



## Differences in Stepping and Functional Level While Using the Genium and C-Leg Microprocessor Knees

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**INTRODUCTION** Preliminary comparisons between the C-Leg and Genium microprocessor knee systems (MPKs) have revealed biomechanical improvements with the Genium system. Some of these were observed during hill walking and some on flat ground. Data also suggest stair ascent is also improved with Genium use. However, multidirectional stepping, observational analysis of hill walking and functional level have not been formally compared between these two MPK systems. These are specific functions observable to clinicians and appreciable to users themselves. Thus, the purpose of this report was to determine if functional level, observational analysis of hill ascent and multi-directional stepping are improved with Genium relative to C-Leg.

**METHOD** *Subjects:* 20 TFAs (19 Male, 6 Female) were studied. Study protocols were approved by the University of South Florida's IRB, and informed consent was obtained prior to data collection.

Randomized experimental A-B crossover. The 4 square step test (4SST) was assessed by time with a stopwatch to assess multi-directional stepping. The amputee mobility predictor (AMP) was assessed in accordance with published protocols to rate functional level through walking, mobility and transitional movements. The Hill Assessment Index (HAI) was used to rate the quality of subject's ability to ascend a 5deg ramp and finally, the Galileo (Orthocare Innovations, Washington, U.S.) was used to monitor step activity and calculate functional level using the manufacturer's proprietary algorithm which considers multiple aspects of step activity.

*Procedures:* TFAs were randomized to C-Leg or Genium knee for phase A testing. After an accommodation and training period (Highsmith et al., 2014), subjects performed the aforementioned assessments. Subjects switched knee type, and re-accommodated and re-trained, prior to returning for phase B testing.

*Data Analysis:* Step activity data were monitored for 1 week in accordance with manufacturer specification and laboratory test steps were not included in functional level determinations. The 4SST was tested 3 times per condition with a rest between trials to mitigate fatigue. Other tests were only rated a single time given their ordinal scaling.

Statistical significance was determined by comparing means or medians of the dependent variables between knee conditions using either paired sample t tests when data sets were continuously scaled, and normally distributed and complete. Otherwise, non-

parametric equivalent tests were used. Significance was set a priori at  $p \leq 0.05$ .

### RESULTS

All four of the assessments resulted in statistically significant improvements with Genium use. See results in table 1:

Table 1. Outcome Measures:

TEST	C-Leg		Genium		p value
	Central Tendency	Variance	Central Tendency	Variance	
4SST	12.2	3.3	11.1	3.4	0.04
AMP	42	33 to 45	44	39 to 46	$\leq 0.001$
HAI	5	3 to 11	11	3 to 11	0.001
Functional Level(SA)	3.4	1.8 to 4.0	3.6	2.0 to 4.3	0.01

4SST is 4 square step test. AMP is amputee mobility predictor.

HAI is hill assessment index. Functional Level is determined via Step Activity (SA) monitoring. Central Tendency is mean(SD) for 4SST and is median(range) for all other tests. Statistical Significance is  $p \leq 0.05$ .

### DISCUSSION

Use of the Genium system significantly ( $p < 0.05$ ) improved multi-directional stepping, transitional movements, hill ascent quality and functional level as determined by step activity. The addition of kinetic and kinematic feedback at both the knee and ankle regions seems to enhance the ability of the knee to respond in a manner enabling the patient to walk more confidently and safely thus performing at a higher level on these multiple different tasks. Further, the addition of the axial load sensor and gyroscope seems to improve the ability to step multi-directionally (i.e. laterally, rearward) and uphill. These improvements ultimately resulted in improved community use and a higher functional level based on step activity monitoring (community based) and also during transitional movements as measured with the AMP. These improvements in stepping and mobility skills are clearly important in contributing to higher levels of functional capability.

### CONCLUSION

Genium knee use seems to improve stepping ability and transitional movements resulting in higher functional levels. in community ambulating persons with unilateral TFA.

### CLINICAL APPLICATIONS

Genium knee use may be beneficial for users who want or need to walk hills or multi-directionally on a routine basis.

### REFERENCES

Highsmith et al., Technology & Innovation, 15, 349-358, 2014.  
 Gailey et al., APMR, 83, 613-627, 2002