Prospective Clinical Evaluation Comparing Standard Axillary Crutches vs. The HANDS FREE Crutch

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ABSTRACT

Purpose: A new device which allows hands free ambulation whilst being non-weight bearing unilaterally was developed. The purpose of this pilot study was to compare this newly developed Hands Free Crutch (HFC) to standard axillary crutches (SAC) with respect to patient acceptability/preference, comfort, function and safety.
Methods: This pilot study used a crossover design with 6 patients having lower extremity foot and/or ankle injuries randomized to two-weeks of using one type of crutch followed by two-weeks of the other type of crutch. Function was measured after both time periods using the MFA and SF-36 questionnaires, in addition to eliciting information regarding patient acceptability, comfort and feelings of safety. Quantitative analysis was undertaken using paired non-parametric statistical tests (WSR and sign test).
Results: Age ranged from 17 to 45 years (mean 31 years). All patients found the HFC easy to learn and use. All found the HFC easy to ambulate with, while 3/6 found ambulating with SAC difficult although the small sample precluded reaching statistical significance ($p=0.08$). Similarly activities of daily living were easier to accomplish with the HFC ($p=0.07$). None of the patients found the HFC to be uncomfortable, while 2/6 found the SAC to be uncomfortable. Only one patient preferred the SAC overall. The HFC was associated with a better overall MFA score ($p<0.05$), better coping ($p<0.05$), and a trend toward better lower extremity function and activities around the house ($p=0.07$). SF-36 physical function tended to be better with the HFC ($p=0.08$) in addition to SF-36 vitality ($p=0.07$). The HFC was well-accepted, safe and easy to use. There was a clear trend for better function with the HFC.
Significance: Patients who need to be non-weight bearing due to pathology below the knee now have the ability to maintain use of their upper extremities with the HFC. Potential applications are many.

INTRODUCTION

A unilateral musculoskeletal injury to the lower extremity can render a limb unable to bear weight, either due to pain or due to the nature of the injury, which may be worsened by weight bearing. To solve this problem crutches are used to eliminate weight bearing through the affected extremity while still allowing ambulation. Crutches have been in use for centuries. Crutches have been depicted in Egyptian tombs to as far back as 2830 B.C.[1] Throughout history, various crutch apparatuses have been studied, introduced and utilized for patients with restricted weight bearing.[2-5] The standard axillary crutches (SAC) (Fig. 1) are still predominately used in North America even though there are existing alternatives. This is perhaps owing to the fact that the SAC is economical and an alternative has not yet demonstrated superiority over the SAC. Although the SAC is in common usage numerous authors have described potential drawbacks of the SAC. Previous work by Goh et al. has demonstrated that leaning on the SAC during ambulation produces a sevenfold increase in the force that runs through the axilla.[6] Indeed, this increased force through the axilla can lead to bilateral brachial plexus compressive neuropathy (crutch palsy)[7], axillary artery aneurysms[8], acne mechanica[9], and suprascapular neuropathy.[10] Additional complications can arise from prolonged SAC use such as shoulder joint degeneration[11]and carpal tunnel syndrome.[12,13] Driver-Jowitt has even described a case of death due to crutch use caused by over exertion.[14] Fatigue and difficulty of use are other detriments experienced by users of SAC's.[3] The limitatations inherent in the design of the SAC led one of our patients to develop an alternative. His desire to continue working as a farmer after his calcaneus fracture was not possible without the use of his hands. Hence, he developed a device which fully relieves the upper extremities of bearing weight yet still allows the injured limb to remain non-weight bearing during ambulation. This device called the Hands Free Crutch (HFC) (Fig. 1) transmits weight through the flexed knee, thus avoiding weight bearing through the remaining lower extremity, and allowing full use of the upper extremities. The HFC mimics the peg leg that was used in earlier centuries for individuals suffering from leprosy and amputation.

The purpose of this preliminary investigation was to evaluate the early design of the HFC with respect to function, comfort, patient preference, and safety in comparison to the SAC.

METHODS

Patients 16 to 60 years of age with a unilateral below knee injury requiring non-weight bearing for a minimum of four weeks were considered eligible for this pilot study. The decision regarding weight-bearing status was made independently by the treating physician prior to fracture clinic referral or follow-up. Patients were not included if they were unable to communicate in English or cognitively impaired. Similarly patients living outside of Canada were not included to avoid loss of follow up. Patients with a concurrent orthopaedic injury or previous total hip or total knee replacement were also excluded. Prior to commencement of the study approval was granted by the hospital's ethics board.

Two types of crutches were used in this study. Six pairs of wooden SAC's were used weighing 1.9kg per pair and six prototype HFC's were used also weighing 1.9kg each. The HFC overall length was 36" and the tibial tray that held the knee flexed was 12.5" in length. After obtaining informed and written consent, patients were randomized to either a HFC or SAC for the first two-week period. Pre-injury demographic data and function data were collected using the pre-injury form of the MFAI and a SF-36 survey. The SF-36 and the Musculoskeletal Function Assessment Instrument (MFAI) were both used to gather functional outcomes. The SF-36 is a validated general health status measurement instrument for which US normative data is available.[15] The MFAI was developed specifically for the evaluation of outcomes following traumatic musculoskeletal injuries. This instrument has also been fully validated, however to date no normative population data has been published.[16,17] After randomization, patients were fitted and taught crutch walking in the fracture clinic with the appropriate crutch. Standard SAC crutch

teaching and fitting was used.[18] When patients were randomized to the HFC we measured the unaffected limb from the mid patella to the floor to determine the height of the tibial tray. We then adjusted the thigh straps accordingly. Instruction was given on HFC walking in the fracture clinic until patients felt comfortable ambulating in the device. For potential safety reasons patients were also given a SAC. After the first two-week non-weight bearing period patients returned for a follow-up visit completing a second MFAI and SF-36 survey, as well as a crutch-specific survey that evaluated their experience for the assigned crutch with respect to patient comfort, acceptability, safety, and other crutch specific outcomes (Appendix 1). Patients were then crossed over to the other assigned crutch for a further two-week period after which a third MFAI, SF-36 and crutch-specific survey was completed. Patients also provided an overall preference rating on this second crutch-specific survey.

Statistical Methods

As the main purpose of this pilot study was to establish safety and acceptability of the HFC, the analysis was largely qualitatative and descriptive. For the functional outcome comparisons a desktop PC running SPSS version 10.0 for Windows 95 was used. HFC – SAC differences were analyzed using paired non-parametric statistical tests (WSR and sign test). All statistical tests were two-sided using a 5% significance level. The pre-injury baseline MFA and SF-36 surveys were excluded from the analysis as it was obvious that at least 3 of the 6 patients misunderstood that these surveys were to represent the pre-injury state (i.e., functional outcome appeared to be much worse pre-injury).

RESULTS

Study Cohort Demographics

Six patients, 5 males and 1 female, mean age was 31 (range, 17 - 45 years), were assessed using validated functional assessment questionnaires (MFAI and SF-36) and a crutch-specific survey following each 2 week period on the assigned crutch. Demographic and injury characteristics of the study cohort are given in Table 1.

Patient Preference & Safety

As illustrated in Fig. 2, 5 out of 6 subjects (83%) preferred the HFC overall. There was no statistical difference with respect to safety. Only one patient felt safer when using the SAC, while 3 out of 6 patients felt unsafe at some point while using the SAC but did not feel unsafe at anytime while using the HFC. Two patients felt unsafe on both types of crutches.

Functional Outcome

All six patients completed the Musculoskeletal Functional Assessment Instrument (MFAI) and the SF-36 questionnaires following both two-week periods. The HFC was associated with a better (lower) overall MFAI score (16.0 ± 14.8 vs. 25.2 ± 18.23; $p<0.05$), better coping (20.4 ± 13.9 vs. 31.5 ± 30.6; $p<0.05$) and a trend toward better lower extremity function (25.8 ± 28.7 vs. 39.2 ± 34.6; $p=0.07$) and activities around the house (29.6 ± 34.2 vs. 48.2 ± 29.5; $p=0.07$). In fact, there was a trend toward better function in the scores for 8 out of the 10 MFAI subscales/categories. There was no statistically significant difference in any of the 8 SF-36 domains nor in the physical and mental component summary scores between the HFC and SAC crutches, although the score for the physical function (73.3 ± 28.2 vs. 52.5 ± 26.2; $p=0.08$) and vitality (72.5 ± 18.4 vs. 65.8 ± 13.6; $p=0.07$) domains tended to be better (higher) with the HFC. Also of interest was the perfect score of 100 for the role emotional domain when patients were

using the HFC, which seems to mirror the positive MFAI findings of being better able to cope when using the HFC.

The SF-36 analysis, which compares general health status to the normal United States population, indicated that when using the SAC, patients had a significantly lower score in both the physical and mental component summary scores, whereas, when using the HFC patients only had a significantly lower mental component summary score. Scores for 3 of the 8 SF-36 domains (physical function, role physical, and role emotional) were significantly lower than the U.S population norms, when using the SAC, as compared to only the score for role physical domain being significantly lower than the U.S. population norms when using the HFC. Table 3 summarizes the MFAI and SF-36 responses.

The analysis of the crutch specific surveys did not yield statistical significance in any of the categories, but ambulation (2.0 ± 0.0 vs. 3.0 ± 1.1; $p=0.08$) and activities of daily living (2.5 ± 1.2 vs. 4.0 ± 0.7; $p=0.07$) both approached the 5% significance level. Comparison of the responses to the crutch specific survey following each of the two-week time periods is summarized in Table 2.

DISCUSSION

Even in this small pilot study, patients experienced better overall function (including emotional function) when they were able to use their hands while being non-weight bearing for lower extremity injuries with the HFC. To further illustrate this the MFAI, SF-36 and the crutch specific survey all had trends towards better function, ambulation and activities of daily living. These findings coincide with other studies and anecdotal reports on similar hands free devices.[19,20] Another notable finding is the acceptability and vast preference towards the HFC. The patient's overall choice is an expression of satisfaction and is an important measure of

partiality. Also of interest was the fact that the subjects emotionally did better when using the HFC compared to the SAC, both the MFAI and the SF-36 demonstrated this. Intuitively it makes sense that the subjects would emotionally do better with the HFC since they are more functional and not feeling as incapacitated as they would with the SAC. This also explains the trend for higher vitality with the HFC.

We received a tremendous amount of rich qualitative data from the crutch specific survey. This data was not analyzed, but it did provide us with a better understanding and appreciation of the study subjects experiences. The general themes that emerged from the qualitative data are consistent with that of the quantitative data. The subjects commented on the luxury of having their hands free, particularly during activities of daily living. Patients also commented on feeling more mobile as articulated by one subject who commented "...it made me feel more normal as I could participate in more things." The majority of subjects also complained of pain and bruising in the axilla when they used the SAC. These comments on pain and bruising are in agreement with previous work reporting increased forces running through the axilla during SAC use.[6] Patients also responded that stair climbing was difficult and HFC application was time consuming. These issues need to be addressed in future HFC designs.

Safety during HFC use was not thoroughly proved or disproved. The one patient that felt unsafe on the HFC and safe on the SAC still selected the HFC in the overall preference rating. Just as ironic is the 1 patient who selected an overall preference for the SAC even though they felt unsafe on it and not unsafe on the HFC. Some of our patients felt unsafe on both crutch designs which tells us that crutches regardless of design require balance, strength and agility and a feeling of insecurity can be expected in some people.

It is plausible that other factors could have contributed to limited function. Potential extraneous variables such as time lapse from date of injury to date of enrollment, operative vs. nonoperative management and type of lower extremity injury could have all influenced the level of pain subjects experienced, thereby limiting their ability and desire to carry out functions. We did not build these variables into the entry criteria nor did we analyze the potential contribution of these factors on responses because we felt by randomizing and crossing over the subjects we achieved control and homogeneity in the groups.

We are not positive why half the subjects misinterpreted the pre-injury MFAI and SF-36 considering they were all labeled as such, but perhaps a more detailed explanation on filling out the surveys would have avoided this.

CONCLUSION

A HFC is a viable alternative for patients required to be non-weight bearing during ambulation. This pilot study has provided data that will guide the refinement of future HFC designs. Further research is needed to delineate the range of injuries for which this crutch might be appropriate and to study the effects of long-term use on knee extension, swelling and other soft tissue problems. Energy expenditure and gait analysis while using the HFC are other areas that have to be studied.

Table 1

Patient Demography

SUBJECT	SEX	AGE	INJURY
1	M	17	Fractured Distal Tibia
2	M	45	Ruptured Achilles Tendon
3	F	33	Ruptured Achilles Tendon
4	M	30	Fractured Talus
5	M	20	Fractured Talus
6	M	43	Ruptured Achilles Tendon

Figure 2

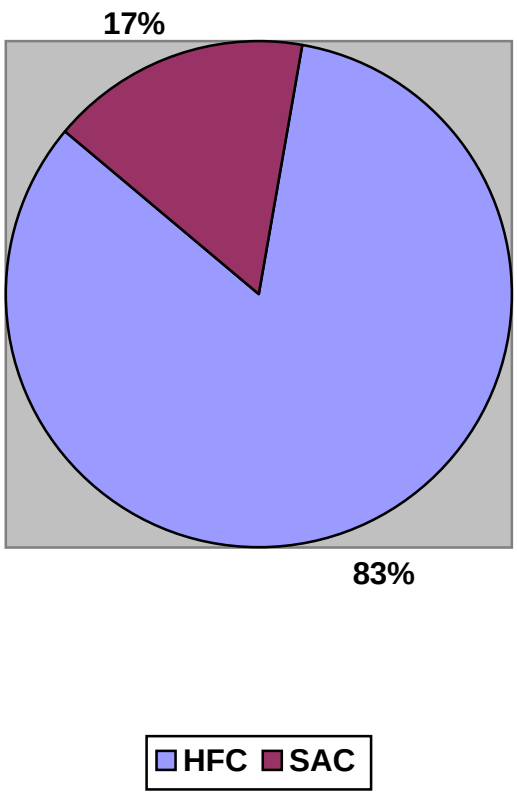

Table 2

TREATMENT	**Hands Free Crutch**			**Standard Axillary Crutch**			
CRUTCH SURVEY (best = 1)	*Mean*	*Median*	*SDev*	*Mean*	*Median*	*SDev*	*HFC – SAC Difference*
Learn	1.83	2.00	0.41	2.33	2.00	1.37	- 0.50
Ambulate	2.00 [5]	2.00	0.00	3.00	3.00	1.10	- 1.00
ADL	2.50	2.00	1.22	4.00 [5]	4.00	0.71	- 1.50
Comfort	2.00	2.00	0.63	3.00	3.00	1.41	- 1.00
Safe	0.50	0.50	0.55	0.80 [5]	1.00	0.45	- 0.30

Note: For some variables, data was not available for all patients; the n used in the analysis is given in the square brackets [n].

Table 3

MFAI (best = 0)	*Mean*	*Median*	*SDev*	*Mean*	*Median*	*SDev*	*US norms*	*HFC – SAC Difference*
Overall Score	16.00	11.50	14.79	25.17	23.00	18.23	NA	- 9.17 *
Movement	25.83	17.50	28.71	39.17	42.50	34.56	NA	- 13.33
Fine Motor	4.76	0.00	7.38	2.38	0.00	5.83	NA	2.38
Home	29.63	16.67	34.19	48.15	50.00	29.54	NA	- 18.52
ADL	9.26	8.33	10.34	14.81	11.11	14.34	NA	- 5.56
Sleep	5.56	0.00	8.61	13.89	16.67	12.55	NA	- 8.33
Leisure	41.67	50.00	34.16	54.17	50.00	40.05	NA	- 12.50
Relationships	5.00	0.00	8.37	10.00	0.00	20.00	NA	- 5.00
Cognition	0.00	0.00	0.00	0.00	0.00	0.00	NA	0.00
Emotional	20.37	13.89	21.28	31.48	30.56	22.95	NA	- 11.11 *
Job	0.00	0.00	0.00	12.50	0.00	20.92	NA	- 12.50
SF-36 (best = 100)								
Physical Component	44.78	48.73	6.37	43.23‡	42.83	3.83	50.00	1.55
Mental Component	35.74†	36.00	4.74	37.95‡	36.43	5.53	50.00	- 2.21
Physical Function	73.33	77.50	28.23	52.50¶	45.00	26.22	84.15	20.83
Role Physical	66.67†	75.00	37.64	29.17†	12.50	40.05	80.96	37.50
Bodily Pain	93.33‡	100.00	10.33	88.33	90.00	13.29	75.15	5.00
Social Function	85.42	93.75	18.40	70.83	56.25	34.16	83.28	14.58
Mental Health	83.33	82.00	9.27	84.00¶	86.00	6.20	74.74	- 0.67
Role Emotional	100.00[a]	100.00	0.00	72.17†	100.00	44.36	81.26	27.83
Vitality	72.50	75.00	18.37	65.83	67.5	13.57	60.86	6.67
General Health	73.50	77.00	19.61	80.17	82.00	16.47	71.95	- 6.67

*p<0.05 for test of mean difference between Hands Free Crutch and Standard Axillary Crutch

† p<0.001 for test of difference from US population norms for mean score

‡ p<0.01 for test of difference from US population norms for mean score

¶ p<0.05 for test of difference from US population norms for mean score

[a] t cannot be computed because the standard deviation is zero.

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