Single-Case Study: Traditional Thermoplastic AFO Versus Adjustable Dynamic Response™—A Crossover Single-Case Study

Taffy E. Bowman, CPO

ABSTRACT

Past studies have suggested that ankle-foot orthoses (AFOs) improve walking, however, it is unclear what biomechanical designs are most effective. This 10-week trial investigated the effects of a traditional thermoplastic style AFO compared with an Adjustable Dynamic Response™ (ADR™) AFO in a single-case subject. The subject was a 74-year-old man affected by postpolio syndrome with a prior history of AFO use. Patient usage and activity levels were measured with a StepWatch™ Activity Monitor, gait characteristics were measured with a GAITRite® System, and patient satisfaction was measured with a standardized AFO satisfaction questionnaire. The subject wore the traditional AFO for the first 5 weeks of the trial and the ADR™ AFO for the remaining 5 weeks of the trial. Weeks 1 and 5 were considered washout periods, and data were not collected for these weeks with the StepWatch Activity Monitor. Patient usage and activity levels were improved in the ADR™ AFO over the traditional AFO showing an average of 6,606 steps per day in the ADR™ AFO compared with 4,504 steps per day in the traditional AFO. The subject also spent more time engaged in moderate to high activity levels, versus low activity levels, in the ADR™ AFO compared with the traditional AFO. Gait characteristics, such as increased velocity and increased step length, were improved in both AFOs compared with no AFO at all with slightly higher improvements in the ADR™ AFO over the traditional AFO. The AFO satisfaction questionnaire suggested a higher level of patient satisfaction in the ADR™ AFO over the traditional AFO. (J Prosthet Orthot. 2010;22:84–90.)

KEY INDEXING TERMS: AFO, ankle-foot orthosis, Adjustable Dynamic Response™, ADR™, StepWatch Activity Monitor, SAM, GAITRite, AFO satisfaction questionnaire

Traditional ankle-foot orthosis (AFO) designs and related components have been suggested to improve walking. They are prescribed to control knee and ankle instabilities and to improve biomechanical function at the knee and ankle during the gait cycle. Orthotic management has historically focused on locking or limiting motion to provide stability and safety for patients with lower limb gait dysfunction. Adjustable dynamic response™ (ADR™) ankle components and orthoses, incorporating elastomer technology, may allow for greater ankle motion that improves biomechanical function and stability of the knee and ankle during gait through a process of fine tuning first, second, and third rocker.

The purpose of this single-case study was to determine the effects of two different AFO designs on activity levels in the patient’s environment, temporal-spatial gait characteristics, and patient satisfaction of an individual with postpolio syndrome affected by weakness and instability of his right lower limb. The patient, a 74-year-old man who has worn an AFO for several years, agreed to participate in this study to help understand the effect of different AFO designs on his gait. By allowing improved biomechanics during gait with an ADR™ AFO, it is hypothesized that the ADR™ AFO will increase walking activity levels in the patient’s living environment, improve temporal spatial gait characteristics such as velocity, and offer improved patient satisfaction over his traditional AFO.

METHODS

A 10-week trial was conducted to evaluate the patient usage and activity levels, gait characteristics, including velocity, step length, and single support, and patient satisfaction in a traditional AFO versus an ADR™ AFO. Patient usage and activity levels were monitored with a StepWatch™ Activity Monitor (SAM), and gait characteristics were evaluated with a GAITRite® system. Patient satisfaction was measured with an AFO satisfaction questionnaire developed in conjunction with Good Shepherd Rehabilitation Hospital in Allentown, PA.

The participant presents with significant atrophy of the right lower limb and ambulates with hyperextension at the
knee on the right side without any orthosis. He presents with fair dorsiflexion and plantarflexion, good knee extension and flexion, and good hip extension and flexion. His left side is unaffected, and although he is retired, he lives a fairly active lifestyle. The patient has been compliant at different times with both AFOs being looked at in this study before the 10-week trial beginning. Specifically, he has worn his traditional AFO for approximately 10 years and his ADR™ AFO for 1 year. The patient signed consent forms before participating in the study.

During the study period, the patient wore the traditional AFO for weeks 1–5 and the ADR™ AFO for weeks 6–10. The AFO that was not being worn was kept by the orthotist during the off weeks. The initial week in both orthoses was considered a washout period, and the parameters were only measured with the SAM for the remaining 4 weeks (28 days) in the orthosis. The SAM was attached to both of the subject's AFOs with a simple hook and loop attachment method during the weeks being worn for the trial (Figure 1). The information from the SAM was downloaded at the end of week 5 and the end of week 10 by the orthotist. The GAITRite was measured at the end of week 5, and therefore, the temporal-spatial gait parameters were obtained in both AFOs at this juncture of the study. Several walking trials were recorded with no AFO, with the traditional AFO, and with the ADR™ AFO. The patient was instructed to walk at a comfortable (self-selected) walking speed for all the trials. The data being presented was prepared by a research assistant at Good Shepherd Rehabilitation Hospital in Allentown, PA. The satisfaction survey was completed independently by the subject at the end of weeks 5 and 10.

AFO DESIGN 1—TRADITIONAL DESIGN

The traditional AFO worn in weeks 1–5 was made of 3/16 in polypropylene and was a hinged design with Model 740 Tamarack Flexure Joints™ medial and lateral (Figure 2a, b). An adjustable dorsiflexion stop strap was mounted posterior to help promote knee stability. The strap was set to stop more than 20° of dorsiflexion. The footplate was trimmed at the sulcus length, and the medial longitudinal arch and first metatarsal area were lined with ¼ in firm Plastazote®. A window was cut out in the posterior calf section, and one 2 in rigid proximal calf strap made of Dacron backed hook and loop was used for suspension.

AFO DESIGN 2—ADR™ AFO

AFO design 2 that was worn in weeks 6–10 was made of a carbon composite laminate hinged with an Ultralite® ADR™ ankle joint medial and a Model 740 Tamarack Flexure Joint lateral (Figure 3a, b). The footplate was originally trimmed at the sulcus length and then trimmed back proximal to the metatarsal heads to allow increased comfort and more flexibility for the patient. The footplate was lined with ¼ in firm Plastazote. A large window was cut out at the posterior calf area, and one 2 in hook and loop strap with a felt pad was used for suspension.

Figure 1. Picture showing attachment of StepWatch™ to ankle-foot orthosis with hook and loop.

ADR™ ANKLE COMPONENT BIOMECHANICS AND SETTINGS

The ADR™ ankle joint uses elastomer rods in the anterior and posterior channels to assist the restraining eccentric work of the tibialis anterior during loading response and the gastroc-soleus complex during terminal stance² (Figure 4). The posterior channel augments the tibialis anterior and the anterior channel augments the gastroc-soleus. The elastomer rods are compressed within the channels by adjusting the set screws at the top of the component, which creates the ADR™. The elastomers work to dynamically restrain ground reaction forces during stance instead of creating a rigid stop or hold. The component allows 40° of dorsiflexion and 40° of plantarflexion and also has two smaller stop channels for creating rigid stops as needed. No rigid stops were used in this case study. The posterior elastomer channel was compressed until two rows of screw threads were exposed, and the anterior elastomer channel was compressed until three rows of screw threads were exposed. These settings were obtained with the AFO on during walking trials to optimize observational gait parameters.

RESULTS

PATIENT USAGE AND ACTIVITY LEVELS

Patient usage and activity levels were measured with the StepWatch Activity Monitor in both the traditional AFO and the ADR™ AFO. Twenty-eight days of data were collected in each orthosis and then analyzed.

In the traditional AFO, the patient averaged 4,504 steps per day, and in the ADR™ AFO, the patient averaged 6,606 steps per day. The SAM only records steps for one leg, so the numbers have been doubled from the data collected to represent both right and left steps. This represents a 47% increase in activity in the ADR™ AFO over the traditional AFO (Figure 5).

The patient's activity levels were also analyzed according to low, medium, and high level activities as defined by
Figure 2. A, Posterior/medial view of traditional ankle-foot orthosis (AFO) with StepWatch™ Activity Monitor attached. B, Lateral view of traditional AFO with StepWatch Activity Monitor attached.

Figure 3. A, Medial view of Adjustable Dynamic Response™ (ADR™) ankle-foot orthosis (AFO) with Ultraflex ADR™ ankle joint and StepWatch™ Activity Monitor attached. B, Lateral view of ADR™ AFO with Tamarack Flexure Joint and StepWatch Activity Monitor attached.

StepWatch. Low activity is defined as fewer than 15 steps per minute, medium activity level is defined as ranging from 15–40 steps per minute, and high activity is defined as more than 40 steps per minute (Figure 6). The patient demonstrated a 6.7% increase in high activity level in the ADR™ AFO over the traditional AFO, an 8.1% decrease in low activity in the ADR™ over the traditional AFO, and a moderate activity level increase of 1.4% in the ADR™ AFO over the traditional AFO.

GAIT CHARACTERISTICS

Gait characteristics were measured using the GAITRite system with no AFO, with the traditional AFO, and with the ADR™ AFO. Three main characteristics including velocity, step length, and single support will be reported on.

Velocity was shown to be highest in the ADR™ AFO with a centimeter/second rate of 81.6 compared with 77.8 in the traditional AFO and 74.6 with no AFO (Figure 7).
This shows a 5% increase in velocity in the ADR™ AFO over the traditional AFO and a 9% increase in velocity in the ADR™ AFO compared to no AFO. In a recent study by Wening et al., gait parameters in 40 acute and chronic hemiplegic subjects were looked at with and without an AFO. In this study, an α of 5% in gait parameters was set as a level of statistical significance.3

Step length with the GAITRite system is measured along the line of progression, from the heel center of the current footprint to the heel center of the previous footprint on the opposite foot (Figure 8). The right and left step lengths were recorded as being the longest with the ADR™ AFO, but not of the level deemed statistically significant in the study by Wening et al.,3 but may be clinically significant.

Single support time is the time elapsed between the last contact of the current footfall and the first contact of the next footfall of the same foot. It is also equal to the swing time of the opposite foot as defined by the GAITRite System. The patient demonstrated minimal change in symmetry of single support time between no AFO, the traditional thermoplastic AFO, and the ADR™ AFO (Figure 9). Single support time symmetry was slightly greater with no AFO versus the traditional thermoplastic AFO or the ADR™ AFO.

PATIENT SATISFACTION

Patient satisfaction was measured through a 21-question AFO satisfaction questionnaire developed in conjunction with Good Shepherd Rehabilitation of Allentown, PA. The questionnaire was originally developed for AFO research with stroke patients and is shown in Figure 10.

The patient reported the traditional AFO felt lighter to him than the ADR™ AFO but the appearance of the ADR™ AFO was more acceptable to him than the traditional AFO. Through the questionnaire, he reported that the ADR™ AFO was more comfortable, that he felt he walked faster, and that he was more confident in the ADR™ AFO than the traditional style AFO. Also, he felt he could go longer distances and felt less fatigued with the ADR™ AFO than the traditional. There was no difference in satisfaction or answers for any of the remaining items such as the impression of the fit of the brace, how it fit in his shoe, or how difficult or easy it was to put on or take off the brace.

![Average Steps per Day](image_url)

Figure 5. Average steps per day in traditional ankle-foot orthosis (AFO) versus Adjustable Dynamic Response™ (ADR™) AFO.
Figure 6. A. Percentage of time spent in each activity level for thermoplastic ankle-foot orthosis (AFO). B, Percentage of time spent in each activity level for Adjustable Dynamic Response™ (ADR™) AFO.
**DISCUSSION**

The findings in this single-case study support the hypothesis that the improved biomechanical design of the ADR™ AFO over the traditional AFO allows for improved patient usage and improved patient satisfaction. Improved gait characteristics such as velocity may be significant to improved gait function, but larger studies with more patients and greater power are needed to validate the statistical and clinical significance of a greater than 5% improvement rate. However, improved velocity may be a factor in achieving the higher activity levels. Larger crossover studies could be designed for patients wearing traditional then ADR™ AFOs to more fully understand the gait characteristic changes between an ADR™ AFO versus a traditional AFO.

To the author's knowledge, this is the first time it has been described in the literature how the StepWatch Activity Monitor has been incorporated into an AFO for usage and activity monitoring. Bjorson et al.⁴ reported on the usage of the SAM for monitoring activity level of youth with cerebral palsy and youth who are developing typically, but were mounted to the lateral aspect of the ankle using a knitted cuff, not an AFO. In a previous study by McDonald et al., the SAM was used to document 3 days of ambulatory activity in 97 youths who were developing typically between the ages of 6 and 20 years.⁵ These studies were dependent on patients putting the monitors on and were subject to compliance issues. For future studies looking at AFO usage and activity levels, the author recommends the SAM be attached directly to the AFO as performed in this single-case study design for ease of use and compliance.

Also, this is the first reported use of a standardized AFO satisfaction questionnaire being documented in the literature to the author's knowledge. The author suggests an AFO satisfaction questionnaire of this nature be adopted and used as a standard part of future AFO studies.

Limitations of this single-case study include the limitations of the GAITRite to measure kinetics and the kinematics of gait in the ADR™ AFO versus the traditional AFO. Future research comparing AFO designs and biomechanical improvements of one to another should be looked at with a more sophisticated motion analysis system that allows the kinematics of gait to be understood within the comparison AFOs and without an AFO. This would potentially help further the evidence base for AFO use and help practitioners to select AFO designs and components that are most biomechanically effective.

**CONCLUSION**

Overall, this single-case study provides insight for future clinical research designs comparing AFOs and how to quantify outcomes such as patient usage and activity levels in an AFO, temporal-spatial gait parameters with an AFO, and patient satisfaction with an AFO. In addition, this case study suggests possible patient benefits for using an improved biomechanical ankle joint with ADR™ versus more traditional AFO designs. For this patient, activity level, velocity, and patient satisfaction all improved when wearing the ADR™ AFO versus the traditional AFO, suggesting a positive corre-
Figure 10. Continued.

The author thanks Dr. Philip Bryant, Miriam Ludwig, and Daniela Daran of Good Shepherd Rehabilitation, Allentown, PA, for their assistance and help with the AFO satisfaction survey and the use of the GAITRite system for this study. The author also thanks the help and support of Kim Coleman and the team at Orthocare Innovations for their direction and input on the use of the SAM.

REFERENCES


