WALKING ENERGY EXPENDITURE IN SOLDIERS WITH LOWER EXTREMITY INJURIES WITH AND WITHOUT A DYNAMIC ANKLE FOOT ORTHOSIS

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ABSTRACT

Purpose: Injury rates to the lower extremity for soldiers have led to increased ankle-foot orthotic (AFO) prescription. The purpose of this study was to compare the effects of no brace, the TAFO, and the DAFO on steady-state physiologic responses during walking in soldiers with lower extremity injuries. **Methods**: Six male service members with drop foot were tested at baseline in no brace, a TAFO, and a DAFO; three and six month data collection sessions involved repeated testing in the no brace and the DAFO. **Results**: There were no statistically significant differences between the three brace conditions at baseline testing and there were no statistically significant differences in no brace and the DAFO over time. **Conclusions**: The subjects' demonstrated measured physiological responses within reported norms for healthy subjects at baseline or by month three. Analysis of physiologic responses showed no reduction in energy expenditure in the DAFO when compared to the TAFO and no brace.

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PART I

Introduction

Injuries to the upper and lower extremities represented 50% - 54% of all combat casualties in soldiers that served in Operation Iraqi Freedom and Operation Enduring Freedom (3, 21, 24, 25). Half of these injuries occurred in the lower extremity (24, 25). Although some limbs were surgically reconstructed instead of amputated, permanent nerve and musculoskeletal damage often occurred in the limb salvaged individuals. These subsequent motor and proprioceptive deficits commonly led to gait complications, such as drop foot, a condition characterized by a toe drag during the swing phase of gait and a foot slap at heel strike (30). An abnormal gait from loss of plantarflexion power as well as insufficient forward propulsion result from this type of neurological impairment (22).

Abnormal gait patterns associated with lower extremity nerve injuries (2, 4, 9, 11, 12, 31) are often corrected via prescription of an ankle-foot orthotic (AFO). The use of the traditional AFO (TAFO) issued to military service members for management of lower extremity neuropathy improved walking gait characteristics (12, 13) but may lack the stability and dynamic support necessary for return to athletic activity or combat (23). A carbon fiber dynamic AFO (DAFO) has shown promise for improving gait function beyond that observed in the TAFO (2, 14) through the use of a continuous carbon fiber composite design which provides higher energy storage and return (31). Improvements in gait biomechanics attributed to the design of the DAFO may facilitate a more efficient gait, decreasing the energetic cost of walking (2, 7, 11). These gait improvements may

allow for increased activity levels leading to improved oxygen uptake and delivery and an increase in aerobic fitness even to the point of allowing reinstatement of military service members to active duty (26, 27).

Previous research has demonstrated the benefits of AFO use on energy expenditure, an important aspect of improved efficiency during gait (7, 8, 11, 17, 20). However these changes in energy expenditure have not been evaluated over time and have primarily been evaluated in populations with lifestyles potentially less active than military service members such as individuals with cerebral palsy, polio, or stroke (7, 8, 11, 17, 20). Additionally, inconsistencies in methodology and measurement parameters make comparisons between these studies difficult (8). Therefore, the purpose of this study was to compare the effects of no brace, the TAFO, and the DAFO on steady-state physiologic responses during walking in soldiers with lower extremity injuries. We hypothesized 1) a decrease in walking energy expenditure when wearing the DAFO compared to no brace during initial testing, 2) a decrease in walking energy expenditure when wearing the DAFO compared the TAFO during initial testing, and 3) a decrease in walking energy expenditure in no brace and the DAFO over a six month period.

Methods

Research Design

A repeated measures design was conducted for this prospective study consisting of three conditions: the no brace condition, the TAFO condition, and the DAFO condition. The independent variables of this study were brace condition (no brace, TAFO, DAFO) and time. The dependent variables were rate of oxygen consumption (VO_2) (ml/kg/min), oxygen cost (OC)(ml/kg/m), physiological cost index (PCI)(beats/m),

energy expenditure (EE) (Kcal/min), and rating of perceived exertion (RPE). Subjects were tested at baseline, 3-month, and 6-month intervals. Baseline measurements were collected within two weeks of the subject's receipt of the DAFO and included assessment in the no brace condition, the TAFO, and the DAFO. Three and six month data collection sessions involved repeating testing in the no brace and the DAFO conditions.

Participants

Six male volunteers were recruited from Tripler Army Medical Center by the same Physical Medicine and Rehabilitation physician, who diagnosed each subject with drop foot and prescribed the TAFO. Subjects were included if they were between 18 and 55 years of age and had worn the TAFO for at least one month and less than two years. Additional inclusion criteria included absence of transient lower extremity nerve palsy and the ability to continuously walk for ten minutes. The study was approved by the University of Hawaii Human Studies Program and the Tripler Army Medical Center Human Use Committee/Internal Review Board Committee.

Instruments

Physiologic responses during walking were assessed on a Quinton Medtrack T65 Treadmill (Cardiac Science, Corp., Bothell, WA) using an open circuit indirect calorimetry system. A metabolic cart containing an Oxygen Analyzer (Oxygen Analyzer S-3A/I, AEI Technologies, Naperville, Illinois, USA) and Carbon Dioxide Analyzer (Carbon Dioxide Analyzer CD-3A, AEI Technologies, Naperville, Illinois, USA) was used to collect metabolic data. A head support and mouthpiece with a two-way non-rebreather valve (Hans Rudolph, Kansas City, Missouri, USA) was fitted for the subject and connected to the metabolic cart. Calibration was performed prior to each trial

according to the manufacturer's instructions. A Polar Pacer T31 heart rate monitor (Polar Electro Oy, Finland) was used to collect heart rate during each trial. A wall-mounted stadiometer (Mondel 67032, Seca Telescopic Stadiometer, Contry Technology, Inc., Gays Mills, WI, USA) was used to collect height. A Befour PS6600-ST scale (Befour, Inc., Saukville, WI, USA) and Detecto Certifier scale (Model 442, Detecto Scale Company, Webb City, MO, USA) were used to collect weight. Each DAFO was made by Dynamic Bracing Solutions (San Diego, CA) and custom fitted by the same certified orthotist.

Data Collection Procedures

Prior to data collection, all subjects completed an informed consent process and signed an approved consent form (Appendix A). Anthropometric data including height, weight, and resting heart rate were collected for all subjects. Height and weight were collected with each subject three times: in athletic shoes only for the no brace condition and in athletic shoes with either the DAFO or the TAFO for the respective braced conditions. Ambient temperature, barometric pressure, and relative humidity were recorded from a Davis VantageVUE (Davis Instruments, Hayward, CA, USA). All metabolic testing was performed at a maximum self-selected walking velocity (a minimum of 1.0mph) with the treadmill at a 1% grade (18). The self-selected walking velocity was determined by having the subject walk shod on the treadmill at a maximum comfortable walking pace that could be maintained for eight minutes. Subjects' preferred walking velocity was used for all follow-up metabolic testing in each condition. Subjects were provided a ten-minute break between test conditions.

Subjects were instructed to wear their own athletic shoes for each condition. During data collection in the TAFO and the DAFO conditions, subjects wore athletic shoes that differed in size to accommodate the foot component of each AFO. Subjects were asked to report RPE at the end of each eight-minute walk for chest and breathing, legs and joints, and overall feeling of exertion according to Borg's Perceived Exertion and Pain Scales (6). Metabolic calculations were made from measurements in steady-state conditions as an average of the last four minutes of each trial (1).

Statistical Analysis

Statistical procedures were conducted using SPSS (version 20) with an alpha level of $p<0.05$. Freidman's Test was used to determine the difference in the physiologic responses for rating of perceived exertion (RPE), oxygen consumption (VO_2), physiologic cost index (PCI), oxygen cost, (OC) and energy expenditure (EE) between the DAFO and the TAFO, the DAFO and no brace, and the TAFO and no brace conditions. Physiological cost index was calculated as walking heart rate minus resting heart rate, divided by walking velocity and expressed in beats/meter (1). Freidman's test was also conducted to determine the effects of no brace and the DAFO on walking physiologic responses over time.

Results

Six subjects qualified for this research study, however three were excluded from baseline (month zero) analysis due to an error in data collection, inability to walk without the use of an AFO and discontinued use of the TAFO due to development of deep vein thrombophlebitis. The subjects included in analysis for this portion of the protocol are described in Table 1.

Table 1
Subject Descriptive Data and Gait Velocity – No Brace, TAFO, and DAFO at Baseline

Sub #	Sex	Age (y)	Avg. Weight-NB (kg)	Avg. Weight-TAFO (kg)	Avg. Weight-DAFO (kg)	Avg. Height-NB (cm)	Avg. Height-TAFO (cm)	Avg. Height-DAFO (cm)	Velocity (m/min)
104	M	21	77.10	80.30	83.20	171.45	171.45	174.24	93.30
105	M	33	78.90	76.20	79.70	190.00	190.00	191.71	76.70
106	M	25	101.88	99.70	103.57	181.71	180.09	182.89	71.70

NB=No Brace; TAFO=Traditional ankle-foot orthotic; DAFO=Dynamic ankle-foot orthotic

The same six subjects qualified for the longitudinal portion of the study, however three subjects were excluded from the analysis comparing no brace and the DAFO over time due to inability to perform the no brace condition at month zero, an error in data collection at month zero and month six, and premature withdrawal from the study. The subjects included in analysis for this portion of the study are described in Table 2.

Table 2
Subject Descriptive Data and Gait Velocity – No Brace and DAFO Over Time

Subject	Gender	Age (y)	Avg. Weight-NB (kg)	Avg. Weight-DAFO (kg)	Avg. Height-NB (cm)	Avg. Height-DAFO (cm)	Velocity (m/min)
102	M	44	74.13	75.87	178.73	180.67	90.00
105	M	33	78.90	79.70	190.00	191.71	76.70
106	M	25	101.88	103.57	181.71	182.89	71.70

NB=No Brace; DAFO=Dynamic ankle-foot orthotic

No Brace, TAFO, and DAFO

Physiological responses were analyzed using the Freidman's test to determine difference between values for VO_2, PCI, OC, EE, and RPE for no brace, TAFO, and

DAFO conditions (Table 3). The means and standard deviations for VO_2, PCI, OC, EE, and RPE for no brace, the TAFO, and the DAFO at baseline were reported in Table 4. There were no statistically significant differences between each condition for any variable. All RPE ratings were lowest in the DAFO and highest in the TAFO conditions (Figure 1).

Table 3
Freidman's Test –RPE, VO_2, PCI, OC, & EE in No Brace, TAFO, & DAFO at Baseline

	χ^2	Exact Sig.
VO_2 (ml/kg/min)	4.67	0.20
PCI (beats/m)	2.00	0.53
OC (ml/kg/m)	0.67	0.99
EE (Kcal/min)	4.67	0.19
RPE - Chest	0.80	0.89
RPE - Legs & Joints	2.00	0.67
RPE - Overall	0.80	0.89

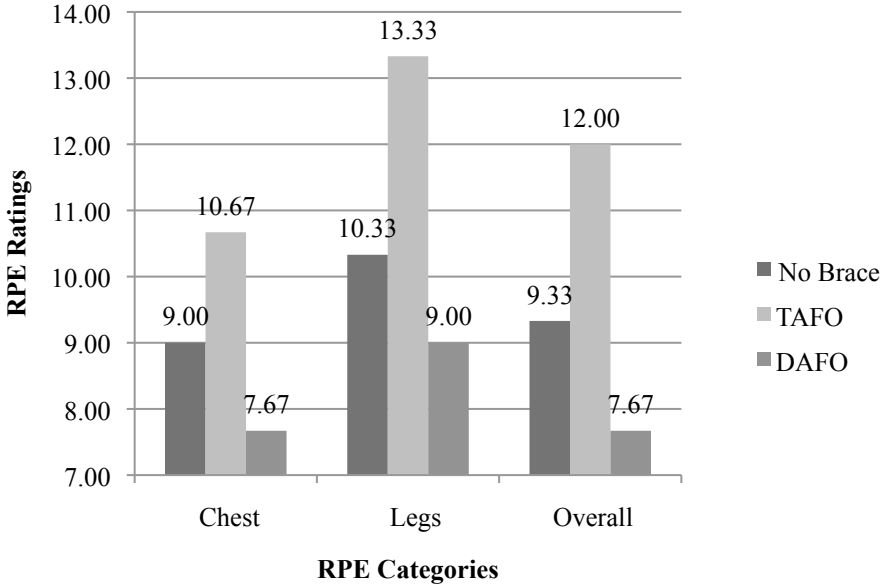
N=3, DF=2, RPE: rating of perceived exertion; VO_2: Oxygen consumption; PCI: physiological cost index; OC: oxygen cost; EE: energy expenditure; TAFO: traditional ankle-foot orthotic; DAFO: dynamic ankle-foot orthotic

Table 4
Descriptive statistics –RPE, VO_2, PCI, OC, & EE – No Brace, TAFO, & DAFO at Baseline

Brace condition	VO_2 (ml/kg/min)	PCI (beats/m)	OC (ml/kg/m)	EE (Kcal/min)	RPE Chest	RPE Legs	RPE Overall
No Brace	16.58 (5.00)	.45 (.27)	.20 (.03)	6.73 (1.72)	9.00 (2.00)	10.33 (3.05)	9.33 (2.50)
TAFO	15.03 (3.90)	.52 (.13)	.20 (.03)	6.21 (1.44)	10.67 (4.70)	13.33 (5.90)	12.00 (7.00)
DAFO	16.08 (3.80)	.65 (.16)	.20 (.02)	6.88 (1.35)	7.67 (1.50)	9.00 (2.00)	7.67 (1.50)

Mean (SD), n=3
RPE: rating of perceived exertion; VO_2: rate of oxygen consumption; PCI: physiological cost index; OC: oxygen cost; EE: energy expenditure; TAFO: traditional ankle-foot orthotic; DAFO: dynamic ankle-foot orthotic

Figure 1
Ratings of Perceived Exertion - No Brace, DAFO, & TAFO at Baseline



No Brace and DAFO Over Time

Three subjects completed the 6-month protocol. Results from the Freidman's test conducted to compare differences for VO_2, PCI, OC, EE, and RPE for the no brace and the DAFO conditions at months zero, three, and six were reported in table 5. Means and standard deviations for VO_2, PCI, OC, EE, and RPE for the no brace and the DAFO conditions at month zero, three, and six were reported in table 6. Ratings of perceived exertion for no brace at months zero, three, and six were reported in Figure 2 and RPE for the DAFO at months zero, three, and six were reported in Figure 3. There was no statistically significant difference in the variables over time for any of the conditions.

Table 5
Freidman's Test –RPE, VO_2, PCI, OC, &EE – No Brace & DAFO at Baseline, Three Months, & Six Months

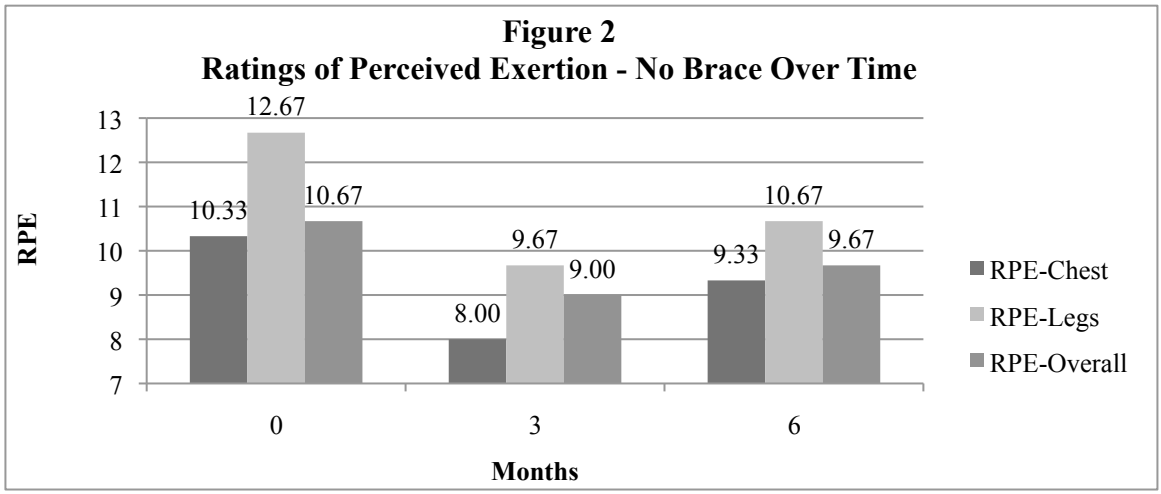
	No Brace		DAFO	
	χ^2	**Exact Sig**	χ^2	**Exact Sig**
VO_2 (ml/kg/min)	4.67	.19	4.67	.19
PCI (beats/m)	.67	.94	4.91	.11
OC (ml/kg/m)	4.67	.19	4.67	.19
EE (Kcal/min)	4.67	.19	4.67	.19
RPE-Chest	2.60	.44	1.64	.50
RPE-Legs	2.67	.36	2.67	.36
RPE-Overall	1.40	.56	4.67	.19

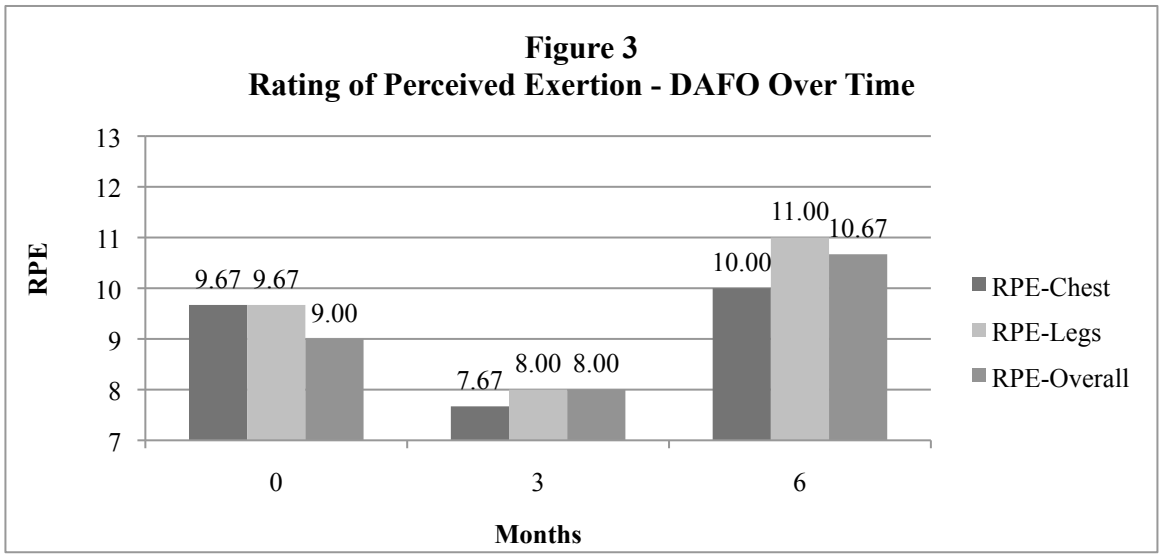
n=3, df=2; RPE: rating of perceived exertion; VO_2: oxygen consumption; PCI: physiological cost index; OC: oxygen cost; EE: energy expenditure; TAFO: traditional ankle-foot orthotic; DAFO: dynamic ankle-foot orthotic

Table 6
Descriptive statistics –RPE, VO_2, PCI, OC, & EE – No Brace & DAFO at Baseline, Three Months, & Six Months

Brace Condition	Month	VO2 (ml/kg/min)	PCI (beats/m)	OC (ml/kg/m)	EE (Kcal/min)	RPE Chest	RPE Legs	RPE Overall
No Brace	0	14.31 (1.06)	.40 (.20)	.18 (.01)	5.69 (.63)	10.33 (3.06)	12.67 (1.53)	10.67 (3.22)
	3	13.33 (1.85)	.42 (.23)	.17 (.00)	5.41 (.61)	8.00 (1.73)	9.67 (2.31)	9.00 (2.00)
	6	14.13 (2.23)	.41 (.23)	.18 (.01)	5.65 (.59)	9.33 (2.52)	10.67 (3.79)	9.67 (3.06)
DAFO	0	15.44 (2.77)	.67 (.17)	.19 (.01)	6.28 (.35)	9.67 (4.04)	9.67 (2.31)	9.00 (3.00)
	3	14.20 (2.00)	.41 (.09)	.18 (.01)	5.77 (.18)	7.67 (2.08)	8.00 (2.00)	8.00 (2.65)
	6	14.24 (2.98)	.43 (.22)	.18(.02)	5.72 (.41)	10.00 (3.00)	11.00 (2.65)	10.67 (3.06)

Mean (SD), n=3; RPE: rating of perceived exertion; VO_2: rate of oxygen consumption; PCI: physiological cost index; OC: oxygen cost; EE: energy expenditure; TAFO: traditional ankle-foot orthotic; DAFO: dynamic ankle-foot orthotic





Discussion

This study was designed to compare the effects of no brace, the TAFO, and the DAFO conditions on steady state physiological responses over time in active military service members with lower extremity neuropathy. Measurements of VO_2, heart rate, and walking velocity provided a method to determine the metabolic cost of gait disability and functional performance. It was expected that VO_2, PCI, OC, EE, and RPE would decrease with the use the DAFO compared to no brace and decrease in the DAFO compared to the TAFO. It was also expected that with continuous use of the DAFO, the

same physiological responses would decrease in the DAFO and in no brace conditions over time.

The energy expenditure of pathological gait was compared to the corresponding values in healthy subjects to determine improvements in energy efficiency of gait. Oxygen cost, a calculation of VO_2 per body mass per distance traveled (ml/kg/m), determined the energy cost for a specific distance (20, 29). Physiological cost index, a calculation of walking heart rate minus resting heart rate, divided by walking velocity (beats/m) provided an estimate of cardiovascular difficulty of a task for an individual (1). Physiological cost index was shown to be a reliable marker of energy expenditure (1, 16), and has been proposed as an alternative to VO_2 measurements due to the positive linear relationship between heart rate and oxygen uptake at submaximal workloads (20). For the same reason PCI, could also be considered an accurate measure of exertion and compared to RPE.

Baseline measurements suggested the DAFO was detrimental to energy efficiency of gait when compared to no brace or the TAFO. Rate of oxygen consumption, PCI, and EE were highest in the DAFO. Rate of oxygen consumption and EE were lowest in the TAFO, and PCI was lowest in the no brace condition. There was no change in OC between the three conditions. However, all RPE were lowest in the DAFO and highest in the TAFO. Increased physiological responses combined with a reported decrease in ratings of perceived exhaustion while in the DAFO could be attributed to the added weight (1-7 kg) of the footwear and brace worn during the DAFO trials. On average, recorded weight increased by 2.86kg in the DAFO compared to the no brace condition. However, recorded weight decreased by .5kg in the TAFO

compared to the no brace condition. While the TAFO allowed for improvement in energy expenditure during gait, the thermoplastic design could have contributed to perceptions of increased exhaustion. The energy return provided by the DAFO, however, may have allowed for ambulation to feel easier and more comfortable, which could have been perceived as less exhaustive.

Energy expenditure increased, improving by 1% in no brace (5.41 - 5.69 Kcal/min) and 9% in the DAFO (5.72 - 6.28 Kcal/min) condition over the six-month data collection period. A comparison of EE to reported normal values in the literature showed that the range of EE in no brace (5.41 - 5.69 Kcal/min) and EE in the DAFO (5.72 - 6.28 Kcal/min) for the subjects in the current study were within the range reported previously for healthy controls (5.69-6.89 Kcal/min)(5), which also suggested higher cardiovascular fitness of the subjects in the current study compared to subjects typically examined in AFO research. However, a comparison of EE to reported normal values in the literature showed that the subjects in this study had higher EE than for healthy velocity matched subjects (2.69-4.75 Kcal/min) (10). Walking at the same velocity with increased energy expenditure may signify the extent to which gait disability in our subjects affected energy efficiency.

Physiological cost index exhibited the greatest improvement over time though this increase was not statistically significant (p=.11). Initially, PCI in the DAFO (.67 beats/m) was higher than reported normal values (.55-.30 beats/m) (1, 16, 28). By month three and month six, PCI in the DAFO (.41; .43 beats/m, respectively) were within reported norms of healthy individuals (1, 16, 28). There was a 40% improvement of PCI from month zero to month three and a 36% improvement in PCI from month zero to

month six in the DAFO. This suggested that walking became less exhaustive over time when using the DAFO. The cardiovascular fitness level of the subjects in this study could explain the relatively low PCI and subsequent improvement. A comparison of percent improvement of PCI and other physiological responses in this population over time might be more beneficial and relevant than comparing the raw values of previous literature. It has been shown that long term use of bracing can increase the efficiency of ambulation while wearing the brace (29). Therefore, examination of these changes over a longer period of time in the present study may have allowed our subjects the necessary time to establish a more normal gait in the DAFO.

In contrast to previous results (17, 20), PCI in the DAFO for the subjects of this study did not decrease below PCI in no brace condition at the six month. Previous AFO research has reported PCI from 1.53-1.07 beats/m in no brace and 1.16-.72 beats/m in the AFO (17, 20). Physiological cost index in no brace at month zero, three, and six (.40; .42; and .41 beats/m, respectively) was within the reported norms for healthy individuals. These findings may be interpreted to mean that the subjects in the present study did not need external bracing form the DAFO in order to attain an efficient gait as evidenced by the low PCI values in no brace condition. However, due to the limitations of the analyses employed, it was not possible to quantify the improvements of a single subject who was unable to walk without a brace at month zero but could perform this task at month three and month six of data collection.

Previous research (8, 11, 17, 20) has produced similar results to those in the present study; use of the DAFO decreased energy expenditure for subjects in both a no brace condition and in the DAFO condition. Improvements were seen in the no brace

condition from month zero to month three for VO_2 (14.31 to 13.33 ml/kg/min), OC (.18 to .17 ml/kg/m), and EE (5.69 to 5.41 Kcal/min). These improvements reflected a 7%, 6%, 5% decrease, respectively. However, there were no statistically significant changes in the walking energy expenditure over time in the no brace condition or in the DAFO condition. Oxygen Cost improved by 2% in no brace and 8% in the DAFO after six months of DAFO use but was not statistically significant. Interestingly, OC in no brace (.17 - .18 ml/kg/m) and the DAFO (.18 - .19 ml/kg/m) conditions of the subjects in the current study were within the range for OC of healthy subjects (.15 - .23 ml/kg/m) (28, 29) and was around half of those reported OC values in previous studies for no brace conditions (.58 - .63 ml/kg/m) and AFO conditions (.41 - .51 ml/kg/m)(11, 20). The improvement in OC reported in previous studies (12-35%) was significantly greater than the improvement seen in this study (11, 20). The low OC values for the subjects of this study could also be due to a less pronounced gait disability than seen in polio, stroke, and cerebral palsy subjects studied in previous AFO research.

Rate of oxygen consumption over time for the subjects in this study were also within values for healthy subjects found in the literature (28, 29). The VO_2 in healthy subjects has been reported between 12.10 – 16.10 ml/kg/min walking a velocities between 69-80 m/min (28, 29). In the present study the VO_2 was 13.33 - 14.31 ml/kg/min and 14.20 - 15.44 ml/kg/min in the DAFO conditions, respectively which were well within the reported healthy norms. Danielsson and Sunnerhagan (2004) and Maeda, Kato, and Azuma et al. (2009) reported that the average VO_2 in no brace (8.60-12.00 ml/kg/min) and the AFO (8.80-11.20 ml/kg/min) conditions were lower than no brace VO_2 (13.33 - 14.31 ml/kg/min) and DAFO VO_2 (14.13 - 15.44 ml/kg/min)

conditions seen in the current study (11, 20). Danielsson and Sunnerhagan (2004) and Maeda, Kato, and Azuma et al. (2009) also reported lower VO_2 with the use of an AFO compared to no brace condition, however the subjects in each study were acclimated to the use of the AFO (11, 20). These results, again demonstrate the need for a longer period of acclimation to the DAFO.

Gait velocity (71.10-90.00 m/min) for the subjects in this study could be a factor related to increased VO_2. Previous AFO studies reported velocities in no brace (15.50-23.00 m/min) and AFO (20.40-29.00 m/min) conditions that were more than 50% slower than the velocities of the subjects in the current study (11, 20). The gait velocities of the subjects in the current study were within the range for average walking velocities of healthy adults (60-100 m/min) (29).

Ratings of perceived exertion, though statistically insignificant, were still clinically relevant for AFO research in this population. Lower values of perceived exertion were reported in the DAFO compared to no brace condition at month zero and month three. By month six RPE values were slightly higher in the DAFO compared to no brace condition. Powers and Howley (2009) reported that gait velocity below or above an individuals comfortable walking pace could be perceived as more exhaustive, thus producing a higher reported RPE (27). Subjects in the present study anecdotally reported dissatisfaction with the slow rate of velocity in the DAFO by month three, which may have accounted for the increased RPE in the DAFO at month six of data collection.

A substantial limitation of this study was the small sample size, which may have contributed to some measures having inadequate power. The subjects were obtained

from a small and geographically limited subject pool in the Pacific Islands and Japan. The location of subjects as well as the single month visit format created an inability to effectively monitor DAFO use over the six months. Additionally, the difference in injury severity for each subject led to variable use of the DAFO, a potential confounding factor in study results. One subject could not walk without the use of a brace at month zero and thus had to be eliminated from the study for analysis. However, after consistent use of the DAFO, when measured at month three and six, this same subject was able to perform the no brace portion of the protocol. Another subject discontinued use of the TAFO due to development of deep vein thrombophlebitis, but use of the DAFO did not exacerbate this condition in the same manner. The inability for one subject to walk in no brace and the inability for another subject to walk in the TAFO explained discrepancies in the data analysis of the three different brace conditions and for the analysis of the two brace conditions over time.

In conclusion, the subjects in this study had measured physiological responses within reported normal values for healthy subjects at study onset or by month three. An analysis of physiologic responses showed no reduction in energy expenditure in the DAFO condition when compared to the TAFO and the no brace condition. Unfortunately, the study protocol and subsequent analyses failed to statistically capture the potential contribution that consistent use of the DAFO over time could have on gait disability in a no brace condition. Additional research employing a varying velocity and longer study duration may better show the benefits of the DAFO.

PART II

Review of Literature

The use of an ankle-foot orthotic (AFO) has been more frequently prescribed to correct the abnormal gait patterns associated with cerebral palsy, polio, stroke, and lower extremity neuropathy (2, 8, 11-13, 17, 20, 31). Injuries to the lower extremities have led to peripheral nerve damage resulting in abnormal gait patterns such as drop foot causing insufficient forward propulsion (2, 9, 11, 12, 31). Within the military lower extremity nerve injuries were often resulted from explosive devices (25).

Upper and lower extremity injuries represented 50 - 54% of all combat casualties of soldiers that served in Operation Iraqi Freedom and Operation Enduring Freedom (3, 24, 25). Half of these injuries occurred in the lower extremity (24, 25). Although some limbs were surgically reconstructed instead of amputated, permanent nerve and musculoskeletal damage often occurred in the limb salvaged individuals. The types of AFO available to help these soldiers have been compared to one another in the literature (8, 17, 20, 31). However, the effect of an AFO on energy expenditure in the literature (2, 7, 8, 11-13, 17, 20) was not researched over time and primarily evaluated in populations with cerebral palsy, polio, or stroke whose lifestyles were potentially less active than that of military service members.

Lower Extremity Injury Prevalence in Combat

Combat casualties in the military have been recorded since World War II (3). A more comprehensive documentation of injury tracking, including type, location, and epidemiology of injuries sustained in battle has been instituted beginning with the recent conflicts in Iraq and Afghanistan (3). This database tracked the injured soldier from

point of injury, through various levels of care, and reported length of time return to duty or medical discharge (21, 24-26).

Belmont et al. (2010) conducted one of the first prospective studies of combat casualties on soldiers serving in Operation Iraqi Freedom and Operation Enduring Freedom (3). The authors defined a combat casualty as any injury sustained during combat that removed the soldiers from duty longer than 72 hours. During Operation Iraqi Freedom and Operation Enduring Freedom the researchers used the Joint Theater Trauma Registry to track injury incidence and epidemiology in soldiers from all branches of the military. The 1,566 soldiers used for the study incurred a total of 6,609 combat injuries. Fifty-four percent of these injuries were extremity injuries that were further classified as soft tissue injuries and fractures, 53% and 26% respectively. Both the soft tissue and fracture injuries were evenly distributed between the upper and lower extremity, suggesting that roughly 27% of the injuries sustained by these soldiers were to the lower extremity. (3)

Owens et al. (2007, 2008) also compiled combat injury data on the current conflicts in Iraq and Afghanistan (24, 25). The 2007 study focused on the amount and type of extremity injuries in combat by using the same Joint Theater Trauma Registry as used by Belmont et al. (24). The 2008 study compiled the epidemiology of all combat wounds in the same conflicts using the same combat casualty database (25). Owens et al. found that the incidences of combat casualties were distributed through out the body in similar distribution to previous wars. The distribution of combat wounds for the recent conflicts was 30% in the head and neck, 6% in the thorax, 9% in the abdomen, and 54% in the extremities. The upper extremity injuries accounted for 28% of all extremity

injuries while 26% were to the lower extremities. The most common mechanism for injury to any body region was by explosive devices (79%). (24, 25)

Masini et al. (2010) discussed ways to prevent and treat infected foot and ankle wounds sustained in the combat environment. The study reported that 54% of combat casualties from Operation Iraqi Freedom and Operation Enduring Freedom were to the extremities, with equal distribution of injuries to the upper and lower extremity (21). Injuries occurring in the upper and lower extremities required the greatest use of medical resources, caused the greatest long term disability, and accounted for the greatest number of days lost. Eighty-eight percent of injuries in the lower extremity occurred distal to the knee. Techniques for managing combat wounds and wound infection critiqued in the study included microbial culture, antibiotics, irrigation, and timing of operative procedures, coverage and closure of wounds, fixation, and antibiotic beds. Masini et al. concluded that management of combat wounds and fractures were made more difficult by the combat environment, the different levels of medical facilities, and varying evacuation procedures and times. (21)

Owens et al. (2011) investigated the types of athletic activities that lower extremity trauma patients were able to pursue after limb salvage (26). Ten active duty soldiers were followed through an aggressive rehabilitation program. The program consisted of two phases: an 'in-frame' phase in which the soldiers started rehab with external fixation of fractures still in place and a 'brace' phase. The 'brace' phase began after removal of the external fixation while the soldiers continued the rehabilitation program in a custom made carbon fiber AFO. Eight out of the ten patients retuned to running, ten returned to weight lifting, and seven returned to cycling. Three out of the

ten returned to active duty assignments, two with Special Forces and one with the Army Rangers. Owens *et al.* concluded that with aggressive rehab, an energy storing AFO, and running gait retraining, an active recreational life style could be restored for patients who have undergone lower extremity limb salvage. (26)

In conclusion, injuries to the extremities were prevalent in the military during the conflicts in Iraq and Afghanistan due to the lack of protective gear for the arms and legs. Lower extremity injuries were the most debilitating to active duty service members. Many faced the decision to amputate or salvage limbs. (21). Neuropathy was a common sequela often associated with limb salvage. The importance of injury tracking has been evident in determining total time lost from active duty, the number of soldiers who did not return, and what was needed to return more soldiers to active duty.

Lower Extremity Neuropathy

To understand the abnormal gait patterns associated with central and peripheral neuropathy affecting the lower extremity, an understanding of normal gait is needed. The gait cycle is split into a stance phase and a swing phase (15, 30). The stance phase is then split into four time periods: heel strike, mid-stance, terminal stance, and pre-swing. Swing phase of gait is divided into three time periods: initial swing, mid-swing, and terminal swing.

Stance phase begins with heel strike, when the ankle is in a neutral position. The tibialis anterior is activated to keep the toes up and control ankle plantarflexion as the body moves to mid-stance. The knee is in extension at the beginning of heel strike and then starts to felx to allow the stance leg to accept the full weight of the body during mid-stance. The hip extends throughout the stance phase to help the body move forward. In

mid-stance the ankle begins to move into dorsiflexion as the tibia advances over the foot by contraction of the triceps surae. The ankle reaches maximum dorsiflexion in terminal stance and the triceps surae muscles now contract to raise the heel for push-off. Push-off is needed to advance the body forward and prepare the limb for the swing phase of gait. Maximum hip and knee extension are seen in terminal stance. Pre-swing starts when the heel is lifted and the ankle achieves peak plantarflexion due to continued contraction of the triceps surae. Then, the tibialis anterior begins to contract to bring the ankle back into neutral and hold the weight of the foot up during swing. The knee and hip also start to flex to prepare the limb for swing. The leg acts as a jointed 'double pendulum' during the swing phase of gait due to this hip flexion that leaves lower leg 'behind' resulting in knee flexion. (15, 30)

The actions of hip flexion, knee flexion and ankle dorsiflexion are important for ground clearance of the toes during swing. Continued hip flexion and the return of knee extension occur in mid-swing in preparation of the limb for heel strike. The tibialis anterior is still contracting in mid-swing to keep the ankle dorsiflexed and the toes up. Terminal swing is marked by rapid knee extension from the return swing of the lower leg in the 'double pendulum'. Once toe clearance has occurred the tibialis anterior continues to contract in anticipation for the greater contraction forces needed to lower the foot after heel strike. The prerequisites for normal gait in order of priority are (1) stability of the entire lower limb in stance phase, (2) clearance of the ground by the foot in swing phase, (3) proper pre-positioning of the foot in terminal swing, (4) adequate step length, and (5) maximal energy conservation (15). Due to the damage caused to the central and peripheral nervous systems in cerebral palsy, stroke, polio, and lower extremity injury

two or more of the prerequisites for normal gait are absent. (15, 30) Various compensatory movements, such as steppage gait, vaulting, circumduction of the hip, and hip hiking, are attempted to correct for a gait deviation resulting from an absent prerequisite. (22)

McHugh et al. (1999) discussed the details of the deviated gait patterns associated with lower extremity neuropathy in particular drop foot. The muscles responsible for dorsiflexion contributed significantly to ankle control during the stance phase of gait. When dorsiflexion was insufficient, the foot rapidly plantarflexed in early stance phase. This movement caused an audible slap on the ground at heel strike. During the swing phase of gait the weight of the foot and toes were not properly supported and the toes were at risk of dragging. Plantarflexion, equally important to ankle motion as dorsiflexion, helped to stabilize the knee and ankle. Plantarflexion weakness led to instability at the ankle joint and decreased forward propulsion at push-off. McHugh et al. suggested that the use of an AFO could help support the foot and provide the ankle joint with more stability and energy return for better forward advancement of the body. (22)

Blaya et al. (2004) described drop foot as caused by damage to the peroneal nerve resulting in paralysis of the muscles the nerve innervates: the tibialis anterior muscle and the peroneal muscle group (4). The gait complications from drop foot included a toe drag during the swing phase and a foot slap after heel strike. Joint stiffness, plantarflexion power, degrees of dorsiflexion in swing, and the number of foot slaps on the ground were compared in three conditions on two male subjects with drop foot. Both subjects were 62 years of age, one walked at a gait speed of 1.22 m/s and the other

walked at 1.07 m/s. The three conditions consisted of a zero-impedance or no brace condition, constant-impedance or traditional brace condition, and a variable-impedance or active brace condition. The active brace was custom made and designed to have force, power, and joint stiffness sensors attached to it. The stiffness and impedance of the active orthotic was adjusted in real time as the treadmill speed changed. The authors found that variable impedance decreased the number of foot slaps, improved plantarflexion power and increased the number of degrees of dorsiflexion during swing when compared to zero impedance and constant impedance conditions at any speed. It was concluded that the ability to control and vary impedance during walking for drop foot patients might improve gait biomechanics when compared to zero (no brace) or constant (ridged brace) impedance. However, great advancements in technology are needed to be able to mass-produce a brace with such capabilities that is also functional. (4)

In conclusion, drop foot is a common outcome in limb salvage patients and those suffering form lower extremity neuropathy. An AFO has been prescribed to help return prerequisites of normal gait for individuals with drop foot. The more normal gait achieved by the use of an AFO have led to fulfilling the fifth prerequisite of gait, maximal energy conservation. Energy expenditure has been used to determine the efficacy of an AFO in walking.

Energy Expenditure

Measurement of physiological energy cost has been proven to be a reliable method of quantitatively assessing the penalties imposed by gait disability. It was helpful to compare individuals with abnormal gait and who wear an orthotic to healthy

subjects. Booyens and Keatinge (1957) examined energy expenditure in twenty healthy men and women (5). An evaluation of the range of variation and differences in gender for energy expenditure (Kcal/kg/hr) was conducted. Subjects walked 550 yards in two data collection sessions on an outdoor track while expired air was collected to calculate energy expenditure. During one data collection session, the subjects were asked to walk at a self-selected comfortable walking pace. During the other session, subjects were asked to walk a self-selected fast comfortable walking pace. Each data collection was timed and the subject's number of strides was counted. The range of velocities for the female subjects was 5.44 - 6.48 km/hr and the range of velocities for the male subjects was 5.52-6.52 km/hr. The velocities were later corrected to 5.47 km/hr for the comfortable walking velocity and 6.44 m/hr for the fast walking velocity for all subjects. The authors found that at both velocities, women (4.49 Kcal/kg/hr, 5.12 Kcal/kg/hr) expended significantly less energy than men (4.93 Kcal/kg/hr, 5.86 Kcal/kg/hr) at both the comfortable walking velocity and the fast walking velocity, respectively ($p<0.05$). The authors attributed the lower energy expenditure in women to the shorter stride length of the female subjects and therefore less vertical movement of the pelvis during walking. However, there was no correlation between stride length and energy expenditure for individual variation, leading the authors to conclude that muscular training and efficiency, weight of cloths and shoes, and slight differences in posture and rhythm of movement affect energy expenditure to a greater degree than stride length. Booyens and Keatinge also point out previous studies that found no significant difference in energy expenditure between men and women when walking at slower and faster velocities. (5)

Cotes and Meade (1960) attempted to derive relationships between biomechanical and physiological variables involved in walking that could potentially provide a broader basis for predicting energy expenditure (10). With ten army recruits, Cotes and Meade had each subject walk flat on a treadmill, at varying gradients up and down at several different speeds. The majority of subjects walked at 1, 2, 3, 3.5, and 4 mph on the flat and a down gradient of 8%. Two subjects walked at these speeds on up gradients of 4, 8, and 12%. The subjects walked continuously for about one and a half hours with the speed changing while they were walking. Expired air was only collected after 6 minutes of walking at the new speed and/or gradient. The authors used foot and stride length, total vertical lift of the trunk, and oxygen consumption to calculate work of lift per minute, gradient work per minute, and metabolic energy expenditure. Cotes and Meade found a positive relationship between foot and stride length and height, stride length and amount of vertical trunk lift, vertical trunk lift and walking velocity, walking velocity and oxygen consumption, and oxygen consumption and lift work. It was also discovered that the most efficient walking velocity was not the slowest speed but one that produced the lowest amount of energy expenditure when walking on level ground. Energy expenditure continued to decrease to 2% down gradient then plateaued there after. At the time of testing the authors calculated variables to come up with prediction equations. Through calculation and prediction equations, the authors concluded that the sequence of gait appeared to be governed by the principle of minimal energy expenditure no matter what the speed or gradient.

Thomas et al.'s (2009) study comparing common measures of energy efficiency in healthy subjects took the calculation and comparison of these measures a step further

(28). The authors' aim was to evaluate gross cost, net non-dimensional cost (NN cost), and energy efficiency index (EEI) in day-to-day variability within individuals, for the impact of age and body parameters, and clinical relevance. Gross cost was defined as walking oxygen consumption plus resting oxygen consumption in J/kg·m. Net non-dimensional cost was defined as subtracting the resting energy from the walking energy, leaving only the energy increment needed for walking. This value was then normalized for body weight and height. Energy efficiency index was defined as walking heart rate minus resting heart rate divided by velocity (beats/m). Forty-two healthy subjects participated in three separate data collection session over one month. Each session consisted of a 10 minute resting period and a 10-minute walking period in which oxygen consumption and heart rate were collected. The subjects were asked to walk a comfortable self-selected walking pace. The authors found that the day-to-day variability was statistically insignificant for all variables. Age and body parameters accounted for 42% of the variance seen in gross cost, 25% of the variance seen in NN cost, and 7% of the variance seen in EEI. The findings in this study led the authors to conclude that exposure to equipment does not change day-to-day variability. The increased variance in gross cost due to age and body parameters suggested that gross cost would not be a valid measure of energy efficiency when comparing values across a large age range. Net non-dimensional cost and EEI could allow comparison among subjects with a greater difference in ages. Walking velocity impacted NN cost and EEI the greatest, which was expected by the authors. (28)

Borg (1982) developed and validated a scale used to determine a participant's rating of perceived exertion (RPE) and pain during different activities (6). Applying

ratio properties to a category scale, Borg developed a rating scale in which numbers were anchored with verbal expressions of intensity level. The author was able to demonstrate a correlation between the ratings on the scale selected by the participant to a more objective measurement of blood lactate. Blood lactate closely related to energy expenditure as blood lactate concentrations and time to lactate threshold were used to predict oxygen consumption, and therefore energy expenditure. (6)

Bregman et al. (2011) estimated the energy cost of walking from stiffness of a carbon fiber AFO in a mechanical model (7). Energy cost of walking could be calculated by adjusting the stiffness of the AFO to decrease or increase the amount of energy stored and returned by the AFO. The authors found that the optimal AFO stiffness resulted in energy cost (.27 J/m/kg) more than three times lower than the energy cost (>.81 J/m/kg) at the lowest AFO stiffness. This minimal energy cost corresponded to a walking speed of .65 m/s. When the AFO stiffness was adjusted to allow the greatest energy return to the patient the resulting energy cost was, .47 J/m/kg. The authors concluded that it is not only the amount of energy returned by the AFO, but also the timing of energy return by that determines the energy cost of walking. (7)

Maeda et al.'s (2009) study on stroke patients focused on how much metabolic cost was affected by the use of an AFO (20). The aim of the study was to determine the affect of a plastic AFO on oxygen consumption, heart rate, OC, PCI, and walking velocity. Eighteen post-stroke subjects walked for six minutes with and without the use of the AFO. All subjects were at least six months post-stroke and experienced with the AFO. Walking velocity, VO_2, OC, PCI, and heart rate were compared in the two conditions. Walking OC (m/kg/m) and PCI (beats/m) was calculated from VO_2 and heart

rate. The change in walking velocity and PCI were significantly different between walking with the AFO and without. The results showed that use of the plastic AFO increased walking velocity by an average of 6m/s and PCI decreased by an average of .37beats/m. The decrease in VO_2, OC, and heart rate were, .8 ml/kg/min, .22 ml/kg/m, and 2 bpm respectively. There was no significant difference in VO_2, OC, or heart rate. Maeda concluded that prescription of a plastic AFO was appropriate in stroke patients to help improve walking distance, velocity, and efficiency. The use of the AFO helped increase the physical activity level of stroke patients, improving quality of life. (20)

Danielsson et al. (2004) calculated energy cost of walking and measured walking speed in stroke patients unbraced and with a carbon composite AFO (11). The hypothesis stated that the AFO would decrease energy cost while increasing walking speed. The authors tested ten adult hemiparetic patients who had a stroke at least six months prior to the start of the study and who were habituated to the carbon composite AFO. They walked on a treadmill at a self-selected speed unbraced and then self-selected another speed to walk with the use of the AFO. Oxygen consumption, heart rate, and walking speed were collected for five minutes in each condition. Danielsson et al. reported an average walking speed of .27 m/s unbraced and .34m/s with the AFO; a 20% increase. When walking unbraced VO_2 was 8.6 ml/kg/min and with the AFO, at the increased speed, was 8.8 ml/kg/min. Energy cost while walking unbraced was .58 ml/kg/m and with the AFO, again at the increased speed, was .51ml/kg/m. There was no difference in heart rate between the two conditions and the authors cite the difference in speed to the increased VO_2 and lack of change in heart rate. The non-matched speed design of this study was recognized as a limitation. The authors concluded that the use

of a carbon composite AFO in stroke patients may increase walking speed and decrease energy cost during walking. (11)

Buckon et al.'s (2004) purpose was to determine how a hinged AFO, a solid AFO, and a posterior leaf spring AFO affected proximal joint dynamics, energy expenditure, and functional skill performance (8). Over the course of one year, sixteen children with spastic diplegia participated in four data collection sessions. The first session consisted of baseline measurements taken three months after no use of any type of an AFO. The second, third and fourth data collection sessions were done after the participants wore each type of AFO for three months. The order in which each AFO was worn during the first three months, the second three months, and the last three months, was chosen at random for each subject. Buckon et al. reported that energy cost was significantly reduced in all three AFO conditions compared to no brace, in fast walking velocities and self-selected walking velocities. Oxygen consumption was reduced in the hinged AFO and solid AFO during both velocities, however due to the ability to walk at a higher velocity, the posterior leaf spring AFO did not significantly reduce VO_2. Velocity during self-selected walking did not change significantly between the brace conditions. Fast walking velocity was significantly higher in the posterior leaf spring AFO than the hinged AFO or the solid AFO. Buckon et al. looked for differences in energy cost greater than 13% for the AFO to be considered beneficial to the participant. Four out of the sixteen participants demonstrated no benefit from AFO use. Seven out of the remaining twelve participants demonstrated considerable benefit from the solid AFO or the posterior leaf spring AFO, and five benefited most from the hinged AFO. Although lower extremity proximal joint dynamics were not significantly affected,

significant improvements were seen in gait parameters, energy expenditure, and gross and fine motor function.

Hachisuka et al. (2007) measured oxygen consumption, PCI, number of steps, step length, and walking velocity in post-polio subjects in knee-ankle-foot orthoses (KAFO). The conditions in which these variables were measured included no brace, an ordinary KAFO, and a carbon fiber KAFO. Oxygen consumption and heart rate were collected during five minutes of walking at a self-selected velocity in each of the three conditions for 11 adult post-polio subjects. The findings in this research study were similar to studies done on other AFO types (8, 11, 20). A significant decrease in VO_2, oxygen cost, and PCI was seen when wearing the carbon fiber KAFO compare to no brace and the carbon fiber KAFO compared to the ordinary KAFO. Oxygen consumption was 13.5 ml/kg/min without the use of an orthotic and 11.4 ml/kg/min with the use of the carbon fiber KAFO. Oxygen cost in no brace and the carbon fiber KAFO was .46 ml/kg/m and .30 ml/kg/m, respectively, and PCI was 1.07 beats/m and .72 beats/m respectively. Oxygen consumption between the ordinary KAFO and the carbon fiber KAFO was 14.0 ml/kg/min and 12.8 ml.kg/min, respectively, OC was .37 ml/kg/m and .32 ml/kg/m respectively, and PCI was .95 beats/m and .81 beats/m, respectively. While wearing the carbon fiber KAFO there was a 9% decrease in VO_2, a 14% decrease in OC, and a 15% decrease in PCI compared to the ordinary KAFO. There was a 16% decrease in VO_2, a 35% decrease in OC and a 33% decrease in PCI with the use of the carbon fiber KAFO compared to walking without an orthotic. These improvements in walking with a carbon fiber KAFO, along with anecdotal reports from the subjects that the carbon fiber KAFO was lighter, fit better and felt more durable during walking led

Hachisuka et al. to conclude that it is positively indicated for patients with muscle weakness induced by lower motor neuron lesions like polio survivors. (17)

Bailey et al. (1995) and Graham et al. (2005) examined the reliability and validity of PCI (1, 16). Fifteen healthy, non-smoking females with no respiratory conditions, walked at a self-selected speed for four minutes. Non steady-state heart rate was measured and recorded during the first three minutes of walking, steady-state heart rate was measured and recorded during the fourth minute of walking and post-exercise heart rate was measured and recorded for ten seconds. All three heart rate measurements were found to be a reliable in calculating PCI. However, the subjects' PCI calculations were higher than results found in previous studies. Bailey et al. speculated the results were due to subjects being unfamiliar with the treadmill and therefore perceived walking to be slower than the subjects' actual walking speed. Physiological cost index was a reliable measure of energy expenditure in populations for comparisons between studies, however an additional limitation affecting the results was the single gender (female) sample. (1) Graham et al. used 15 healthy men and 25 healthy women to walk around two different sized tracks at a comfortable walking velocity (16). Heart rate and oxygen consumption were collected during each walking trial. Physiological cost index and OC were calculated from VO_2 and velocity. Each subject walked on a long track and a short track on two different days and was observed by the same researcher to determine intrarater reliability. Then walked each track again on a third day and was observed by a different researcher to determine interrater reliability. Intrarater ($r= .73$, $r= .79$) and interrater ($r= .62$, $r= .66$) reliability were acceptable between PCI scores from the long track and the short track, respectively. Correlations between PCI and VO_2 and PCI and OC were

weak. Graham et al. concluded that PCI scores are reliable but not valid as a measure of energy cost of walking in healthy subjects. (16)

Though Cotes and Meade and Booyens and Keatinge used instruments that are now considered outdated and not capable of calculating respiratory exchange ratio, the variable used in modern studies to derive energy expenditure (Kcal/min), their calculations were close to what is measured in current research. Advances in technology have allowed a more comprehensive evaluation of energy efficiency of gait and therefore the most common reported variables have been changed and updated. Energy expenditure now includes variables such as rate of oxygen consumption (VO_2), oxygen cost (OC), and physiological cost index (PCI). In conclusion, advances in technology have redefined energy expenditure to include more variables that can be collected and in turn more variables that can be calculated. With more potential variables comes the need for research to validate and find them reliable. Energy expenditure provided a quantitative measure to the amount of effort it takes individuals to walk or run and how much efficiency changes when gait disability is present. Energy expenditure presented effort for particular tasks and biomechanics presented why an individual's gait requires more effort.

Biomechanics

The understanding of normal biomechanics presented earlier was needed to understand why the gait deviations occur with neuropathy and how AFO use improves the kinetics and kinematics of those who need an AFO. However few studies compared the gait of AFO users to the gait of healthy individuals for several reasons such as, inhabitual use of the AFO or a condition in which AFO use would not have improved

gait enough to be considered normal. Gait in a no brace or barefoot conditions were more commonly used to compare gait in an AFO.

Ounpuu et al. (1996) evaluated the effectiveness of a plastic AFO, deemed a posterior leaf spring AFO (23). Ankle joint kinematics and kinetics were evaluated in 31 children with cerebral palsy walking with and without the AFO. Each subject walked down a 30-foot runway surrounded by infrared cameras collecting the kinematic data and force plates in the ground of the runway collecting kinetic data. The hypotheses asked whether the posterior leaf spring AFO could restore the ankle rockers closer to normal gait. Ounpuu et al. found statistically significant improvement in ankle angle in terminal swing, a decrease in maximum plantarflexion in mid-swing, and an associated decrease in plantarflexion range of motion in the third ankle rocker. There was also an increased plantarflexion moment in the AFO compared to the no brace in stance. The incidence of a dorsiflexion moment in the AFO was 29 out of 31 subjects and without the brace were 11 out of the 31 subjects. In the AFO, energy absorption increased in the second rocker, and energy generation decreased in the third rocker. The authors concluded that the posterior leaf spring AFO was effective in reducing drop foot in swing therefore improving and in some cases, creating a first rocker. Peak dorsiflexion and dorsiflexion range of motion were similar in the two conditions and close to normal values, which revealed that the AFO was able to maintain the second rocker. This was due to design features and the flexibility of the AFO. However, the function of the third ankle rocker was decreased by the use of the AFO due to decreased amount of plantarflexion allowed by the brace. This decrease in peak plantarflexion angle at terminal stance also decreased ankle power generation. Therefore the posterior leaf spring AFO reduced the

ability of the ankle to contribute to push-off in terminal stance. Ounpuu *et al.* concluded that the posterior leaf spring AFO improved ankle function but did not augment ankle function through storage and return of mechanical energy. (23)

Diamond and Ottenbacher (1990) conducted a case report on one 35-year-old male with hemiparesis comparing barefoot walking to walking in a pre-fabricated polypropylene AFO and a custom made tone-inhibiting dynamic AFO (TIAFO) (13). Over twelve data collection sessions walking velocity, step length, cadence, and stance time were recorded in each of the three conditions. The order of the conditions was randomly assigned at each data collection session. Diamond and Ottenbacher found that there was a significant increase in all variables with use of the pre-fabricated AFO as well as the TIAFO compared to barefoot walking. Walking velocity was the fastest and step length was the longest in the TIAFO. There was no significant difference in cadence or stance time between the two AFO types. Diamond and Ottenbacher found that while both the pre-fabricated AFO and the TIAFO showed an improvement in gait characteristics, the custom made dynamic AFO had more significant improvements in ambulation. Thus the authors concluded that the use of a custom made AFO may result in a more normal gait due to greater attention to support and alignment of the foot. (13)

The effect of chronic AFO use on activities of daily living had not been studied until de Wit et al. (2004) (12). The subjects included twenty stroke victims who were at least six months post stroke and had been wearing an AFO for at least six months. The subjects had only had one stroke and wore a plastic, nonarticulated AFO and were randomized into two groups. The first group walked on a ten-meter walkway with an AFO first and the second group walked shod, no brace first. The tests used to determine

clinical relevance for the use of an AFO were: maximum comfortable walking velocity, timed up and go (TUG) test, and a stairs test. Increased walking velocity of 20cm/s was considered clinically significant for maximum comfortable walking velocity. An increase in ten seconds for the TUG test and a 15 second increase for the stairs test was used for clinical relevance. The changes in walking velocity, TUG test, and the stairs test were statistically significant but did not meet the criteria for being clinically significant as set by de Wit *et al.* Limitations of the study were small sample size, length of time post stroke, and the chronic use of an AFO by the subjects. The authors concluded that AFO use may be more dependent on how confident the subjects felt while wearing the AFO and how much easier each task was while wearing the AFO. (12)

Loke (2006) discussed the need for custom designed orthoses that address the needs of each individual and to the goals of each individual (19). As the creator of the DAFO, Loke realized that a much more in-depth gait analysis and understanding of the underlying condition was essential to create a custom brace. The author outlines five case studies in which each patient wore a conventional AFO and a DAFO. The variables measured and compared among a no brace condition, a conventional brace condition, and a DAFO condition were velocity, stride length, endurance, and stance-to-swing ratio. In all subjects, velocity increased from no brace to conventional brace and from the conventional brace to the DAFO (85.1, 94.98, 162.9 ft/min, respectively) as well as stride length (28.2, 29, 39.7 inches, respectively), and endurance (678, 1381, 8548 feet, respectively). The normal stance-to-swing ratio is 60:40 and although every subject did not achieve this ratio, all the subject's stance-to-swing ratios approached the normal in the DAFO. The author attributes the improvements to increased balance, trust, tri-planar

control, preventative measures through the rehabilitation process, proper understanding of the mechanical levers in the body, and the pathomechanics of each subject. In order for outcomes with orthoses to continue to advance, Loke cites the need for orthotists to have a deeper understanding of compensatory movements, mechanical laws, balance, and support systems in order to provide effective braces. (19)

Bartonek et al. (2007) were the first to report the effects of a carbon fiber spring orthotic (CFSO) on gait biomechanics (2). A comparison was made between nineteen children. Twelve of the pediatric subjects suffered myelomeningocele, six had arthrogryposis, and one child presented with neuropathy. These disease states profoundly affected gait parameters such as plantarflexion power, and hip, knee and ankle kinetics and kinematics. Plantarflexion power, hip and knee extension and flexion, dorsiflexion, and plantarflexion were analyzed during walking with the subjects in their regular orthotic and the new CFSO. The CFSO increased hip extension in terminal stance, knee extension during initial contact, and knee flexion during swing in all subjects. All subjects also had increased dorsiflexion, plantarflexion, and hip flexion moments with the use of the CFSO. Increased stride length, ankle power, and positive and negative work were also observed with the CFSO. Bartonek et al. concluded that the use of the CFSO improved ankle kinematics and kinetics in their subjects. (2)

Faustini et al. (2008) described how the design of a carbon fiber AFO could improve gait. One functional goal of a contemporary rigid AFO was to achieve smooth, efficient walking by providing a variable level of support and mechanical energy return to the ankle during the stance phase of gait. Faustini et al. investigated the use of selective laser sintering as a manufacturing process for passive-dynamic AFO, such as

the continuous carbon fiber AFO. The objective was to determine if a custom made carbon fiber AFO could be reproduced using selective laser sintering. Faustini et al. found that the carbon fiber AFO could be replicated through selective laser sintering, however the materials used to replicate it could not mechanically store and return as much energy as carbon fiber. (14)

Wolf et al. (2007) published a short communication of a pilot done on 15 subjects with myelomeningelceal wearing a carbon fiber AFO. The study evaluated ankle kinetics and kinematics in a conventional hinge type brace and a carbon fiber brace. Maximum plantarflexion, range of motion in the first rocker, maximum dorsiflexion, range of motion in the third rocker, and ankle power in the third rocker were significantly improved in the carbon fiber AFO compared to the hinged AFO.

Churchill et al. (2003) justified the use of a shod condition versus a barefoot condition to compare AFO use and its effectiveness (9). The authors found that in drop foot, the toe or the whole foot, as opposed to the heel, was the point of contact with the floor at the start of the stance phase. Mechanically preventing the foot drop with the use of an AFO gave patients with this gait pattern the capability to heel strike. The objective was to examine the relative effects of footwear and an AFO on hemiplegic gait. Five subjects' biomechanical data was collected for kinematic analysis of spatiotemporal parameters. Churchill et al. found that with the use of footwear stride length increased by 5 cm. An additional 5 cm increase in stride length was seen with the use of an AFO. Velocity increased both in footwear and again in the AFO, while swing time decreased in footwear and in the AFO. The authors concluded that footwear had a statistically significant contribution to the improvement of spatiotemporal parameters and that it was

important to use a shod condition as a baseline to better determine the benefit of an AFO. (9)

In conclusion, energy expenditure was an important aspect in measuring how efficient and beneficial an AFO can be for deviated gait patterns caused by central or peripheral neuropathies. However, the effect of an AFO on walking energy expenditure in the literature (2, 7, 8, 11, 12, 17, 20) primarily included individuals with cerebral palsy, polio, or stroke whose lifestyles were potentially less active than that of military service members. Additionally, inconsistencies in examined variables and methodologies within these studies made conclusions difficult to compare (8). Therefore, a gap in the literature exists evaluating the effects of the AFO on steady-state physiologic responses in active military service members with lower extremity injuries.

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APPENDIX A

Approved Consent Form

VOLUNTEER
AGREEMENT
AFFIDAVIT

For use of this form,see AR 70-25 or AR 40-38,the proponent agency Is OTSG

PRIVACY ACT OF 1974

Authority:	10 USC 3013,44 USC 3101, and 10 USC 1071-1087.
Principle Purpose:	To document voluntary participation in the Clinical Investigation and Research Program. Home address will be used for identification and locating purposes.
Routine Uses:	The home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.
Disclosure:	The furnishing of your home address is mandatory and necessary to provide identification and to contact you if future Infonnation indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) ·VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

A PHOTOCOPY OF THIS FORM MUST BE SIGNED BY ALL VOLUNTEERS.
Approved by the TAMC HUC/IRB on 18 Jun 12 for TAMC # 31410
This version of the consent form expires on 26 Jun 13

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

!,_____

having full capacity to consent and having attained my _____ birthday, do hereby

volunteer/give consent as legal representative for———————————

———————————to participate in an jnyestjgational study entitled

Functional Analysis of Dynamic Ankle-Foot Orthoses to Improve Outcomes in Partial Lower Extremity Paralysis under the direction of Dr. Gerard M. Antoine conducted at the Tripler AMC Physical Medicine and Rehabilitation Services Department and the University of Hawaii Human Performance and Biomechanics Lab.

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by Richard H. Todd, MPT, DSc, or David P. Newman, PT, DPT, OCS

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

the Center Judge Advocate

at Tripler Army Medical Center, Tripler AMC, HI 96859-5000 (808) 433-5311
(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefrts; however, lithe person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits *to* which I am/the person I represent is otherwise entitled.

PART A(2) ·ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____

having full capacity to assent and having attained my _____, do hereby volunteer for

_____ &estjgatjonal

stydyen@ed _____

_____

under the direction of _____

NOT APPLIC

conductedat _____ _____

(Name of Institution)

(Continue on *Reverse)*

DA FORM 5303-R, MAY 89 PREVIOUS EDITIONS ARE OBSOLETE

PART A(2) -ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD) (Cont'd.)*

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were full and complete satisfaction. Should any further questions arise concerning my rights I may contact answered to my

NOT APPLICABLE

at

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however. I may be requested to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

PART B- TO BE COMPLETED BY INVESTIGATOR

PARTICIPATION INFORMATION: You have been invited to participate in a clinical investigational/research study conducted at Tripier Army Medical Center and the University of Hawaii's Human Performance and Biomechanics Lab. It is very important that you read and understand the following general principles that apply to all participants in our studies: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

NATURE OF STUDY: The purpose of this study is to measure the changes in level of function and quality of life of soldiers with partial lower extremity paralysis after the issue of a custom dynamic ankle foot orthosis (AFO). The device being tested is commercially available, however no study has examined its use with a physically active population.

EXPECTED DURATION OF SUBJECT'S PARTICIPATION: This study will last approximately seven months from the date of enrollment. This includes one month before being fitted for the custom AFO, and then six months of follow-up after being issued the brace. Participants will be expected to follow-up monthly after brace fitting for a 1.5 hour gait and metabolic testing session at the University of Hawaii, and to follow their regular physical therapy and medical appointments as indicated by their physician.

WHAT WILL BE DONE: After study enrollment, your physician will perform an electromyographic (EMG) and nerve conductive study (NCS) as part of the standard follow-up for your condition. At this time you will be scheduled for an appointment with the orthotist who will take measurements and a cast of your leg

in order to fabricate the custom dynamic AFO. You will also be scheduled with an appointment for evaluation by a physical therapist who will measure the range of motion in the joints, strength of the muscles, and muscle mass in your lower extremity.

You will also be asked to report to the Human Performance and Biomechanics Lab at the University of Hawaii for metabolic testing and gait analysis. You will be asked to wear your physical training uniform and your normal running shoes. First, you will fill out a brief survey about your current AFO and your current quality of life, and then your height and weight will be measured by a member of the research team who is a certified athletic trainer. Next, you will be given 10 minutes for a self- selected warm-up (i.e. riding a stationary bike or stretching). Before beginning the treadmill metabolic test, you will be asked to select a comfortable walking speed on the treadmill and instructed that you will need to maintain this speed for eight minutes (the duration of the test). After selecting your speed, the treadmill will be stopped and you will be fitted with a heart rate monitor, headgear and breathing mask. Throughout the duration of the test you will breathe through the mask that is connected via ventilation tubes to a metabolic cart that will determine your oxygen consumption and energy expenditure during the walking test. At the time of test initiation the treadmill will be started and the speed of the treadmill will be set to your previously determined comfortable walking speed. You will be instructed to maintain this speed for eight minutes. Upon completion of the test, the treadmill speed will be immediately decreased to allow you to walk at an easy pace to cool down, the headgear and breathing mask will be removed at this time as well. You will complete this procedure without an AFO and wearing your current AFO with a 10 minute rest period between trials.

After you complete the metabolic testing, you will be given 10 minutes to rest. During this time, reflective markers will be placed on several bilateral landmarks on your body (ex: shoulders, low back, hips, thighs, shins, ankles and feet) for the gait analysis. Measurements and marker application for female volunteers will be performed by a female member for the research team. You will be asked to walk at a self-selected pace down an 18-meter runway. You will perform three successful trials for each leg without an AFO and while wearing your current AFO, and then in both conditions while jogging. The entire procedure will take approximately two and a half hours.

The metabolic and gait analysis will be repeated while wearing your new custom AFO within one week after being issued the new brace, this session should last approximately 1 hour. You will be asked to keep a journal on your use of the new custom AFO and return this journal to study personnel monthly. You will also be asked to return to the Human Performance and Biomechanics lab monthly(+/- one week) to repeat the metabolic and gait analysis while wearing your new custom AFO monthly for six months after you are issued the brace. You will also repeat the anthropometric measures and the EMG/NCS at six months as part of the standard care for your condition.

If you are unable to continue participation in the study due to a change of station, military discharge, or if you withdraw for any reason, you will be asked to complete an exit study visit. Study procedures that will be done at the early exit visit include leg measurements, and EMG, NCS and anthropometric testing in the Physical Medicine and Rehabilitative Services and Physical Therapy Departments at Tripier as well as gait and metabolic analysis (shoes only and DBS-AFO) at the Human Performance and Biomechanics Lab at UH. AFO use journal and quality of life data will also be collected at the exit study visit.

All testing procedures will be explained to you again at each data collection session. The table below explains the data collection time line:

Procedure	Brace Fitting and Issue		Follow-up months					
	1 to 28 days before brace issue	1 to 14 days	1	2	3	4	5	6
thEMG/NCS	X							X
Anthropometries	X							X
Gait Analysis: shoes only	X				X			X
Gait Analysis: current AFO	X							
Gait Analysis: custom AFO		X	X	X	X	X	X	X
Metabolic Analysis: shoes only	X				X			X
Metabolic Analysis: traditional AFO	X							
Metabolic Analysis: custom AFO		X	X	X	X	X	X	X
Quality of Life Survey	X		X	X	X	X	X	X
AFO use journal			X	X	X	X	X	X

INCLUSION AND EXCLUSION CRITERIA: All service members with drop-foot will be eligible for study participation. Service members with transient lower extremity nerve palsy, those who have used a traditional AFO for more than two years or less than one month, and those unable to continuously walk for 10 minutes will be excluded from study participation.

REASONABLY FORESEEABLE RISKS OR DISCOMFORTS: Due to the level of physical activity involved in the gait and metabolic analyses, there is a risk of injury. Subjects may also have some discomfort, muscle cramping or soreness during or after test sessions. The Human Performance and Biomechanics lab is equipped with a fall prevention system; however there is chance of falling during the walking and running tests. There is a very remote chance of cardiac arrest and/or death. These risks are comparable to routine rehabilitation and activities of daily living, and will not affect subjects' rehabilitation and recovery. The investigators are BOC certified athletic trainers and First Aid/CPRIAED trained. In the event of any physical injury from the gait and metabolic analyses, only immediate and essential medical treatment is available including an AED. First Aid/CPR and a referral to a medical emergency room will be provided. All data will be collected by medically certified personnel associated with the research study.

COMPENSATION FOR INJURY: Should you be injured as a direct result of participating in this research project, you will be provided medical care at TAMC, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. This is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

BENEFIT(S) TO THE SUBJECT OR TO OTHERS: Participants will receive one custom Dynamic Bracing Solutions AFO with the goal of improving your physical function and improving your quality of life. Subjects may not receive direct or immediate benefits from participation in this study. However, you will obtain information regarding their neuromuscular function and walking and running characteristics. Results of this study may assist military physicians, physical therapists and athletic trainers improve the standard care for patients drop foot. You will not be paid for participating in this study.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT: If you do not wish to participate in this study, you will receive standard therapy as deemed appropriate by your physician.

CONFIDENTIALITY: Information gained because of your participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of medical science. Information from this study may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. Complete confidentiality cannot be promised because information bearing on your health may be required to be reported to appropriate medical or command authorities.

Your medical records relating to this study may be reviewed by the Institutional Review Board (IRB) at Tripier Army Medical Center, Clinical Investigation Regulatory Office at Fort Sam Houston, Texas and other government agencies as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially, and in the event of publication regarding this study, your identity will not be disclosed.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA Authorization form for this study will be provided to you separately, and you will be asked to sign that form.

PRECAUTIONS TO BE OBSERVED BY SUBJECT BEFORE AND FOLLOWING THE STUDY: As with any physical activity, subjects may have some discomfort, muscle cramping or soreness during or after test sessions. Report any discomfort to the study investigators.

CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: (a) Health conditions or other conditions that might occur which may be dangerous or detrimental to you or your health; (b) if military contingency requires it; (c) if you become ineligible for military care as authorized by Army regulation; (d) if the safety monitor determines that continued treatment under this study may be harmful to you.

COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN STUDY: Participants are responsible for their own transportation to and from Tripier Army Medical Center and the University of Hawaii. Participants will be reimbursed for parking fees at the University of Hawaii. In accordance with AR 40-38, paragraph 3-30)(2), daily charges for inpatient care will be waived while the volunteer is in the hospital if the volunteer would not normally enter the hospital for treatment but is requested to do so as part of a research study or as a result of adverse reaction to the drug(s) or procedure(s) used in this study. This also applies to the volunteer's extension of time in a hospital for a research study when the volunteer is already in the hospital.

SIGNIFICANT NEW FINDINGS: Any significant new findings developed during the course of this study that could affect your willingness to continue participation will be made available to you. The results of the research will be made available to you if you so desire. In some cases complete results may not be known for several years.

APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY: Approximately 15 service members will be involved in this study.

DOMICILIARY CARE STATEMENT: The extent of medical care provided, should it become necessary, is limited and will be within the scope authorized for Department of Defense (DOD) health care beneficiaries. Necessary medical care does not include domiciliary (home or nursing home) care.

FOR FURTHER INFORMATION: For questions about the study, contact the principal investigator:

Dr. Gerard M. Antoine
Chief, Physical Medicine and Rehabilitation Services
(808) 433-6958

For questions about your rights as a research participant, contact the Tripier Army Medical Center's Institutional Review Board (which is a group of people who review the research to protect your rights) at (808) 433-6709 or the University of Hawaii's Committee on Human Subjects at 808-956-5007. For questions about research related injury, contact the Center Judge Advocate at Tripier Army Medical Center at (808) 433-5311.

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. A COPY OF THE VOLUNTEER AGREEMENT AFFIDAVIT WILL BE PROVIDED TO YOU.

I have read the above explanation and agree to participate in the investigational study described.

I do[] donot[] (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN **(if volunteer is a minor)**
PERMANENT ADDRESS OF VOLUNTEER	SIGNATURE OF WITNESS	DATE

NOT APPLICABLE

PERSON OBTAINING CONSENT:

TYPED NAME OF WITNESS:

Print Name and Title: ----------

Signature: ----------

Date: _____

APPENDIX B

Data Collection Forms

Date: _____ Subject ID: _____

Data Collection Session: 0-0 1 2 3 4 5 6

Metabolic Data Collection Sheet 1

Age: _____Gender: _____ **Resting Hear Rate (bpm):_____**

Height **Shoes Only**(cm): _____ Height **Shoes + TAFO** (cm): _____

Wt **Shoes Only** (kg): _____Wt **Shoes + TAFO** (kg):_____

Pre-Test %O_2(From Computer):_____

Self-Selected Treadmill Speed (mph): _____ Time from Calibration to Test Start: _____

No AFO (shoes only)
Post-Test RPE: Chest & Breathing: _____Legs & Joints: _____Overall: _____

Post-Test O_2% (From Computer): _____

Peak VO_2 (ml/kg/min):_____ Max Heart Rate (bpm):_____

Total O_2 Drift Time: Calibration Time + 8 minutes= _____

Pre-Test %O_2(From Computer):_____

Time from Calibration to Test Start: _____

Traditional AFO
Post-Test RPE: Chest & Breathing: _____ Legs & Joints: _____ Overall: _____

Post-Test O_2% (from computer): _____

Peak VO_2 (ml/kg/min):_____ Max Heart Rate (bpm):_____

Total O_2 Drift Time: Calibration Time + 8 minutes= _____

Additional Test Notes:

Date: _____ Subject ID: _____

Data Collection Session: 0-0 1 2 3 4 5 6

Metabolic Data Collection Sheet 2 (DBS ONLY)

Age: _____ Gender: _____ **Resting Hear Rate From Sheet 1 (bpm):_____**

Wt **Shoes + DBS-AFO** (kg):_____Height **Shoes + DAFO**(cm): _____

Self-Selected Treadmill Speed From Sheet 1 (mph): _____

Pre-Test %O_2(From Computer):_____

Time from Calibration to Test Start: _____

DBS-AFO
Post-Test RPE: Chest & Breathing: _____ Legs & Joints: _____ Overall: _____

Post-Test O_2% (from computer): _____

Peak VO_2 (ml/kg/min):_____ Max Heart Rate (bpm):_____

Total O_2 Drift Time: Calibration Time + 8 minutes= _____

Additional Test Notes:

Date: _____ Subject ID: _____

Data Collection Session: 0-0 1 2 **3** 4 5 **6**

Metabolic Data Collection Sheet 3

Age: _____Gender: _____ **Resting Hear Rate (bpm):_____**

Height **Shoes Only** (cm): _____ Height **Shoes + DAFO** (cm):_____

Wt **Shoes Only** (kg): _____ Wt **Shoes + DAFO** (kg):_____

Self-Selected Treadmill Speed From Sheet 1 (mph): _____

Pre-Test %O_2(From Computer):_____

Time from Calibration to Test Start: _____

No AFO (shoes only)
Post-Test RPE: Chest & Breathing: _____ Legs & Joints: _____ Overall: _____

Post-Test O_2% (From computer): _____

Peak VO_2 (ml/kg/min):_____ Max Heart Rate (bpm):_____

Total O_2 Drift Time: Calibration Time + 8 minutes= _____

_____

Pre-Test %O_2 (From Computer):_____

Time from Calibration to test start: _____

DBS – AFO
Post-Test RPE: Chest & Breathing: _____ Legs & Joints: _____ Overall: _____

Post-Test O_2% (from computer): _____

Peak VO_2 (ml/kg/min):_____ Max Heart Rate (bpm):_____

Total O_2 Drift Time: Calibration Time + 8 minutes= _____

Additional Test Notes: