

Relative influence of orthotic support features within an open frame AFO versus a total contact AFO on function, endurance, and activity level in patients with spastic equinovarus secondary to chronic stroke

Final Report

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Abstract

Studies have recommended a variety of orthosis characteristics to compensate for the biomechanical deficits associated with neuromuscular conditions.¹⁻²² Most research investigating mechanical properties of AFOs has focused on sagittal plane characteristics.^{1-15,18,20,22} However, patients suffering from neuromuscular disorders often have biomechanical deficits that result in tri-planar involvement. Traditionally, total contact orthoses are recommended to provide the highest level of support for the postural deficits associated with these conditions. Alternatively, open frame orthotic designs are sometimes used. Open frame orthoses offer a variety of benefits including significantly decreased weight and accommodation for fluctuating edema. This report summarizes two case studies which document the delivery of orthotic care and clinical outcomes for two patients. The optimization of orthotic care is suggestive of the relative influence of the orthotic support of open frame versus total contact AFOs on function, endurance, and activity level in patients with spastic equinovarus secondary to chronic stroke. Specifically, the relative influence of the supramalleolar extension²³ within the open frame orthosis was isolated and evaluated. Outcomes were measured using activity monitors, the 10mWT, the 6MWT, stride length, and subjective questionnaires. The 10mWT and 6MWT have been previously used and validated in the stroke population.²⁴⁻²⁶

Specific Aims:

Throughout the field of orthotics, a variety of orthoses are used to compensate for gait deficiencies. While many orthotic designs are effective to some degree in managing the postural deficits associated with spastic equinovarus associated with stroke, more research is required to determine which features are most efficacious for these patients. The aim of this pilot study is to shed light on a very specific aspect of this topic.

Though there are significant functional benefits to the feature set of open frame orthotic designs for this patient population, total contact designs are often used due to the prevailing opinion that the support of these orthoses is necessary to control the postural deficits of this patient population. The objective of this pilot was to determine the relative influence of orthotic support within custom open frame AFOs versus custom total contact AFOs in chronic stroke patients who exhibit spastic equinovarus. Specifically, whether open frame AFOs are effective in controlling this posture when specific support elements of total contact designs are omitted in favor of decreased weight and increased accommodation. The open frame design in this study incorporates a supramalleolar extension, also referred to as a Sabolich trimline²³, to control hindfoot posture in the frontal plane and a multi-function ankle joint to optimize sagittal ankle support. All other features, including arch support and forefoot containment, will be omitted from the open frame AFO.

The efficacy of the open frame AFO was compared to a total contact AFO design. These AFOs were fabricated such that all other features of the orthoses were as similar as possible to isolate the effect of the supramalleolar extension versus the total contact structure employing additional elements of support. The isolation of variables is an important aspect of this research design. By using an open frame with only a supramalleolar extension, the effects of this feature were more effectively isolated. The goal of this study is an increased awareness of the relative influence of orthotic supportive elements used to manage spastic equinovarus. With the knowledge of which support elements are necessary to the success of orthotic fitting, orthoses will be more optimally designed.

This is a pilot report that summarizes two case studies. The goal of this pilot was not to derive a definitive answer to the questions posed. Rather, it was used to improve the study design with the intention of implementing it in a future, larger multi-facility efficacy study. By employing established outcome measures that require minimal training or equipment to administer, a larger group of patients can be tested to increase the power of the study.

Background and Significance:

795,000 people experience a stroke every year in the United States.²⁷ Many people suffering from common neuromuscular disorders, including stroke, have secondary gait impairments. AFOs are frequently prescribed to aid in compensating for gait deviations associated with these disorders. Studies have recommended a variety of AFO stiffnesses, in both plantarflexion and dorsiflexion, to compensate for the biomechanical deficits associated with some neuromuscular conditions.^{1-4,9,18,20,22} A previous pilot study demonstrated the effects of incrementally manipulating three key sagittal plane characteristics: the resistance to dorsiflexion, resistance to plantarflexion, and initial ankle alignment.²⁸ Data suggest that these three variables, when isolated from one another, may have predictable and systematic influences over sagittal gait kinematics. While some research has been conducted to expose the effects of AFO properties related to sagittal plane mechanics, anecdotal evidence strongly suggests that a

properly fitting orthosis with effective tri-planar control is important in the success of the orthosis treating these biomechanical deficits. This is especially true for patients suffering from neuromuscular conditions who have tri-planar involvement and tone, where the sagittal plane influence of the orthosis may be biomechanically coupled to the support of the foot and ankle in other planes and may also indirectly influence kinematics up the kinetic chain to the knee and trunk.

Open frame custom AFO designs, such as Townsend Design's Premier Series AFO or Becker Orthopedic's Shadow AFO, are used in a variety of applications. These open frame designs offer many benefits over total contact designs. Open frame AFOs are much lighter weight than total contact AFOs and are less bulky. Decreased bulk of the footplate allows for more intimately fitting shoes to be worn. The contact area is also minimized, allowing for volume fluctuations and breathability. These orthoses are typically easier to don due to their lower profiles, which may be an advantage for neuromuscular patients who could potentially also have upper extremity involvement. Despite the wide range of benefits for these open frame orthoses, their effectiveness at controlling the tri-planar postural deficits of spastic equinovarus has not been rigorously evaluated. Specifically, the features of the orthoses that may impact their efficacy have not been explicitly identified. This study focuses on the relative influence of one orthotic support element, the supramalleolar extension, with the intent of broadening the base of knowledge of this feature's effectiveness in controlling spastic equinovarus.

Methods:

Patients: Patients included in this study suffered a stroke at least 6 months prior to recruitment and were wearing an AFO daily at the time of recruitment. Patients were independent ambulators without an assistive device as well as with and without their AFO. Patients were excluded from the study if they had less than 10 degrees of range of motion at any lower extremity joint or if they exhibited severe hypertonia in their affected lower extremity (Modified Ashworth Scale 3 or above). Two patients were recruited for this pilot study.

Apparatus: Patients wore three different orthoses during the course of the study. The first orthosis tested was the patient's own orthosis that they had been wearing prior to enrollment in the study. This will be referred to as the polypropylene AFO, or PP AFO. This orthosis was not the focus of this study, but use and outcomes were measured against this orthosis as a basis for comparison. This aided in determining which measures were sensitive enough to detect differences among conditions. The overall design of this orthosis was not controlled, but the design was very similar for both patients. The PP AFOs were total contact, polypropylene, articulated AFOs with a posterior calf shell, free motion thermoformable joints, and a fixed plantarflexion stop. Patient 1's PP AFO had a padded lateral supramalleolar trim line, a sulcus length footplate, and the posterior stop was set for an ankle angle of 5 degrees of plantarflexion. Patient 2's PP AFO had a full length footplate and the ankle angle at the plantarflexion stop was set to 10 degrees of plantarflexion. (Unless otherwise noted, the ankle angle refers to the angle measured from the lateral border of the foot to the bisection of the lower leg.) The second orthosis will be referred to as the Total Contact Triple Action AFO, or TC TA AFO. This AFO was a custom hybrid double upright AFO. It was fabricated using wet lamination, carbon fiber and acrylic resin to provide a rigid structure, which isolated the control of sagittal stiffness and ankle alignment to the ankle joints. Triple Action ankle joints were used to facilitate optimization of sagittal plane mechanics

including plantarflexion resistance, dorsiflexion resistance, ankle range of motion, and ankle alignment. The TC TA AFOs had a total contact pre-tibial shell and lateral supramalleolar extension. The footplate incorporated all clinically relevant contours to manage the patients' foot posture. Patient 1 required the use of two Triple Action ankle joints to provide adequate active influence over sagittal plane kinematics, while Patient 2 required only one Triple Action ankle joint and a single axis companion joint medially. The third orthosis will be referred to as the Frame Triple Action AFO, or F TA AFO. This orthosis was fabricated exactly the same as the TC TA AFO, with the exception of a flat footplate attached using a caliper plate to the ankle joints and minimal contact trim lines. The only coronal support element present in the F TA AFO was the lateral supramalleolar extension and associated three-point force system.

Each patient was provided with New Balance model 813 shoes. These shoes were chosen based on several factors including high bending stiffness of the sole, outsole rocker profile, limited outsole compressibility, and a wide/deep toebox.

StepWatch activity monitors were employed to measure relative activity while wearing the AFOs during the testing period. This device uses a combination of position, timing, and acceleration to detect the number of steps as well as the rate at which steps are taken. It has been previously used to investigate activity level after stroke and has been proven to be reliable with this population.²⁹⁻³⁰

Two different survey instruments were used. The first was a modified version of the Prosthetic Evaluation Questionnaire.³¹ Questions from Group 1, 4, 6, and 7 of the PEQ were used, and the term "prosthesis" was replaced with "orthosis." It was also changed from a time frame of four weeks to two weeks.

The second survey was the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST)³² with the "Services" section omitted. The test was administered verbally after all three AFOs had been worn. While the test was being read all three of the AFOs were visible, and the patient completed the QUEST simultaneously for each AFO condition.

Procedures: Prior to participation, the study was described in detail to each potential patient, and he or she signed a consent agreement. Each patient was fully evaluated including strength and range of motion testing as well as observational gait analysis. All procedures were consistent with the routine delivery of orthotic care with inclusion of accepted outcome measures.

After evaluation the patients' affected lower extremities were cast, and diagnostic check orthoses were used to verify correct fit prior to lamination per customary orthotic practice. The two custom AFOs previously described were fit by an experienced and certified orthotist, and the optimal ankle joint settings were determined based on the manufacturer's standardized optimization procedure. For Patient 2, the same mold was used to fabricate both orthoses, with the exception that modifications were made to eliminate all supportive elements from the footplate on the F TA AFO prior to lamination. For Patient 1, the mold could not be salvaged after fabrication of the TC TA AFO, so the F TA AFO was made from a mold poured from the TC TA AFO. The Frame and Total Contact AFOs were checked to ensure nearly identical dimensions and ankle joint placement. Emphasis was placed on proper

modification and implementation of the lateral supramalleolar extension on both orthoses such that both orthoses derive similar support from those features.

For each orthotic condition, the patients wore StepWatches for at least 12 days. They wore one StepWatch on the shoe of their uninvolved limb and one on their AFO. Data from the affected side has been shown in many studies to be less reliable than the uninvolved side, so this data was only used to determine when the AFO was worn. Only steps collected from the uninvolved side were analyzed and only at times when the AFO was worn.

Patients completed outcome measures for each of the three orthosis conditions as well as a no orthosis condition, if applicable. These included the 10mWT, 6MWT, and stride length. Walking tests were administered over several visits to reduce fatigue. The OEQ was administered in written form for each condition directly after the patient was wearing each device. The QUEST was administered verbally with all three tested AFOs visible at the end of the study as a means of direct comparison for all conditions.

Results:

Note – This section is a summary of the results, but values and figures were removed. Comprehensive results will be presented at the 2017 AOPA O&P World Congress.

Patient 1

Patient 1 was a 78 year old male who is 5'7" and weighs 200lbs. He is 17 years post right CVA with left upper and lower extremity neuromuscular deficits. His ankle ROM is limited to 0 degrees with the knee extended and 10 degrees with the knee flexed. He has a 5 degree knee flexion contracture and a 30 degree hip flexion contracture. He has weakness of all joint motions in his left lower extremity, with his weakest muscle group being his plantarflexors at 3-/5 MMT. He also has spasticity of 2 on the MAS scale of his ankle and knee. Walking without an orthosis he exhibits plantarflexion and toe drag during swing phase. At terminal swing he does not reach full knee extension. He has alternating flat foot or forefoot initial contact. His knee is stiff throughout stance. During loading response he lacks knee flexion, and he has limited tibial progression through the remainder of stance.

There were statistical differences between tested conditions for the 10mWT and stride length measurements. The patient walked with the fastest velocity with the F TA AFO, followed by the TC TA AFO, and the slowest velocity with the PP AFO, which was no different than the no brace condition. The patient's stride length was longest with the F TA AFO condition, followed by the TC TA AFO, which was no different than the no brace condition, and shortest with the PP AFO condition. The 6MWT was only performed once per condition, so statistics were not performed on this test. The patient walked about 12% farther during the 6MWT with the PP AFO and TC TA AFO conditions compared to the no brace condition, and about 34% farther with the F TA AFO condition compared to the no brace condition.

Using the QUEST, this patient specified that his three most important considerations were 1) effectiveness, 2) comfort, and 3) safety. Of these top three items, this patient ranked the F TA AFO as the most effective, the PP AFO as the most comfortable, and all three were equally safe.

StepWatch data was collected for all three AFO conditions. The subject took more steps per day with the F TA AFO than with the TC TA AFO, but a similar number of steps with the TC TA AFO as compared to the PP AFO. Distance walked per day was calculated using the steps per day output and the stride length measured for each condition. The patient walked farther per day with the F TA AFO as compared to both the TC TA AFO and the PP AFO. Peak performance and percent steps at three activity levels were unchanged with different AFO conditions. The patient spent more time walking per day while wearing the F TA AFO then while wearing either the TC TA AFO or the PP AFO.

Patient 2

Patient 2 was a 51 year old female who is 5' 1" and weighs 200lbs. She is 20 years post right CVA with left upper and lower extremity neuromuscular deficits. Her ankle ROM is limited to 2 degrees of dorsiflexion with the knee extended and 5 degrees of dorsiflexion with the knee flexed. Her knee extension range of motion is 0 degrees with the hip flexed. She is unable to voluntarily move her ankle in any direction and has significant knee flexion weakness at 2/5 MMT. She also has an MAS score of 1+ for plantarflexion spasticity. Walking without her AFO she exhibits equinovarus and toe drag during swing, lateral forefoot initial contact, rapid knee flexion in loading response, excessive knee flexion throughout stance, delayed heel off, and a shortened right step length.

During the 10mWT this patient walked slower with the no brace condition than all the AFO conditions, but there was no measurable difference in walking velocity between any of the AFO conditions. The patient had the longest stride length with the F TA AFO condition, which was not significantly longer than the TC TA AFO condition. The stride lengths for the F TA AFO and TC TA AFO were longer than the PP AFO condition, which was also longer than the no brace condition. The 6MWT was only performed once per condition, so statistics were not performed on this test. The patient walked about 37% farther during the 6MWT with the PP AFO and TC TA AFO conditions compared to the no brace condition, and about 53% farther with the F TA AFO condition compared to the no brace condition.

Using the QUEST, this patient specified that her three most important considerations were 1) effectiveness, 2) safety, and 3) durability. Of these top three items, this patient ranked the TC TA AFO as the most effective, all three AFOs as equally safe, and the TC TA AFO as most durable.

StepWatch data was only collected for the PP AFO and TC TA AFO conditions. Number of steps per day, peak performance, and percent steps at three activity levels were unchanged with different AFO conditions. The distance walked calculation using the number of steps per day and stride length was farther for the TC TA AFO condition compared to the PP AFO condition. The patient spent more time walking per day while wearing the TC TA AFO then while wearing the PP AFO.

Discussion:

For each of the two patients there were differences measured for each of the different AFO conditions. Because the two patients presented very differently, it is more beneficial to look at each patient separately rather than generalizing their results.

For Patient 1 there was a clear preference toward the F TA AFO. Patient 1 had the fastest 10mWT velocity, farthest 6MWT distance, and longest stride length with the F TA AFO. The only StepWatch outputs that were statistically different among the tested conditions, steps per day and minutes of activity per day, were highest for the F TA AFO condition. The calculated distance walked per day was farthest for the F TA AFO condition. The QUEST reflected that Patient 1 perceived an increase in function with the F TA AFO. He ranked the F TA AFO as the most effective of the three AFOs, and efficacy was his highest ranked priority.

Patient 2 had slightly less agreeance in results. At the time of data collection, Patient 2 was unable to independently don the F TA AFO. This was due to her upper extremity deficits as well as the difference in donning procedure from the F TA AFO, which required the AFO be first placed in the shoe then donned simultaneously with the shoe in a seated position, compared to the method she had been using for the past 15 years, which was to don the AFO first followed by the shoe with her leg elevated. For this reason, StepWatch data was not collected for this condition, and the two-week acclimation period prior to the outcome measures was not completed. Patient 2 had the farthest 6MWT distance and the longest stride length with the F TA AFO. Her 6MWT distance was very similar between the PP AFO and TC TA AFO conditions, but her stride length was longer with the TC TA AFO compared to the PP AFO. Her 10mWT velocities were no different between the three AFO conditions. Minutes of activity per day was the only StepWatch output that was statistically different for Patient 2, and this was higher for the TC TA AFO condition compared to the PP AFO condition. However, the calculated distance walked per day was also higher for the TC TA AFO condition.

One question related to the use of the StepWatches was choosing appropriate output variables for comparison. For both patients, it was discovered that stride length changed depending on orthotic condition, and many of the StepWatch output variables do not take this into account. This could have important implications. If the patients can walk the same distance in fewer steps it may appear as though their activity level has either remained unchanged or decreased if only the number and frequency of steps are considered. For these two patients, minutes of activity per day and the distance calculated from stride length and steps per day seemed to best reflect the functional differences that were measured by the other outcomes and the survey.

One component of the study that was somewhat unclear prior to initiation was the collection method of subjective feedback from the patients. In addition to the functional measures, it was important to ascertain the patients' opinions of the of the AFOs, with the goal of determining whether the results of the functional measures aligned with how the patients viewed the orthoses. Initially the OEQ, which is a rather extensive questionnaire, was used to collect information regarding specific aspects of the orthoses. The OEQ was administered for each orthotic condition after the patients had comfortably worn the AFO for at least two weeks. There are certain questions in the OEQ, such as "How important is being able to walk up a steep hill?" which should yield consistent scores no matter the orthotic condition. However, the patients' scores for these questions was different at each appointment. Even when one patient was provided with the questionnaire that he completed at the previous appointment and instructed to write in answers for a second condition his scores for the control questions still varied. This suggests that the test-retest reliability of this instrument for this purpose was not sufficient. The

second survey instrument, the QUEST, while simpler, proved to be more valuable. This is a much shorter instrument that was administered only once at the very end of the study. It was completed verbally with each of the orthoses visible, and the patients answered each question as it related to each of the three AFOs. This allowed for a direct comparison of the devices. Secondly, it revealed which items were most important to the patients.

Footwear is an important part of the orthotic fitting process that can influence the outcome. It was decided that the patients would be provided with a pair of walking shoes to control stiffness and fit of the shoes. For this project, a desirable shoe was selected, the New Balance model 928. Unfortunately, the manufacturer recently redesigned this shoe model resulting in a shallower toe-box than the original model, which did not allow for accommodation of the AFO. After discussion with the shoe manufacturer, an alternative shoe model was selected, New Balance 813. This style provides all the desirable attributes of the original 928; wide/deep toe box, high stiffness outsole, and rounded heel and toe rockers.

While the StepWatches are a powerful tool, there were several complications with using these devices in this project due to the testing conditions. From a simplicity standpoint, to determine the patient's activity while wearing a specific AFO, a StepWatch would be attached directly to the AFO. This way the monitor would only detect steps being taken while wearing the AFO. However, it has been determined based on previous research that StepWatches are 98% accurate on the least-affected limb after stroke and only 92% accurate on the most-affected limb after stroke.²⁹ Therefore, to determine the activity with the AFO, one StepWatch was attached to the AFO, and an additional StepWatch attached to the patient's least-affected side. This way it was determined when the patient was wearing the orthosis based on the AFO StepWatch, but only the data during those time periods from the second (least-affected side) StepWatch were used for analysis. This increased the accuracy of the data.

One difficulty relating to the use of StepWatches for both patients was donning the StepWatch. For the StepWatches that were mounted to the AFOs this was not an issue. They were simply attached securely to the orthoses and the patients then did not have to worry about donning and doffing the StepWatches. Since these patients have unilateral upper limb involvement, donning and doffing the StepWatch on the least-affected ankle was not realistic. The patients were unable to don the StepWatches securely. One way around this is to simply have the patients leave the StepWatch on their ankle for the entirety of the data collection period. This was not possible as one of the patients swims regularly and the StepWatch should not be submerged. To manage this, the StepWatch for the least-affected side was mounted on the lateral side of the patients' shoes. This was determined to be a suitable alternative as long as this is taken into account during programming, and during the calibration the StepWatch light flashes with every step indicating that it is able to detect steps at a variety of speeds.

There are several limitations to this analysis. Care was taken to schedule patients on the same day of the week and time of day to reduce confounding variables. However, many factors including weather or the patient's fatigue level or mood may have fluctuated between appointments. This may have affected the results for the outcome measures performed in the office over several visits. Weather and life events

during the testing period when the StepWatches were worn may have affected these results as well. The patients were not blinded to the orthotic conditions, so factors such as the cosmesis of the AFOs may have affected the measured variables.

This was a case study report with the results of clinical treatment evaluated using standard measures and with a limited number of participants that was performed to evaluate the proposed protocol. Overall a great deal of progress was made in uncovering and overcoming obstacles with this design.

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