

Comparison of the Easy Strutter Functional Orthosis System™ and axillary crutches during modified 3-point gait

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Abstract—The Easy Strutter Functional Orthosis System™ (ESFOS) was designed to improve assistive device ambulatory efficiency. This crossover design study compared the ESFOS to axillary crutches during modified 3-point gait. Thirty-eight subjects (40–65 years of age) at > 1 year after unilateral total knee or hip replacement participated in this study. Heart rate, mean peak palmar and plantar force magnitude, and onset timing were monitored during self-directed pace ambulation. Between trials, subjects responded to questions on perceived exertion, stability/security, and comfort. One-way analyses of variance were used to evaluate condition differences for ratio or interval data ($p \leq 0.01$). Statistically significant differences were noted for mean peak palmar forces (reduced 45% and delayed 31%), mean peak plantar force onsets (delayed 30%), and energy expenditure index (EEI) (reduced 25%). Wilcoxon signed rank tests were used to evaluate condition differences for ordinal data. Subjects preferred the ESFOS to axillary crutches for comfort and security/stability on flat surfaces and stairs ($p \leq 0.001$). Results suggest greater ambulatory gait efficiency during ESFOS use. Further study is indicated with other patient populations.

Key words: assisted ambulation, biomechanics, perceived exertion.

INTRODUCTION

Ambulating with axillary crutches is often prescribed to reduce or eliminate weight bearing following acute

lower-limb injury or surgery, or during chronic disability [1]. As the user essentially performs a push-up with each step, axillary crutch use increases physiological energy demands and generates increased palmar forces through the device handles [2–5]. Opila et al. reported that the unnatural upper-limb joint loading produced by “crutching” promoted early degenerative changes [5]. During appropriate axillary crutch use, excessive palmar forces may be produced [6,7]. Sala et al., evaluating the association between palmar forces and carpal tunnel syndrome during crutch ambulation, reported mean peak loads of 32.3 ± 9 kg, with the greatest pressure concentrated at the radial side of the palm [7]. Using cadaveric techniques, Cobb et al. reported that palmar forces as small as 1 kg applied to the flexor retinaculum region of the proximal hand substantially increased carpal tunnel and median nerve pressures [8]. The thenar and hypothenar regions were slightly less sensitive to palmar loading forces, but still

Abbreviations: EEI = energy expenditure index, ESFOS = Easy Strutter Functional Orthosis System™, ICC = intraclass correlation coefficient, SEM = standard error of the mean, VO_2 = oxygen uptake.

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displayed significant carpal tunnel pressure increases under a 1 kg load [8].

The upper-limb strength and endurance required for appropriate axillary crutch use prompts many patients to adjust their technique by substituting axillary weight bearing [8–12]. Excessive axillary weight bearing during crutch use may increase axilla reaction forces seven-fold, thereby contributing to the development of neurovascular impairments [6]. Several reports have noted an association between long-term axillary crutch use and axillary artery stenosis, aneurysm formation, and secondary thromboembolic disease [9–12]. Rudin and Levine reported two cases of bilateral radial nerve compression (“crutch paralysis”) associated with 1 to 4 weeks of regular axillary crutch use [13]. Shabas and Schieber reported a case of suprascapular neuropathy from the exaggerated shoulder movements associated with axillary crutch use [14].

Unlike axillary crutches, the Easy Strutter Functional Orthosis System™ (ESFOS) (Orthotic Mobility Systems, Inc., Kensington, MD) (**Figure 1**) was designed to support most of the user’s weight through the axilla without injuring the neurovascular structures. Conceptually, the ESFOS does this by dissipating axillary forces over an approximately 96.8 cm² cushioned support surface that displays a convex frontal plane contour and a concave sagittal plane contour (**Figure 2**). Axillary crutches provide only about 32.3 cm² weight-bearing area when patients inappropriately bear weight through the axillary pads. Bilateral axillary region pressures were measured (model X36, Xsensor Technology Corporation, Calgary, Alberta, Canada) for one subject during ESFOS use during true 3-point gait (nonweight bearing at the left lower limb) at a self-directed pace over a 3.05 m distance on a flat surface. Representative midstance axillary pressure data are presented in **Figure 3** (lighter areas = greater pressure; quartered disc = center of pressure). During ESFOS use, a broad axillary pressure distribution area was observed, with the center of pressure located within a relatively low-pressure region where maximal axillary pressure increases are most likely to occur.

All gaits that use assistive devices are less energy efficient than nonimpaired ambulation [4]. In comparing the energy costs of 3-point axillary or elbow crutch ambulation to normal walking on multiple surfaces among eight nonimpaired subjects, Fisher and Patterson reported almost doubled oxygen uptake (VO₂) requirements with either assistive device [15]. In a related study, Patterson and Fisher reported that crutch walking with a 3-point



Figure 1.
Easy Strutter Functional Orthosis System™.

gait pattern produced VO₂ increases that were similar to upper-body ergometry [16].

Because heart rate is linearly related to VO₂ during continuous, submaximal activity, heart-rate measurements have been used to provide a practical, reliable energy expenditure estimate of walking gait economy among nonimpaired and impaired adults [3,17–22] and children [23–26]. By considering differences in both resting heart rate and preferred walking velocity, the energy



Figure 2.
Easy Strutter™ device axillary support.

expenditure index (EEI) has been shown to provide an effective VO_2 estimate during continuous, submaximal activity [3,23–26]. Rose et al. [23,24] defined the EEI as

$$\frac{\text{Mean Heart Rate (during assisted gait)} - \text{Resting Heart Rate}}{\text{Mean Gait Velocity}}$$

The 10-category Borg perceived exertion scale is a simple scale that has the positive attributes of a general ratio scale [27]. Noble et al. reported a close correlation between ratings using the 10-category Borg perceived exertion scale and increases in blood lactate and muscle lactate levels during exercise among 10 nonimpaired men [28]. Borg and Bhampani et al. have reported on the importance of evaluating associated perceptual stressors

such as stability/security and comfort when considering physical exertion ratings [1,27,29].

The ESFOS was designed to alleviate upper-limb forces and improve assistive device ambulation efficiency [30]. Both the axillary support and the rubber-soled, spring-loaded base (16.5 cm long \times 7.6 cm wide, 125.8 cm²) (**Figure 4**) are believed to improve subject stability/security and comfort during gait on multiple surfaces. In addition to providing a greater floor contact surface area than the 2.54 to 4.45 cm² provided by standard axillary crutches or the 6.99 cm² area provided by oversized crutch tips, the design of the ESFOS enables the device base to maintain ground contact over a longer duration, enabling greater stability, especially when the patient ambulates on wet, slippery, or uneven surfaces. The ESFOS was designed as a rectangle with “articulated” pivot points at each corner. One of the short sides of the rectangle serves as the device base or “foot,” while the opposite side serves as the axillary support. This articulated parallelogram configuration enables the orthotic support and the device base to remain parallel as the long sides rotate during use. The articulated spring-loaded base of the ESFOS may help absorb impact shock and facilitate forward propulsion during gait (**Figure 5**).

The objective of this study was to compare the ESFOS to axillary crutches for select biomechanical (mean peak palmar force magnitude and onset timing and mean peak plantar force onset timing), physiological (EEI and perceived exertion), and perceived stability/security and comfort during flat surface and stair ambulation, while attempting to maintain an approximately 50-percent weight-bearing reduction at the involved lower limb. The modified 3-point gait style, and the 15.24 m course distance were considered consistent with conditions commonly encountered by patients during rehabilitation for a variety of unilateral lower-limb orthopedic surgical procedures (arthroplasty, osteotomy, ligament reconstruction, articular cartilage repair, fracture management).

METHODS

Subjects

Two hundred fifty-three eligible patients (40–65 years of age, >1 year status post-unilateral total knee or total hip replacement surgery) were asked via mailed invitations to return a self-addressed, stamped postcard indicating their

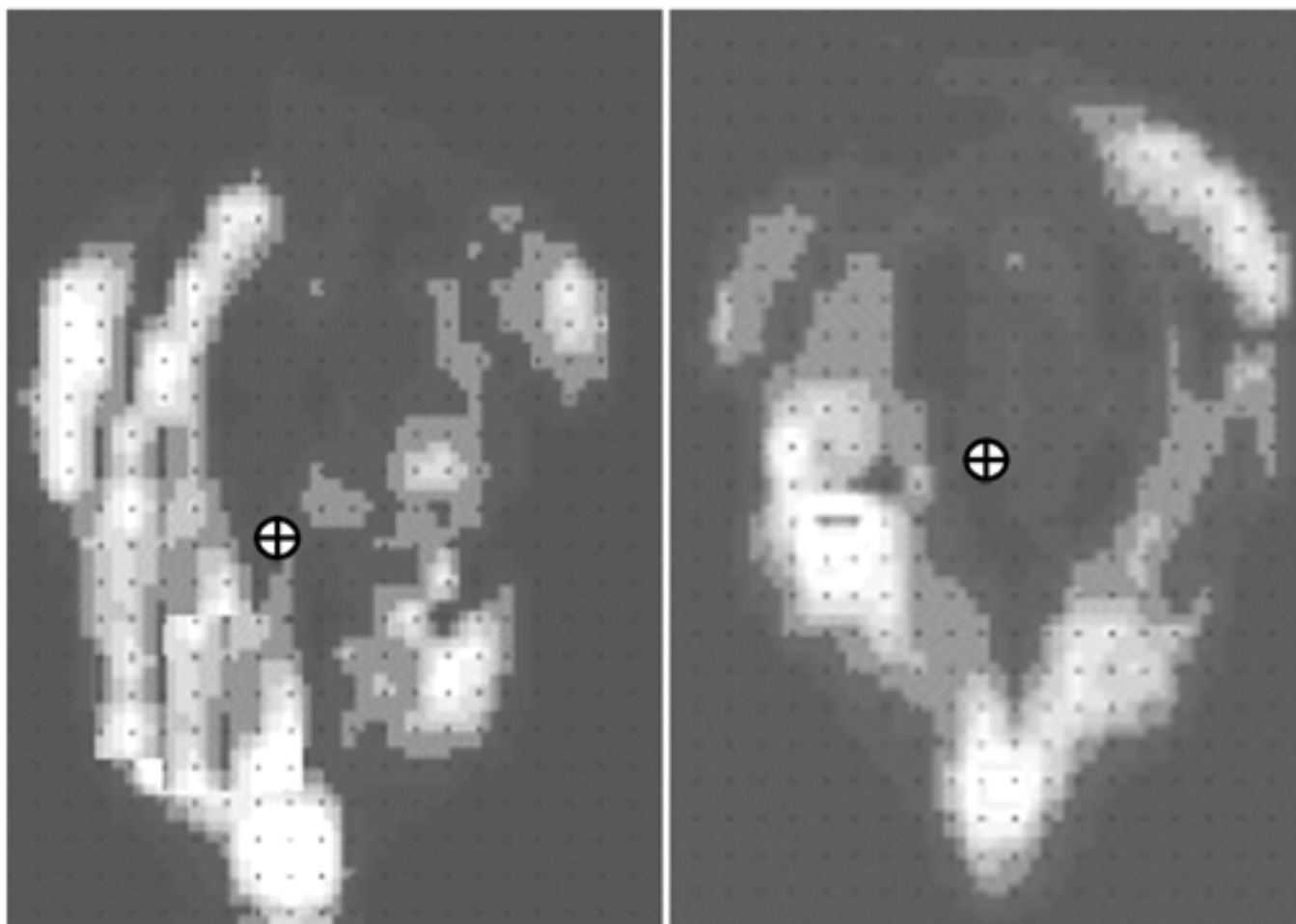


Figure 3.

Left and right side axillary pressures and center of pressure locations (anterior = top of figure).

level of interest in study participation. Following receipt of the postcard, the primary investigator interviewed and screened potential subjects by telephone. Subjects with existing acute medical conditions, pathology or surgical history at the opposite lower-limb knee or hip, balance disorders, cardiac arrhythmia, or pacemaker use were excluded from the study. All subjects had used axillary crutches on flat surfaces and stairs during the acute phase of rehabilitation. All subjects considered their rehabilitation successful. At the time of the study, all subjects ambulated independently without assistive device use. Thirty-eight subjects (14 women, 24 men) were accepted for study participation (**Table 1**). The two orthopaedic surgeons who served as coinvestigators performed all surgeries. The University of South Florida Medical Institutional Review Board approved the study. All subjects provided written informed consent. This study was funded

by a grant from Orthotic Mobility Systems Inc., Kensington, MD. None of the investigators had a proprietary interest in the device.

Data Collection During Ambulation with Assistive Devices

Subjects were fit with axillary crutches using standard protocol [31]. The ESFOS was fit as recommended by the manufacturer, with a 2.54 cm distance between the floor and the device base when subjects stood erect with the orthotic axillary pads touching the axilla [30]. The primary investigator performed all device fitting. Immediately before data collection, subjects practiced equally with the ambulatory assistive device that would be used during each test trial. Subjects practiced proper technique on the flat surface and stairs (15.2 cm step height, 30.5 cm



Figure 4.
Easy Strutter™ device base or “foot.”

step depth, 76.2 cm step width, 76.2 cm × 76.2 cm landing dimensions, four steps) over the entire 15.24 m gait course. The flat surface was covered with wall-to-wall indoor/outdoor carpet, and the hardwood stair steps had an antislip finish. The carpeted surface did not appear to influence subject gait characteristics, although the nonslip nature of the gait course may not have adequately represented performance on a low-friction tiled or wet floor environment [32]. During axillary crutch use, subjects were instructed to use their upper limbs for support and to avoid excessive axillary loading. During ESFOS use, subjects were instructed to bear weight completely through the axillary pads, as recommended by the manufacturer [30]. Subjects were asked to assume a self-directed, comfortable pace, a modified 3-point gait pattern (50% unilateral weight bearing on the involved side, as discussed in the next section) and a “heel-to-toe” progression. Subjects wore a gait belt during practice and data collection

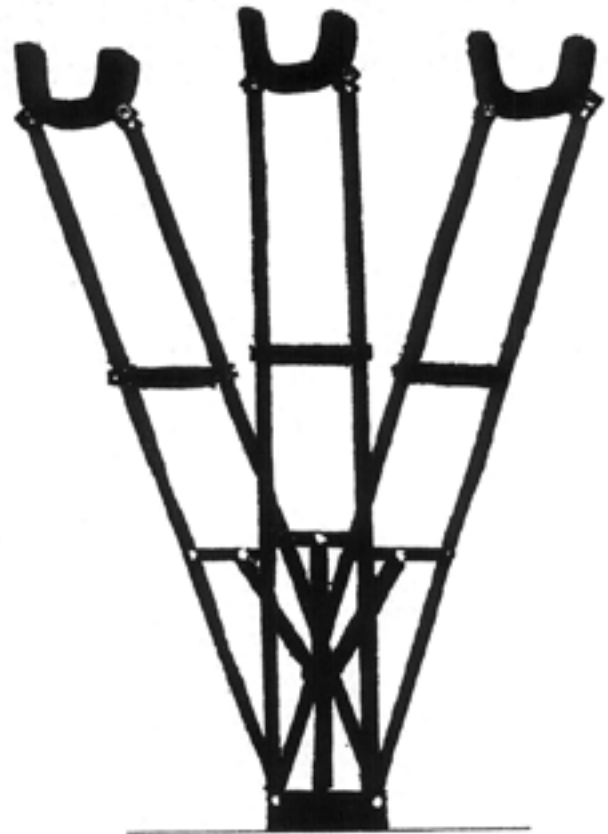


Figure 5.
Articulated parallelogram.

sessions. An investigator provided stand-by supervision during all practice sessions and test trials.

Following a verbal cue to begin, subjects ambulated with axillary crutches and with the ESFOS in an alternating order, following random assignment (coin flip) for the first subject. Subjects ambulated at a self-directed, comfortable pace for 6.1 m on a flat surface, followed by ascending the stairs, turning at the top of the stairs, descending the stairs, and then ambulating 6.1 m back to a start-finish line (15.24 m, or 50 ft total distance). After crossing the start/finish line, subjects were seated and rested for approximately 5 to 10 min. During the rest period, subjects completed the 10-category Borg perceived exertion scale and the perceived security/stability and comfort questions. Following the rest period, testing was repeated using the other assistive device. Heart rate, mean peak palmar and plantar force magnitude, and onset timing were monitored during self-directed pace ambulation. Subjects reviewed the involved-side target weight

Table 1.
Subject demographics.

Subjects	Age Mean \pm SD/ Range (yr)	Height Mean \pm SD/ Range (cm)	Weight Mean \pm SD/ Range (kg)	Subjects with Unilateral Total Knee Replacement	Subjects with Unilateral Total Hip Replacement
Women $n = 14$	52.9 \pm 8.5/40–65	164.6 \pm 5/157.5–175.3	80.3 \pm 25/54.4–136.1	9	5
Men $n = 24$	53.6 \pm 6.1/44–65	178.6 \pm 8/162.6–193	98.8 \pm 18/68–152	12	12
Total $n = 38$	53.3 \pm 7.1	173.4 \pm 9.4	91.9 \pm 22.7	21	17

SD = standard deviation

bearing before practicing with each device and immediately before data collection. Each test trial represented one complete gait course cycle.

By allowing subjects to self-direct their walking gait pace, energy expenditure was believed to be both minimized and more closely related to daily living activity [1,18]. In an attempt to minimize bias, a new pair of light weight, satin-finished, anodized aluminum crutches with push buttons that enabled 2.54 cm (1 in.) adjustments for handle placement and height were used (model 8115-A, Quick-Fit, Invacare Corp., Elyria, OH). The alternating device order created a counterbalanced crossover research design.

Plantar and Palmar Force Measurements

The Pedar System (Novel Electronics Inc., 964 Grand Ave., St. Paul, MN), calibrated per manufacturer protocol [33], was used to measure peak palmar force magnitude and onset timing and peak plantar force onset timing at the side of the total knee or hip replacement following initial heel contact (50 Hz). The plantar force sensor was inserted into a rubber-soled shoe during testing. The forefoot region of a second sensor was placed over the ambulatory assistive device handle to serve as the palmar force sensor. The assumption was made that equal or greater loads would be placed through the upper limb on the side of reduced lower-limb weight bearing among this group of nonimpaired subjects. Stallard et al., in evaluating the peak vertical ground reaction forces of individual Canadian crutches during one-leg swing gait performed by nonimpaired subjects, reported similar forces of 0.54 body weight at the landing leg and 0.51 body weight at the contralateral nonweight-bearing side [34]. Opila et al. reported slightly increased upper-limb moments at the side of the nonweight-bearing lower limb during elbow-crutch-assisted ambulation for a patient

who had sustained a tibial fracture [5]. In an evaluation of 32 patients who were long-term crutch users because of lower-limb orthopaedic conditions, Blankstein et al. reported bilateral wrist joint arthrosis with a similar frequency between sides [35]. By placing the upper- and lower-limb sensors on the same side, we observed generally safer gait patterns and a decreased likelihood of the cables interfering with or otherwise influencing gait characteristics. The palmar force sensor was secured to the device handle by a thin layer of clear polyethylene wrap. Mean peak palmar and plantar force magnitude and onset timing measurements were determined by the analysis of three consecutive steps during flat surface ambulation with Version 7.32 Pedar-Expert Software.

The difference between mean peak plantar force magnitude during three consecutive steps and target peak plantar force magnitude (50% weight-bearing reduction at the involved lower limb) was also determined. Subjects were instructed in 50-percent target weight bearing at their involved lower limb using an electronic digital strain gauge scale (model 8400W-01, Sunbeam Corp., Boca Raton, FL). While standing without an assistive device, subjects positioned the foot of the involved lower limb on the scale and the opposite foot on a platform of equal height, with body weight equally distributed. Subjects were then instructed to shift their body weight toward the uninvolved side until the primary investigator observed an approximately 50-percent reduction of the initial involved-side lower-limb weight-bearing value. Subjects were instructed to attempt to maintain this weight-bearing status at the involved lower limb during the practice session and during all test trials. This procedure was performed immediately before each practice session and was repeated immediately before test trials with each device.

Heart-Rate Measurements

Resting heart-rate and mean exertional heart-rate measurements during assisted ambulation were obtained with the Polar Accurex Plus System with Training Advisor Software (Polar Electro Inc, Woodbury, NY). This system enabled exertional heart rate data to be collected during test trials. Following their arrival at the research laboratory, subjects had resting heart-rate measurements taken before practicing with the initial ambulatory assistive device. The heart-rate sensor was placed directly over the chest of each subject, and a wristwatch style heart-rate monitor positioned at the right wrist of each subject displayed and recorded the telemetered signal. Separate resting heart-rate measurements (10 s duration with subjects in a relaxed, seated position) were taken before ambulation with each assistive device. The second resting heart-rate measurement was taken 5 to 10 min after the first test trial. Following the second resting heart-rate measurement, subjects practiced with the other ambulatory assistive device. Following both test trials, exertional heart-rate data were downloaded to a desktop computer for mean exertional heart-rate determination. Resting heart-rate measurements were subtracted from mean exertional heart-rate measurements over the entire gait course for each condition (ESFOS and axillary crutch ambulation). These values were used for EEI determination.

Two-Dimensional Videography

An 8 mm video camera (model CCD-TR87, Sony Electronics Inc., Tokyo, Japan) at a tripod height of 43 cm was positioned perpendicular to the gait course (2.44 m from a centrally placed 5.1 cm wide \times 3.66 m long white hook-and-pile strip with large [5 cm] and small [1 cm] increment markers), providing a sagittal plane view for involved lower-limb stride length and assistive device-floor angle determination. Reflective markers placed centrally on the lateral aspect of the base and at 41.9 cm proximal to the distally placed marker on both assistive device types enabled device-floor angle determination at initial ground contact. Assistive device-floor angle at initial ground contact was determined by review of the videotape and measurement of the angle formed by the intersection of a line between the reflective markers and a known horizontal line (base of wall-carpet interface) with a handheld goniometer when subjects were directly in front of the video camera. This angle was reported relative to vertical. The two-dimensional kinematic measurement method provided only sagittal plane

kinematic data. However, the sagittal plane was the primary motion plane of the kinematic variables of interest for both gait (stride length) and assistive device (device-floor angle at initial ground contact) characteristics among this group of nonimpaired subjects. Videotape review also enabled determination of the time needed to complete the gait course. Subjects were observed to display more consistent temporal gait characteristics over the central 12.2 m of the course. Since a self-selected gait velocity was used and subjects were cued to begin each trial when they were ready, a distance of 1.52 m (5 ft) from the initial starting point was selected as the start and end point for mean gait velocity calculation. Therefore, mean gait velocity was calculated from the central gait course distance (12.2 m) divided by the time required for its completion. All subjects completed the stairs portion of the course in a continuous manner, without stopping.

Surveys

Perceived exertion during assisted ambulation with each device over the entire gait course was determined with the 10-category Borg perceived exertion scale [27,28]. Perceived levels of stability/security and comfort on flat surfaces and stairs were individually assessed through modified visual analog scale questions. Rather than drawing a perpendicular mark across a 10 cm line (as used with standard visual analog scales), subjects filled in one of a series of 10 dots that best depicted their perceived level of security/stability (end-range descriptors of very secure/stable and very insecure/unstable) or comfort (end range descriptors of very comfortable and very uncomfortable). Before being used in this study, the perceived stability/security and comfort questions were pilot tested for subject comprehension on five subjects, who also assisted with reliability testing of biomechanical and physiological measurements.

Within-Day Test-Retest Measurement Reliability

Pilot testing of five nonimpaired, age-matched men (51 ± 4 yr) using axillary crutches and a modified 3-point gait style with 50-percent weight bearing at their left lower limb revealed high within-day test-retest reliability for plantar force magnitude (intraclass correlation coefficient [ICC] 3,1 = 0.98, standard error of the mean [SEM] = 94 N), palmar force magnitude (ICC 3,1 = 0.97, SEM = 16 N), plantar force onset timing (ICC 3,1 = 0.94, SEM = 0.08 s), palmar force onset timing (ICC 3,1 = 0.97, SEM = 0.17 s), and stance time (ICC 3,1 = 0.97,

SEM = 0.22 s) measurements. High within-day test-retest reliability measurements were also observed for resting heart rate (ICC 3,1 = 0.98, SEM = 2.9 beats/min), mean heart rate during assistive device ambulation (ICC 3,1 = 0.98, SEM = 4.3 beats/min), EEI (ICC 3,1 = 0.96, SEM = 0.18 beats/min), gait velocity (ICC 3,1 = 0.97, SEM = 1.2 m/min), ambulatory assistive device-floor angle (ICC 3,1 = 0.93, SEM = 1.6 degrees), and stride length determination (ICC 3,1 = 0.96, SEM = 4 cm).

Statistical Analysis

A series of one-way analyses of variance (condition) was used to determine statistical differences between devices for mean peak palmar magnitude and onset timing, mean peak plantar force onset timing, EEI, and perceived exertion. A probability level of 0.05 with Bonferroni corrections for multiple comparisons ($0.05/5 = 0.01$) indicated statistical significance. Subject perceptions of security/stability and comfort during flat surface and stair ambulation with each device were compared with Wilcoxon signed rank tests.

RESULTS

As expected, the articulated ESFOS base produced a significantly larger device angle at initial ground contact than the axillary crutch (17.1° vs. 13.8°). The greater device-ground angle observed during ESFOS use created a greater anterior-posterior distance between the device base and the foot of the subject's full-weight-bearing lower-limb during stance. Associated with the larger anterior-posterior base of support, we expected to observe a stride length increase during ESFOS use. Statistically significant differences, however, were not observed for this variable. Variables considered indicative of comparable effort and technique between conditions are presented in **Table 2**. Subjects exceeded the target 50-percent weight-bearing reduction at the involved lower limb similarly with each device (153.1 and 152.8 N over target values for axillary crutches and the ESFOS, respectively). Biomechanical and physiological results are presented in **Table 3**. Mean peak palmar force magnitude was significantly reduced by 45 percent (111.1 vs. 201.8 N), and mean peak palmar pressure was significantly reduced by 50 percent (6.4 ± 5 vs. 12.7 ± 4 N/cm²) during flat surface ambulation when subjects used the ESFOS. Mean peak palmar force onset timing was significantly delayed by

54 percent (1.34 vs. 0.61 s, following initial heel contact) during flat surface ambulation when subjects used the ESFOS. Mean peak plantar force onset timing was significantly delayed by 30 percent (0.97 vs. 0.68 s, following initial heel contact) when subjects used the ESFOS. EEI values were significantly reduced by 25 percent (0.77 vs. 1.03 beats/min) and perceived exertion values were significantly reduced by 63 percent (1.2 ± 1 vs. 3.2 ± 3) when subjects used the ESFOS. Subjects preferred the ESFOS to axillary crutches for comfort on flat surfaces (8.6 ± 1.8 vs. 6.8 ± 2.2 , $Z = -3.4$, $p = 0.001$) and on stairs (8.6 ± 1.4 vs. 6.2 ± 2.6 , $Z = -4.3$, $p < 0.0001$). Subjects also preferred the ESFOS to axillary crutches for security/stability on flat surfaces (9.2 ± 0.9 vs. 7.3 ± 2.3 , $Z = -3.9$, $p < 0.0001$) and stairs (8.7 ± 1.4 vs. 6.6 ± 2.8 , $Z = -3.6$, $p < 0.0001$).

DISCUSSION

In addition to reduced mean peak palmar force magnitudes, other differences suggest superior biomechanical and physiological characteristics during ESFOS use by this subject group. The greater device angle (measured from vertical) of the ESFOS at the instant of initial ground contact created a larger, potentially safer support base between the device and the full-weight-bearing lower limb during stance phase compared to axillary crutches. Since appropriate stance phase foot placement for the partial weight-bearing side was in alignment with the ambulatory assistive device, a longer stride length was expected during ESFOS use. The 1 cm mean stride length increase, however, was not statistically significant. Reduced EEI and 10-category Borg perceived exertion scale values were observed during ESFOS use, even during this relatively short duration, submaximal effort, and continuous study task. More favorable subject survey responses for perceived stability/security and comfort on flat surfaces and stairs provide further support for the ESFOS compared to axillary crutches. These results suggest that ESFOS use reduced physiological demand during ambulation on both flat surfaces and stairs during modified 3-point gait, as subjects attempted to maintain approximately 50-percent weight-bearing at the involved side. Because gait velocity did not differ between conditions, the reduced heart-rate increase observed during ambulation with the ESFOS compared to axillary crutches appears to be the primary EEI-reducing factor.

Table 2.
Gait effort and technique variables.

Variable	Axillary Crutches Mean \pm SD	ESFOS Mean \pm SD	<i>p</i> -Value
Amount > Target Plantar Force (N)	153.1 \pm 164	152.8 \pm 137	0.99
Self-Selected Gait Velocity (m/min)	13.2 \pm 3.9	12.9 \pm 3.4	0.58
Resting Heart Rate (beats/min)	80.6 \pm 14	80.8 \pm 13	0.72
Mean Exercise Heart Rate (beats/min)	93.6 \pm 15	90.6 \pm 15	0.03
Stride Length (m)	0.77 \pm 0.13	0.78 \pm 0.11	0.81
Stance Time (s)	1.67 \pm 0.68	1.89 \pm 0.73	0.19

SD = standard deviation

ESFOS = Easy Strutter Functional Orthosis System™

Table 3.
Biomechanical and physiological results during flat-surface ambulation.

Variable	Axillary Crutches Mean \pm SD	ESFOS Mean \pm SD	Mean Difference	<i>F</i>	<i>p</i> -Value
Mean Peak Palmar Force (N)	201.8 \pm 81	111.1 \pm 91	90.7	20.2	0.0001*
Mean Peak Palmar Force Onset (s)	0.61 \pm 0.59	1.34 \pm 0.95	0.73	15.3	0.0001*
Mean Peak Plantar Force Onset (s)	0.68 \pm 0.28	0.97 \pm 0.53	0.29	7.1	0.01*
Energy Expenditure Index (beats/m)	1.03 \pm 0.53	0.77 \pm 0.44	0.26	5.8	0.01*
Perceived Exertion	3.2 (moderate)	1.2 (very low)	2.0	14.5	0.0001*

**p* \leq 0.01

SD = standard deviation

F = ratio of between-group variance to error variance

ESFOS = Easy Strutter Functional Orthosis System™

These results suggest that patients with poor exercise endurance may benefit from ESFOS use. Similar target plantar force magnitudes and gait velocities between conditions suggest that subjects approached each test trial with similar effort, regardless of which assistive device they used. The limited practice time during testing may not have enabled subjects to optimize their function during gait with the more novel and more skill-dependent ESFOS. The more novel movement available through the articulated axillary support and base segments of the ESFOS device may have led subjects to use a less than optimal stride length in an attempt to maintain appropriate weight bearing. With further practice, we would expect to observe a greater stride length during ESFOS use compared to axillary crutches. Because limited insurance reimbursement for gait training is a realistic concern, further study is needed to describe the minimum training requirements for patients to optimize performance with the technologically more sophisticated ESFOS device.

Mean peak palmar and plantar force onset timing also differed between devices. During ambulation with axillary crutches, mean peak palmar force onset timing

occurred during the initial 40 percent (mean onset at 0.68 s) of stance phase following initial ground contact (mean total stance time of 1.67 s), suggesting that maximal palmar forces were developed to offset the impact forces of initial weight acceptance. During ambulation with the ESFOS, mean peak palmar force onset timing occurred at 71 percent of stance phase (mean onset at 1.34 s) following initial ground contact (mean total stance time of 1.89 s), suggesting that upper-limb forces were developed either to facilitate forward propulsion or to assist with device guidance during advancement. During ambulation with axillary crutches, mean peak plantar force onset timing occurred during the initial 36 percent (mean onset of 0.61 s) of stance phase following initial ground contact (mean total stance time of 1.67 s). As with the upper limbs, this suggests lower limb force production to reduce impact forces. During ambulation with the ESFOS, mean peak plantar force onset timing occurred at 51 percent of stance phase (mean onset of 0.97 s) following initial ground contact (mean total stance time of 1.89 s), suggesting lower-limb force production to facilitate forward propulsion.

The combination of reduced and delayed mean peak palmar forces, delayed peak plantar force onset timing, reduced EEI, and perceived exertion, as well as subject perceptions of greater security/stability and comfort, suggest that the ESFOS was superior to axillary crutches during flat surface and stair ambulation using a modified 3-point gait pattern with 50-percent weight bearing at the involved side. An important consideration that will ultimately influence ESFOS efficacy, however, is the \$475 per unit retail cost, compared to the \$48 per unit retail cost of the comparison device. The substantially greater cost for the ESFOS suggests that it should be prescribed primarily for patients who will require relatively long-term ambulatory assistive device use.

Our results are encouraging and support further study of the ESFOS with other patient populations and additional movement patterns (including transfers). Studies involving patients with impaired upper-limb strength/endurance or poor cardiopulmonary endurance (from neuromuscular or cardiopulmonary system conditions) are particularly recommended, with a more detailed analysis of physiological variables, including anaerobic and aerobic metabolism via blood lactate, anaerobic threshold, and VO_2 measurements. Concurrently, more detailed biomechanical study of internal joint moments will better delineate upper and lower-limb joint forces, and electromyography would document muscle function during gait. Despite the perceived comfort expressed by subjects on both the flat surface and stairs during this relative short duration and short distance task, the increased axillary weight bearing associated with ESFOS use warrants further study of potential changes in axillary neurovascular function during regular and long-term use. Future studies are also recommended using nerve-conduction velocity and blood-flow testing (plethysmography or Doppler) techniques to confirm the capacity of the ESFOS orthotic axillary support for providing long-term, safe axillary weight bearing.

CONCLUSION

Reduced and delayed mean peak palmar forces, delayed mean peak plantar forces, reduced EEI, and perceived exertion values and greater perceived stability/security and comfort on the flat surface and stairs suggest that the ESFOS provides a biomechanically and physiologically more efficient gait than axillary crutches during

modified 3-point ambulation. Based on these promising findings, continued study of the ESFOS with other patient populations is encouraged.

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