is so important for not only the neurological rehabilitation program but rehabilitation and strengthening of the cardiovascular and respiratory systems as well.

Patient compliance in wearing these orthoses has often been poor. Some reasons for this are the clumsiness and heaviness of the brace, discomfort at the heel, and difficulties in wearing the orthosis in conventional shoes. Often, the patient must purchase a larger size shoe to accomodate the orthosis.

Rather than limiting function to prevent "dropping" or "dragging", it is logical that a more productive and beneficial goal for an orthosis for these conditions would be to improve gait so the patient is better able to participate in his/her rehabilitation program. The aim of the development of a new orthosis for management of drop foot has therefore not only been to improve the acceptability and fitting of the brace but also to introduce a more dynamic orthosis, which will make the gait better and lengthen the walking capacity.

There are numerous studies which compare the walking patterns of individuals with lower extremity amputations wearing energy storing feet to wearing non-energy storing feet. Gait is significantly improved when wearing the energy storing feet. Those wearing the energy storing feet show increased stride length, are able to walk at a quicker pace, and are capable of walking longer distances.

The goal in the development of a new orthosis for drop foot is to focus attention to improving gait and increasing walking capacity. We know it is possible to do this for the lower extremity prosthetic wearer by incorporating the properties of an energy storing foot into the prosthesis. We examined how we could use the same properties in a lower extremity orthosis to more efficiently "mobilize" the neurologically impaired foot, as has already been used in an energy storing foot to more efficiently "mobilize" the lower extremity prosthesis.

Material Selection

It was determined that light weight, stability, and dynamic properties were paramount to the efficient function of the energy storing foot, therefore, it seemed logical to emulate these same factors for development of a more functional orthosis for drop foot. To obtain these properties, the choise of materials is of great importance. Finite element analysis led to the development of a material that consists of a thermosetting matrix based on Epoxy compounds and reinforced with glass fiber, carbon and Kevlar. A consistent property in all these materials is their light weight. In addition, glass fiber has good elasticity - an important property to allow the proximal section of the orthosis to "self-mold" to varying calf circumferences. Carbon fiber offers the rigidity required to stabilize the ankle/foot joint complex. Kevlar provides the required reinforcement of the sole to prevent plantar flexion (drop foot) plus the flexibility to improve the toe off of the forefoot during walking to improve "the push off of the foot" during gait and thus normalize the gait as much as possible.

Configuration of the Orthosis

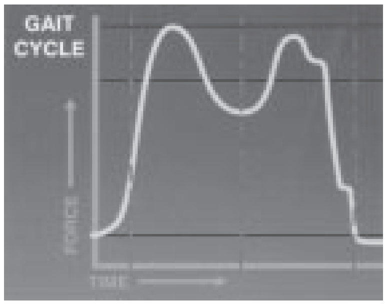
Biomechanical requirements for "normal" gait were examined. At heel strike, the calcaneus everts to trigger functional pronation. For this reason, it seemed crucial to keep the heel "free" to perform this function. Conventinal AFOs use a dorsal calf support. The dynamic response gait orthosis uses an anterior support which allows the heel to perform its biomechanical function and the orthosis avoids contact with sensitive posterior structures such as the posterior calf muscles, Achilles tendon, and the posterior upper corner of the calcaneus. In addition, the anterior support extends up the tibial tuberositas to stabilize the leg during the gait and improve the movement of the knee during walking.

Function

The energy at heel strike is transferred through the Kevlar/carbon fiber sole and helps at the phase of the toe-off. The elasticity of the sole improves the stance phases-especially the forefoot part. The metatarsals act as a fulcrum for the forefoot rocker, which allows body weight to fall beyond the base of support and lengthen the steps. As the upper body moves forward, the tibia applies pressure to the tibial plate, activating the energy in the sole to create the propulsion for the toe-off lift.

Results of Wearing the Dynamic Response Gait Orthosis

An objective study of the walking capacity in ToeOFF™ was performed using a VICON System at the Gait Laboratory, Orthopaedic Department, University Hospital, Lund, Sweden. The patient studied was a male, 35 years of age, with a paralysis of the left Medial Triceps Surae. A comparison of gait was performed to compare results when 1) wearing shoes only, 2) wearing a conventional plastic AFO, and 3) wearing the Toe OFF Dynamic Response Gait Orthosis. The gait-video record demonstrates when wearing ToeOFF: Limp is less evident. You can see decreased drop foot; hip and knee flexion are improved. Stride length is longer and single support time is improved.



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You can observe an improvement in joint mobility when wearing ToeOFF: In the hip joint, there is more hip extension compared to the conventional AFO. This is because the metatarsal heads are able to dorsiflex, thus allowing a better hip position. For the knee joint, at initial contact, the patient is better able to extend the knee when wearing ToeOFF. In the ankle joint, ToeOFF allows the smoothest dorsiflexion and the conventional AFO allows the least motion.

The VICON computer generated measurements compared stride gait analysis for velocity(meters/second), stride length (meters), cadence (steps/minute), and single support time (percent of the cycle):

	Norm	ToeOFF	AFO
Single Support Time (Percent of the Cycle)	40	42	35
Stride Length (Meters)	1,40	1,17	1,11
Velocity (Meters)	1,24	1,19	1,15
Cadence (Steps/Minute)	111	122	124

Summary

At the time of this study, ToeOFF had been prescribed to more than 500 patients with weakness in the foot caused by different types of neurological disorders. The feedback has been very good and, in all cases, ToeOFF has been preferred to conventional splints. Because of the thinness and shape of the ToeOFF the orthosis can easily be put into the conventional shoe and be functional. Padding or other orthotic supplements may be added to the brace for added comfort or to alter knee flexion or extension. Because of the low weight (125 grams), the ToeOFF is accepted well in patients with weak muscles.

The walking capacity is seen to be evidently improved because of the good fit and lightness of the brace and the improved dynamic effect during the gait. The lengthening of the walking capacity is seen in patients to be three to five times increased. Younger patients with i.e. peroneal paralysis can walk 5 km compared to maximal one km without or with conventional drop foot orthose. Because of the strength of the material (carbon and Kevlar especially), the ToeOFF brace is very resistant to the strains seen during weight loading during standing and walking positions.

Further studies to objectively validate increased activity level, lower energy costs during gait, and patient satisfaction and resulting compliance are proposed and approved for further investigation.

For commercial information regarding Toe OFF™, contact Camp Scandinavia, Karbingatan 38, SE254-67 Helsingborg, Sweden, Phone: +46 42 15 9120; Fax: +46 42 15 8316, Website: www.campscandinavia.se.

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