

Patient Preference and Physical Demand for Hands-Free Single Crutch vs Standard Axillary Crutches in Foot and Ankle Patients

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Abstract

Background: Weightbearing restrictions following foot and ankle surgery require the use of appropriate assistive devices for nonweightbearing ambulation during the recovery period. Selecting an appropriate assistive device that safely optimizes mobility and participation in daily activities is important to patient compliance and satisfaction. The purpose of this study was to compare physiologic demand, perceived exertion, and patient preference between a hands-free single crutch (HFSC) and standard axillary crutches (SACs) in foot and ankle patients.

Methods: Using 44 preoperative orthopedic foot and ankle patients who had a mean age of 32 (19–51) years, a prospective, randomized, crossover study was performed. The sample consisted of 35 males and 9 females. The mean body mass index (BMI) was 26 (19–36), the mean height was 1.7 m, and the mean weight was 82 kg. Patient data and preactivity heart rate were recorded for all patients, who were then randomized to either an HFSC or SACs. Each patient was randomly assigned to the device they would utilize first using a random number generator. They then crossed over to the other device after vitals returned to within 10% of their baseline heart rate. Every subject completed a 6-minute walk test (6MWT) using both assistive devices in a crossover manner. Immediately following each 6MWT, postactivity heart rate, self-selected walking velocity (SSWV), perceived exertion using the OMNI Rating of Perceived Exertion (OMNI-RPE), and perceived dyspnea using the Modified Borg Dyspnea Scale were obtained. After completing both 6MWTs, patients were asked which assistive device they preferred the most.

Results: The HFSC was preferred by 86% of patients. Significantly lower dyspnea scores (2.8 vs 5.3; $P < .001$), fatigue scores (2.4 vs 5.5; $P < .001$), preactivity and postactivity change in heart rate (28 vs 46 bpm; $P < .001$), and mean postactivity heart rate (107 vs 122 bpm; $P < .001$) were found using the HFSC compared with the SACs. The SAC group trended toward a higher SSWV (0.8 vs 0.77 m/s; $P = .08$). Those with a BMI greater than 25 also preferred iWALK over SACs ($P < .05$). Neither group had any falls. Sixty-eight percent of patients complained of axillary/hand pain with the SACs, while 7% complained of proximal leg strap discomfort with the HFSC.

Conclusion: The results of the current study in our relatively healthy cohort found that foot and ankle patients who were nonweightbearing preferred the HFSC over SACs. They experienced less physiologic demand as well as discomfort and perceived less exertion when using the HFSC compared with SACs.

Level of Evidence: Level II, prospective comparative study.

Keywords: assistive devices, iWALK, crutches, fatigue, hands-free crutch, 6-minute walk test, perceived exertion

Following lower extremity surgery or injury, patients often require the use of ambulatory assistive devices for mobility and assistance with activities of daily living (ADLs). Standard axillary crutches (SACs), walkers, canes, wheeled knee walkers, and wheelchairs are among the assistive devices prescribed to patients during periods of nonweightbearing as well as protected or partial weightbearing. There

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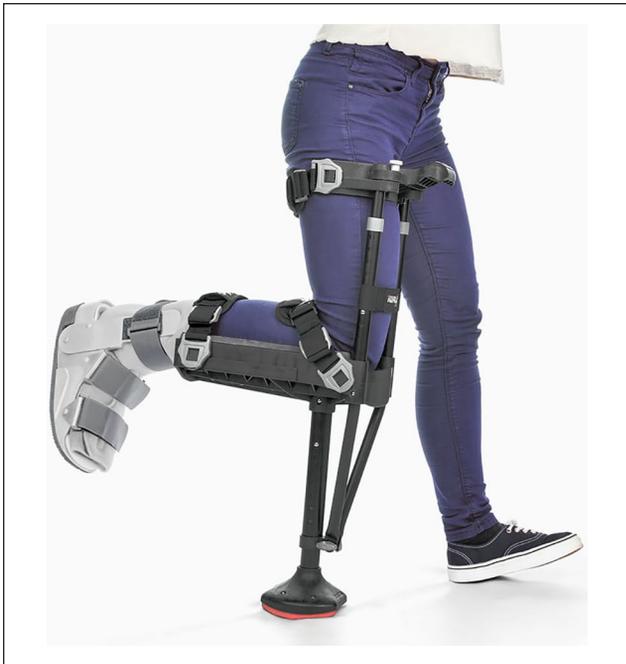


Figure 1. Demonstrates hands-free single crutch (iWALKFree) being worn and its capabilities to be used with nonweightbearing modalities such as CAM boot or short leg cast.

is an estimated 2.9 million Americans requiring the use of these devices.^{7,27} It has been shown that patients are poorly compliant with prescribed weightbearing precautions.¹⁶ Selecting an appropriate assistive device is multifactorial and should be patient specific to improve patient compliance and optimize mobility and safety.^{3,4} Factors to consider include ambulation requirements, weightbearing restrictions, concomitant upper and/or lower extremity disabilities, cognitive function, balance, fitness level, and patient preference.⁸ SACs are the most frequently prescribed ambulatory assistive device; however, they can be awkward and difficult to use. Furthermore, SACs have demonstrated a substantial energy cost compared with normal gait and standard walkers, and they have also been associated with injury.^{13,17,18,22}

As technology and assistive devices continue to improve, healthcare providers have the opportunity to prescribe alternatives that may be associated with improved patient compliance, satisfaction, and quicker return to work. Recently, the hands-free single crutch (HFSC) (iWALKFree, Mansfield, ON) has gained popularity as one of these alternatives (Figure 1). These devices claim to allow for greater comfort, stability, and mobility compared with SACs. In theory, the HFSC also decreases the risk of upper extremity neurovascular injuries compared with crutches. However, no study has directly compared the use of SACs with the HFSC in actual foot and ankle patients with regard to physiologic cost, function, fall risk, and overall patient satisfaction. Understanding these factors

could aid healthcare providers in determining an appropriate ambulatory device that is patient specific.

We hypothesized that compared with SACs, the HFSC would be associated with reduced physiologic demand parameters, perceived exertion, and increased patient preference. The purpose of this study was to compare the physiologic demand and perceived exertion of foot and ankle patients while using SACs versus an HFSC. We also sought to identify patient preference between the 2 devices.

Methods

The current study was a prospective, randomized, crossover-controlled trial comparing 44 preoperative foot and ankle surgery patients' physiologic demands, perceived exertion, and preference while using SACs versus an HFSC (iWALKFree). A power analysis was performed in combination with a generalized power estimation using similar historic papers as there are no known previous studies comparing the 2 devices. Study subjects consisted of preoperative patients within a single orthopedic foot and ankle clinic, between the ages of 18 and 65 years old, community ambulators who required greater than 4 weeks of nonweightbearing. Patients were excluded if they had a symptomatic cardiovascular or respiratory condition, contralateral injury or limiting neuromuscular condition, and inability to perform the functional tests. The subjects, 35 males and 9 females (19-51 years), had a mean age of 32 years. The mean body mass index (BMI) was 26.68, mean height 1.75 meters, and mean weight 82.3 kg.

All subjects underwent a preoperative functional evaluation, where demographic information was collected and included age, gender, height, weight, and BMI. All evaluations were conducted by a single clinical orthopedic foot and ankle surgeon and supporting cast technician in a clinical setting at approximately 5600 feet above sea level. Subjects were randomized into separate groups using a smartphone clinical randomizer trial application: group A started with SACs and group B started with the HFSC. Patients that were injured and currently using a splint or CAM boot were tested in their respective device. All others who were undergoing elective procedures for chronic conditions were fit with a CAM boot to the operative leg to replicate postsurgical conditions. Each assistive device was fit and sized by the senior author prior to initiating testing to ensure consistency. Prior to testing, all subjects were given a brief tutorial on each device and an explanation of proper mechanics and use, followed by 30 feet of ambulation and familiarization. All testing was performed on a single clinical visit.

Testing

Each subject was randomly assigned to which device they would utilize first. This was done using a random number

generator. They then crossed over to the other device after vitals returned to within 10% of baseline. Both ambulatory assistive devices were tested using a modified version of the American Thoracic Society guidelines for the 6-minute walk test (6MWT).² The 6MWT measures the distance the subject travels over a 6-minute period. The test has been previously shown to reflect endurance and functional capacity⁶ and discriminate validity in lower limb amputations^{10,12,22} while serving as a standard for submaximal functional test. The 6MWT has also served as a means of evaluating cardiac and pulmonary treatments due to its proven consistency.⁶ Vital signs, perceived exertion, and dyspnea scores (the patients were asked on a 0-10 scale [0, not short of breath, to 10, feeling very short of breath] where it was difficult to catch their breath) were obtained at baseline, prior to, and immediately following each 6MWT. The test was performed in a single, straight, seldomly used hallway, which allowed for a 30-m straight path with the start, halfway point, and finish lines marked with blue tape. Subjects rested between trials until their heart rate returned to a steady state within 10% of their initial resting heart rate.

After completing 6 minutes, the distance was recorded and the meters per second was calculated, providing the self-selected walking velocity (SSWV). The SSWV has previously been validated to reflect falls risk and functional level of ADLs, while also serving as a standard against which individuals can be compared.^{11,20} Immediately upon completion of the walk, subjects completed the OMNI Rating of Perceived Exertion (OMIN-RPE) worksheet. The OMIN-RPE worksheet is a worksheet with pictures and numbers to represent fatigue. The patients were given the sheet and asked to pick a number between 0-10, with zero being not tired at all, and 10 being very, very tired. They were told that there was no right or wrong answer and just how their bodies felt both with numbers and pictures (Figure 2). Perceived exertion is paramount when selecting an assistive device²⁵ as it correlates with physiological stress.^{13,14} After completion of both trials, the participants were asked which device they would prefer to use after surgery and the chief complaint of the rejected device.

Statistical Analysis

Descriptive statistics (mean values) were performed on all variables. The means for HFSC and SAC results (blood pressure [pre and post], change and worsening of blood pressure, heart rate [pre and post], fatigue, dyspnea, distance, falls) were compared. Subjects were also grouped by blood pressure (elevated, high stage 1+, normal), gender, high dyspnea greater than 5, and fatigue score greater than 5 for analyses. Elevated blood pressures were determined using the Mayo Clinic published blood pressure chart (<https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/blood-pressure/art-20050982>,

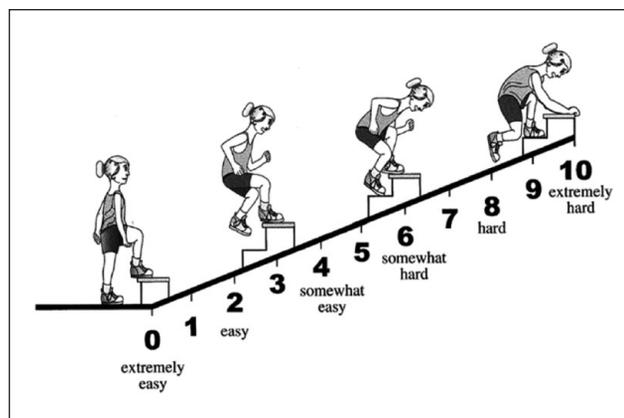


Figure 2. The OMNI Rating of Perceived Exertion (OMIN-RPE) worksheet for adults.

May 2018). Obesity was determined using National Institutes of Health classification (https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi_dis.htm). Regression analyses (Microsoft Excel, Redmond, WA) were used to determine if there was a difference between groups. Variables of preference, HFSC fatigue, SAC fatigue, HFSC dyspnea, and SAC dyspnea were analyzed against age, gender, height, weight, and BMI. Preference was also analyzed against the presence of an acute injury. Regression analysis (Microsoft Excel) was used to test if factors such as gender, height, weight, and BMI predicted patient preference of SACs or HFSC. Paired 2-sample *t* tests were used to compare the differences in systolic and diastolic blood pressures pre- and post-HFSC versus SACs, respectively. Student *t* tests were performed separately for dyspnea and fatigue ratings, distance (meters), and heart rate.

Results

There were no interactions found for preference by age, gender, or BMI; however, those with BMI >25 did prefer HFSC over SACs ($P < .05$). There were 10 subjects with normal blood pressure before HFSC versus 7 in the normal range before SAC use; conversely, there were 34 subjects with abnormal (elevated to high) blood pressure before HFSC versus 37 abnormal (elevated to high) before SAC use. After HFSC, 16 subjects experienced blood pressure changes, 15 with worsened blood pressure and 1 subject with improved blood pressure. After SAC use, 17 subjects experienced blood pressure changes, 14 of those with worsened blood pressure and 3 subjects with improved blood pressure. Heart rates for both groups were comparable with a mean of 79 bpm and 76 bpm for HFSC and SACs, respectively. There was a higher heart rate after SAC use than HFSC, with a higher difference from pre- to postuse of SACs than HFSC. Dyspnea or fatigue for both HFSC and SACs was not significantly affected by age, gender, BMI,

Table 1. Preference, High Fatigue, High Dyspnea, and Associated Pain.

	HFSC % (Absolute No.)	SAC % (Absolute No.)
Preference	86 (38)	14 (6)
5+ fatigue	14 (6)	61 (27)
5+ dyspnea	11 (5)	57 (25)
Associated pain	7 (3)	68 (30)

Abbreviations: HFSC, hands-free single crutch; SAC, standard axillary crutch.

or individual height or weight. There was a difference of dyspnea rating in HFSC versus SAC use, with averages of 2.8 and 5.3, respectively. Thirty-one of the 44 subjects noted a high rating (≥ 5) of dyspnea after SAC than HFSC use. There was a difference of fatigue rating in HFSC versus SAC use with averages of 2.4 and 5.5, respectively. Twenty-seven of the 44 subjects had a fatigue rating of 5 or greater with the use of SACs versus 6 subjects with a fatigue rating of ≥ 5 with HFSC use.

Significant differences were found for dyspnea, fatigue, and heart rate between HFSC and SAC use ($P < .05$, $P < .001$, $P < .001$, $P = .04$, $P < .001$, respectively). Single-factor analyses of variance were performed, which confirmed the significant P values for dyspnea, fatigue, and heart rate. A paired t test for distance yielded no significant differences in values, as did systolic blood pressure measurements before and after HFSC versus SACs for the 6MWT. All confidence intervals were set to 95% for this sample.

Fatigue and dyspnea were both rated on a 1 to 5 scale, with 1 being very little to no fatigue or dyspnea and 5 being extreme fatigue or very short of breath. Both were asked immediately upon completion of each 6MWT and recorded. Each subject was then asked if there was any pain or discomfort or complaints with the device, and the documented associated pain or complaints were recorded. After completion of both 6MWTs, subjects were then asked which device they preferred (Table 1).

The dyspnea, fatigue, and distance traveled were the means of all 44 patients. The percentage heart range change was from the initial set of vital signs to the vitals taken immediately upon completion of each of the 6MWTs. The

means were then compared using paired t tests, and their correlating P values are listed, demonstrating statistical significance for dyspnea, fatigue, and percent heart range change. The distance traveled, although further with the SACs, did not demonstrate statistical significance (Table 2).

Discussion

This prospective, randomized, crossover-controlled study compared HFSC and SACs for nonweightbearing and demonstrated that patients preferred the HFSC to SACs while experiencing less discomfort and less physiologic fatigue. Several methods have been used to evaluate physiologic demand and energy expenditure while using assistive devices. In a laboratory situation, portable VO_2 monitoring is objective and accurate²⁶; however, in a clinical setting with real patients, it is functionally impractical. In the current study, we utilized the 6MWT to replicate the physiological requirements of ADLs.⁶ The 6MWT is validated and has been used to assess exercise tolerance and functional capacity.⁶ The test also served as a means to calculate the SSWV, which has also been validated to assess fall risk and ADL capacity.^{1,6} The physiologic stress from testing allowed subjects to subjectively rate perceived exertion and dyspnea after utilizing each device. In our study, we utilized SACs as an individual control allowing a true head-to-head comparison of the HFSC. Our results demonstrated near-equivocal 6MWT results with participants completing 272 m at 0.76 m/s for the HFSC and 299 m at 0.83 m/s for the SACs. While using the HFSC, participants demonstrated less physiologic demand with 24% change in heart rate (increase average of 28 bpm) compared with 63% (increase average of 46 bpm) while using the SACs. These results correlated with the patient-reported subjective OMNI perceived exertion and fatigue levels of 2.8 and 2.4, which were nearly half those of their reported SAC levels of 5.3 and 5.5, respectively. These findings suggest that physiologic stress and perceived exertion weigh heavily on patient preference and satisfaction.

Traditionally, practitioners distribute axillary crutches and then secondarily consider requesting other devices such as knee scooters and walkers. Prescribing SACs remains the standard, but this practice does not take into consideration the individual patient physiologic demands, capabilities, and preferences. In our current era of evidence-based

Table 2. HFSC vs SAC.

Variable Mean Scores	HFSC	SAC	P Value
Dyspnea	2.8	5.3	<.001
Fatigue	2.4	5.5	<.001
Distance	272	299	.08
HR % change	0.24 (30 bpm)	0.63	<.001

Abbreviations: HFSC, hands-free single crutch; HR, heart rate; SAC, standard axillary crutch.

practice, each assistive device should meet the needs of the specific patient. Each patient's cognitive function, physical endurance, balance and coordination, living environment, judgment, vision, and upper body strength should be considered to maximize compliance and rehabilitation.^{14,27} The HFSC was more recently developed by a farmer looking for a way to return to work while recovering from a lower extremity injury. Even with his initial primitive design, he was able to return to full manual labor and daily farm chores while remaining nonweightbearing on his affected side. The HFSC achieves nonweightbearing by creating a 2-point alternating gait pattern. This pattern requires better balance as the patient must coordinate moving an ambulatory assistive device with the contralateral lower extremity.¹⁸ However, this pattern is unique in the fact it creates an energy-efficient reciprocal gait, allowing both lower extremities to participate in force generation and forward propulsion.^{12,19} The HFSC 2-point gait also narrows the force vectors, which allows improved efficiency while allowing maneuverability in close spaces without altering gait cadence. Much like a through-the-knee prosthesis, the HFSC provides end-bearing proprioception, which allows for improved feedback for walking stability.^{12,21} End-bearing also prevents stress shielding and allows the entire femur and pelvis to maintain cortical stress and theoretically less disuse osteopenia.²⁴ In our military population, femoral neck osteopenia is very important. We have a very high rate of femoral neck stress fractures. Returning to duty with disuse osteopenia increases our service members' risk of further injury; thus, mitigating this risk is of the utmost importance. It should, however, be pointed out that this device does not allow for partial or progressive weightbearing to the extremity; thus, patients who need this due to healing or bone quality would have to switch devices during that time period of PWB.

Due to the lack of publications on the HFSC, we must compare our results to previous ambulatory assistive device literature. In the current study, our patients were able to ambulate on average 0.76 m/s, which has been associated with community ambulation²¹ and independent self-care.^{1,5} As a comparison, a previous study demonstrated an SSWV of 0.38 m/s for a front-wheeled walker and 0.37 m/s for a standard walker.¹³ A more recent study of the 6MWT with similar patient demographics using a wheeled knee walker reported similar results to this study, with the exception of a faster SSWV; however, these findings are confounded in that their population was healthy volunteers and uninjured and used their dominant leg for propulsion.¹⁵ Even though our study did not directly compare HFSC with the front-wheeled scooter, it should be mentioned for completeness. The HFSC does provide an alternating gait pattern with a narrow base and does require a higher level of coordination and balance and thus may not be a good choice for every patient. The scooter is also an alternative, which allows for

nonweightbearing, like the HFSC, and also does not allow partial weight bearing as tolerated. However, it does have a seat and handles and allows for the patient to sit if they need to. It may be a better choice for those with minimal endurance or poorer coordination, but there have been no studies directly comparing the 2 to our knowledge.

SACs can achieve nonweightbearing status by using either a swing-to or swing-through gait pattern. Each of these patterns requires the movement of both crutches simultaneously, followed by a large center of mass oscillation,¹⁵ which requires the hands to bear 1.14 to 3.36 times the body weight while the chest wall is exposed to up to 11% body weight.²³ These physiologic loads to the upper extremity correlate with our findings that 68% of participants reported hand and axillary pain in only 6 minutes of submaximal effort. Our participants also reported crutch fatigue scores on average of 5.52, with 3 participants stopping prior to completing 6 minutes, which similarly correlates with Waters et al,²⁸ who reported that crutch walking for 10 minutes approached the peak values for maximal upper extremity exercise. Our participants also demonstrated a 63% change in heart rate with associated perceived dyspnea of 5.3 following the 6MWT, which directly correlates with those of Fisher and Patterson⁹ and Kocher et al,^{15,26} who found that use of crutches results in twice as much oxygen consumption and heart rate increase compared with baseline. Kocher et al¹⁵ utilized a similar military population and reported a similar 6MWT distance (317/290 m), SSWV (0.9/0.8 m/s), and exertion (6.2/5.5), which further strengthens the consistency of our results and demonstrates the impact of crutches on a young active population.

The limitations of this study include the inconsistency of patients' injuries (acute trauma vs chronic injury) and their recent exposure or necessity to use SACs at the time of the study. Although all patients were indicated for some type of foot and ankle surgery, there was considerable variability in surgical indications as well as timing of surgery. For example, some patients sustained high-energy parachute landing falls with fracture dislocations, whereas others were having surgery for chronic osteochondral lesions and recurrent ankle instability. The injury pattern created variability in terms of utilizing the dominant versus nondominant leg as the support leg, as well as the method of immobilization. Another noted limitation of this study was that leg dominance was not evaluated or recorded; therefore, data and results could not be used to determine if there were any significant differences based on this variable. Some patients had large bulky splints in place, whereas others with chronic injuries were placed in simple CAM boots to replicate postoperative treatment. Another limitation was current patient experience with each device; recent trauma patients were utilizing SACs for days to weeks prior to testing, whereas no patients had prior experience using an HFSC. All testing was performed on a level

surface and did not take into account the realities of uneven terrain faced by patients in normal day-to-day activities. Additionally, we recognize that our patient population, which was mostly composed of active duty service members, who usually have few medical comorbidities along with better balance and coordination, does not reflect the heterogeneity of the general public, and therefore one must be cautious applying our results to the general population.

Conclusion

In conclusion, this study demonstrated that an HFSC was a reasonable alternative to other assistive devices in foot and ankle surgical patients. The HFSC demonstrated superior patient preference, perceived exertion, and physiological demand compared with SACs in an otherwise healthy cohort of mostly active duty service members. This is the first validation study using an HFSC; however, further research is needed to help establish clinical practice guidelines and empower providers to prescribe assistive devices based on individual patient physiological and environmental needs.

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