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THE EFFECT OF TRANSFEMORAL INTERFACE DESIGN ON GAIT SPEED AND RISK OF FALLS

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Falls and diminished walking capacity are impairments common in persons with transfemoral amputation (TFA). Reducing falls and optimizing walking capacity through such means as achieving a more normal gait speed and community ambulation should be considered when formulating the prosthetic prescription. Because walking capacity and balance confidence are compromised with TFA, these outcomes should be considered when evaluating interfaces for transfemoral prosthetic users. The purpose of this study was to compare the effect of TFA interface design on walking capacity and balance confidence A retrospective cohort design was utilized involving unilateral TFA patients who used ischial ramus containment (IRC) and High-Fidelity (HiFi) interfaces (independent variables). Dependent variables included the Activity-specific Balance Scale (ABC) and the two-minute walk test (2MWT). Complete records were available for 13 patients ($n = 13$). The age range was 26 to 58 years. Three patients functioned at the K4 activity level, whereas all others functioned at the K3 level. Mean ABC scores were significantly different ($p \leq 0.05$) at 77.2 (±16.8; 35.6 to 96.9) for IRC and 90.7 (±5.7; 77.5 to 98.7) for HiFi. The mean distance walked on the 2MWT was 91.8 m (±22.0, 58.3 to 124.7) for IRC compared to 110.4 m (±28.7; 64.7 to 171.1) for the HiFi socket ($p \leq 0.05$). Alternative transfemoral interface design, such as the HiFi socket, can improve walking capacity and balance confidence in higher-functioning TFA patients.

Key words: Above the knee amputee; Activity balance confidence; Compression release socket; High-fidelity interface; Ischial containment; Prosthetic socket; Walking tests

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INTRODUCTION

Falling is prevalent among the amputee population particularly when comorbidities exist. Developing and studying fall prevention is a priority for reducing adverse effects and costs. Falls cost $23.3 billion annually. Their mean cost ranges from $3,476 per faller to $10,749 per injurious fall to $26,483 per fall requiring hospitalization. Approximately 20% of falls require medical attention (1,2). Annually, 52.4% of lower limb amputees report falling, whereas 49.2% report fear of falling (3,4). Falling and fear of falling are common among patients with transfemoral amputation (TFA), who have yearly fall rates as high as 66% (5,6). Further studies are required to characterize the mechanisms of falling and to develop appropriate prevention strategies (7). Rehabilitation of amputee Service Members, Veterans, and civilians using prosthetic devices is a priority of the Department of Defense (DoD), the Veterans Health Administration (VA), and Centers for Medicare and Medicaid Services (CMS), respectively. Fall prevention programs have been established and evaluated, including exercise programs designed to improve function and balance (1,2). However, the role of the prosthetic interface in maximizing balance confidence is poorly studied. Exploring interventions, including prosthetic interfaces that may prevent falls and reduce healthcare costs, is a priority in amputee care (8,9).

In addition to reducing falls, walking capacity is another important factor in determining function for TFA patients (10). Poor walking capacity, as evidenced by lower gait speed, is associated with increased comorbidity, falls, and mortality (11). Optimizing walking capacity through such means as achieving a more normal gait speed and community ambulation should be considered when formulating the prosthetic prescription. Because walking capacity and balance confidence are compromised with TFA, these outcomes should be considered when evaluating interfaces for transfemoral prosthetic users. Therefore, the purpose of this study was to compare the effect of TFA interface design on walking capacity and balance confidence.

METHODS

A retrospective cohort design was utilized. All data were collected in accordance with the Declaration of Helsinki. In order to be included in the record review, subjects had to meet the following eligibility criteria:

1. Unilateral TFA
2. 18 to 60 years of age
3. K2 or higher activity level
4. History of prosthetic ambulation without an assistive device ≥2 years
5. No other comorbidities
6. History of use of both socket conditions of interest
7. Complete outcome assessment for both socket conditions

Subjects were excluded if they did not meet all inclusion criteria.

Independent Variable: Interfaces

The Standard of Care (SOC) interface is the ischial ramus containment (IRC). The experimental interface is the High-Fidelity Interface™ (HiFi, biodesigns, inc., Westlake Village, CA,USA) TFA interface design (12) (Figure 1).

Figure 1. Subischial transfemoral HiFi interface.

Dependent Variables: Outcome Measures

The following outcome measures were routinely utilized during clinical evaluation of new prosthetic fittings:

The Activity-specific Balance Confidence Scale (ABC): The ABC Scale is a 16-item self-report measure of balance confidence in performing various activities of daily living (ADL) without falling. Items are scored on a rating scale from 0 to 100, with higher scores reflecting higher levels of balance confidence. An average score is calculated by adding all item scores and dividing by the total number of items. The ABC can be administered in 10 to 20 min and is appropriate for use in the clinical environment (13).

Two-Minute Walk Test (2MWT): The 2MWT was used to determine walking capacity. The six-minute walk test (6MWT) is highly regarded in clinical care; however, Reid et al. determined the 2MWT is as predictive as the 6MWT in determining an amputee's ability to ambulate in the community. The 2MWT was used given its comparable performance to the 6MWT and because it takes less time to administer within the clinical environment (14).

Data Collection Timeline

Patients included in the review were initially fit into an IRC interface and assessed following at least 30 d of accommodation. All data were documented in the clinical prosthetic progress notes. Following eventual rejection or failure, patients were subsequently fit with a HiFi interface. Again, following at least 30 d accommodation, patients were assessed and results recorded in their prosthetic clinic records.

Statistical Analyses

Data were entered into a database and evaluated for completeness and accuracy. Central tendency and variance were calculated. Parametric tests were used when appropriate considering data dependency and normality; otherwise, equivalent non-parametric tests were used. Statistical significance was set *a priori* at $p \leq 0.05$. IBM SPSS (v21, Armonk, NY, USA) was used for statistical analysis.

RESULTS

Complete records were available for eleven males and two females ($n = 13$). The age range was 26 to 58 years. Three patients functioned at the K4 activity level and the remaining 10 at the K3 level. Mean body mass was 85.2 kg (57.7 to 137.7). Subjects' mean

Table 1. Sociodemographic Data

Subject	Prosthetic History (y)	Gender	Amputated Side	Activity Level	Height (Ft. In)	Weight (lbs.)
1	3	M	L	K3	5.5	190
2	13	M	L	K3	5.9	222
3	5	M	R	K3	5.1	165
4	5	M	R	K3	5.9	187
5	6	M	R	K3	5.8	303
6	20	M	L	K4	5.9	185
7	16	M	L	K3	5.9	168
8	33	F	L	K4	5.3	127
9	40	M	L	K3	5.7	180
10	8	M	L	K3	5.9	156
11	25	M	L	K3	5.9	145
12	3	M	L	K3	6	220
13	10	F	R	K4	5.7	190

Figure 2. Activity-specific Balance Confidence Scale. Subjects' mean ABC score was 77.2 (±16.8; 35.6 to 96.9) for the IRC and 90.7(±5.7; 77.5 to 98.7) for the HiFi. The difference was statistically significant (p = 0.02).

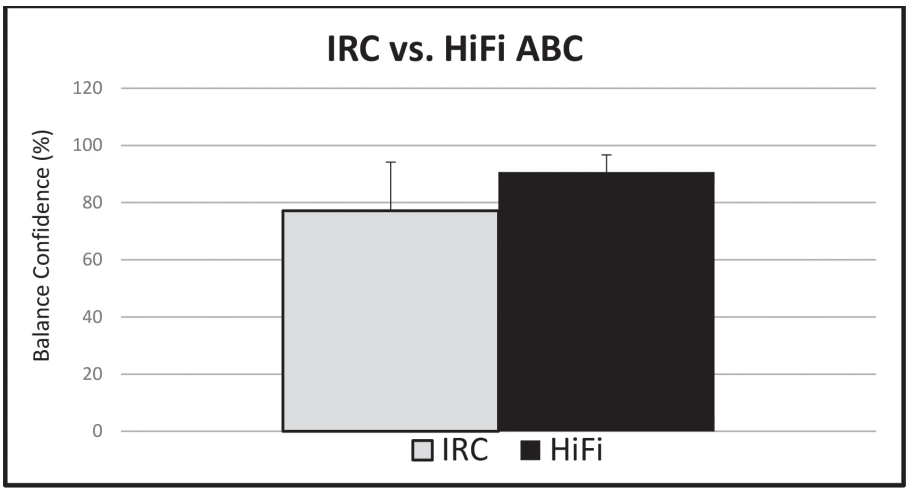
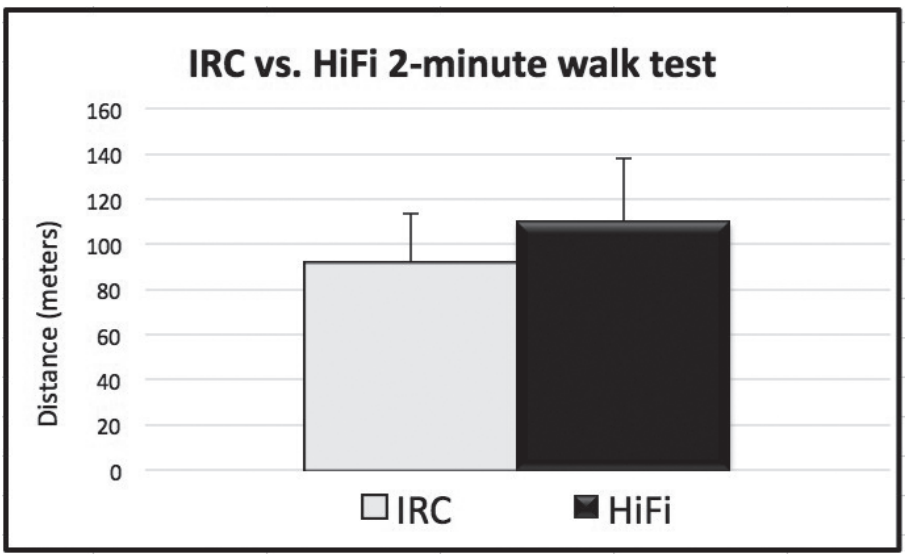


Figure 3. Two-Minute Walk Test. The aggregated mean distance walked on the 2MWT was 91.8 m (±22.0, 58.3 to 124.7) on the IRC compared to 110.4 m (±28.7; 64.7 to 171.1) for the HiFi socket (p = 0.0001).



prosthetic use was 14.4 years (3 to 40) (Table 1).

Subjects' mean ABC score was 77.2 (±16.8; 35.6 to 96.9) for the IRC and 90.7 (±5.7; 77.5 to 98.7) for the HiFi. The difference was statistically significant ($p = 0.02$) (Figure 2). The aggregated mean distance walked on the 2MWT was 91.8 m (±22.0, 58.3 to 124.7) on the IRC compared to 110.4 m (±28.7; 64.7 to 171.1) for the HiFi socket ($p = 0.0001$) (Figure 3).

DISCUSSION

We hypothesized that the less cumbersome walls and subischial trimlines afforded by the HiFi, compared with SOC interfaces, would offer improved freedom of movement. This freedom of movement may enable improved walking capacity and improved prosthetic control as evidenced by improved ABC scores. The minimum detectable change (MDC) for the 2MWT has been previously reported as 34.3 m (15). This threshold was not reached in this study. However, in three previous studies comparing lower extremity amputees using the 2MWT, distances walked reached up to 140 m (14). The majority of amputees tested in these studies had transtibial level amputation. In this study, only transfemoral level amputees were evaluated. TFA patients using the HiFi socket achieved distances similar to transtibial amputees in previous studies. Patients' walking capacity was significantly improved with use of the HiFi interface relative to the SOC alternative, supporting this portion of the hypothesis. Reduced gait speed, an indicator of walking capacity, has been associated with falling (16). This is of particular relevance in the TFA population. Maintaining optimal walking capacity, including normal or near normal gait speed, should be of primary concern in prosthetic design. Prosthetic elements, including the socket, must be considered as potential factors in assisting a patient to achieve variable cadence and faster gait speeds. In this study, the HiFi interface design was determined to have a significant effect on improving walking capacity.

Deathe et al. assessed 17 outcome measures used in amputee clinical trials to assess mobility (17). The ABC scale was recognized as being valid and widely used. The MDC for the ABC has been previously reported as 11 and 13 in studies of other pathologies. MDC has not been established in the TFA population. In this study, the mean difference was a 23.5 point improvement ($p = 0.02$) for the users of the HiFi (90.7) versus the IRC (77.2) sockets. An ABC score of 68 is associated with falling post-stroke (18). In this study, both groups were above this fall risk threshold. Our hypothesis that the improved prosthetic control would yield increased ABC scores was supported. Further, the HiFi group reported ABC scores higher than other patient populations, such as those suffering from Parkinson's or stroke and the elderly. Conversely, when using the IRC socket, ABC scores tended to be similar to scores in these populations (18-20).

The socket has been identified as the most important prosthetic element; however, TFA prosthetic socket fit is problematic using SOC IRC prosthetic socket interface. A subischial compression and tissue release design such as the HiFi may improve comfort and increase user control by utilizing femoral control. This could lead to improved walking capacity and confidence, which could reduce falls. Discomfort and lack of control have been associated with poor socket fit. This reduces function of the prosthesis for the amputee. Although common, the SOC IRC interface design has potential limitations, such as limiting range of motion, decreasing comfort, and interfering with urogenital function, and potential fitting complications affecting overall quality of life (21,22). Benefits of a novel TFA interface such as the HiFi could potentially address areas identified as problematic and lead to alternative interface designs that improve quality of life among TFA patients.

A common conclusion among the aforementioned studies is that falls in amputees can be mitigated with training programs and alternative interventions. To begin a strength and walking program, the use of an effective prosthesis is imperative. Collectively, prior authors also agreed that ongoing research is required to develop appropriate intervention strategies to ameliorate fall risk (6,23-25). Such interventions should consider alternative prosthetic interfaces.

Limitations

A limitation of this study was the small patient population exposed to both socket designs. Socket

studies are expensive, and it can be difficult to control attrition. Interface studies are particularly challenging due to the socket being an intimate part of the prosthesis that can require weeks of accommodation prior to effective use. A paucity of funding has created a void in the understanding of a prosthetic socket interface's role in affecting falls and walking capacity (26).

CONCLUSION

Prosthetic clinical documentation and outcome measure implementation can be effective means of demonstrating changes and improvements in clinical interventions. The Activity-specific Balance Confidence Scale and two-minute walk test are valid measures that can be used to determine differences among intervenions in the transfemoral amputee population. Alternative transfemoral interface design, such as the HiFi socket, can improve walking capacity and balance confidence in higher functioning patients with transfemoral amputation.

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