Published in final edited form as:

Technol Innov. 2014 January 27; 2013(4): 343–347. doi:10.3727/194982413X13844488879212.

THE EFFECT OF THE C-LEG KNEE PROSTHESIS ON SENSORY DEPENDENCY AND FALLS DURING SENSORY ORGANIZATION TESTING

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Abstract

A mechanistic explanation for previously observed safety improvements with microprocessor-controlled prosthetic knees is needed. A repeated measures design of 15 subjects with unilateral transfemoral amputation was used to assess changes between baseline use of their standard of care, mechanical prostheses, and a C-Leg microprocessor-controlled prosthetic knee. The primary outcome measures were sensory dependency scores for somatosensory, visual, vestibular, and visual preference, which were calculated based on a Sensory Organization Test. Falls during posturographic assessment were also recorded. Somatosensory system dependency significantly increased ($p = 0.047$) while using the C-Leg compared to a nonmicroprocessor prosthetic knee (NMPK). Reliance on visual with vestibular input and reliance on vestibular input alone were not significantly increased with C-Leg use ($p = 0.41$ and $p = 0.15$, respectively). When utilizing the C-Leg, there was a significant reduction in the average number of falls ($p = 0.03$). Hence, increased reliance on somatosensory input is a possible explanation for improved balance with use of a microprocessor prosthetic knee (MPK).

Keywords

Amputee; Balance; NeuroCom; Rehabilitation; Safety; Transfemoral

INTRODUCTION

Microprocessor prosthetic knees (MPKs), specifically the C-Leg, reduce falls in transfemoral amputees (TFAs) (5). A recent literature review collectively confirmed that the C-Leg is safer than a nonmicroprocessor prosthetic knee (NMPK) (5). However, no

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mechanistic explanation for the safety improvements has been offered. Therefore, this study's purpose was to determine if C-Leg use favorably increases sensory system utilization, thereby offering a mechanistic explanation for the previously observed safety improvements.

METHODS

Subjects

Sixteen unilateral TFAs consented to participate. Mayo Clinic's Institutional Review Board approved the protocol. Table 1 lists enrollment criteria.

Study Design

A repeated measures experimental design was utilized. Except for knee mechanisms, prosthetic components were unchanged. This eliminated confounding socket-fit issues, foot properties, and accommodation to anything beyond the prosthetic knee. Subjects were first tested using NMPKs and then retested with a C-Leg. The study prosthetist [certified by the American Board for Certification in Orthotics, Prosthetics & Pedorthics (Alexandria, VA, USA) and by Otto Bock HealthCare for C-Leg fittings] evaluated subjects using observational gait assessment and made necessary adjustments to optimize alignment [confirmed with a L.A.S.A.R. (Laser Assisted Static Alignment Reference) posture tool (Otto Bock HealthCare)] and function. Following initial testing, subjects used the C-Leg until they stated that they were accommodated (9).

Sensory Dependency Testing

The Equitest[®] dynamic posturography balance platform (NeuroCom International, Inc., Clackamass, OR, USA) was utilized to assess sensory dependence. Specifically, the Sensory Organization Test (SOT) was used to distinguish afferent contributions of the visual, vestibular, and somatosensory systems to balance. Three consecutive trials in each of six combinations of visual and support surface conditions were collected while the platform and visual surroundings either remained stationary or swayed sagittally to match subjects' estimated center of mass excursions. Specifically, the six conditions were 1) eyes open with fixed surface, 2) eyes closed with fixed surface, 3) eyes open with sway-referenced visual surround, 4) eyes open with sway-referenced surface, 5) eyes closed with sway-referenced surface, and 6) eyes open with sway-referenced surface and visual surround. Individual and composite SOT scores are reported else-where (7). This study performed secondary analyses to derive sensory dependency scores (Table 2). Trials where subjects stepped or touched the wall to avoid falling received a zero score and were classified as a fall.

Statistical Analyses

Comparisons between prosthetic knees were completed using paired *t* tests with a per-protocol analysis (SAS Version 9.5, Cary, NC, USA). Significance was established a priori at 0.05. Effect sizes were calculated post hoc using Cohen's *D* (3).

RESULTS

Fifteen unlimited community ambulators (MFCL K3/4) completed the study (2). Amputation etiologies varied (Table 1).

There was a significant 3% increased reliance on somatosensory system input ($p = 0.047$) while using the C-Leg compared to NMPK. Reliance on visual with vestibular input and reliance on vestibular input alone were both greater (3%, $p = 0.41$, and 1%, $p = 0.15$, respectively) with C-Leg use but were not significant (Fig. 1). The four sensory dependency comparisons (Fig. 1) had small effect sizes (Cohen's $D < 0.20$).

There was a statistically significant 33% reduction in the number of falls when using the C-Leg ($p = 0.03$). NMPK use resulted in 21 falls among seven fallers (average, 1.4 ± 2.3 falls per person) compared with 14 falls among four fallers (average 0.9 ± 2.1 falls per person) while utilizing the C-Leg. This comparison's effect size was small.

DISCUSSION

We hypothesized that sensory reliance would be limited to the somatosensory system. Thus, it was first necessary to determine if C-Leg utilization increased activity. The project's first phase used doubly labeled water to demonstrate increased total daily energy expenditure associated with movement, whereas no significant difference in locomotion energy efficiency between knee conditions occurred (8). Our literature review revealed similar findings where only two of eight articles reported statistical improvements in energy efficiency associated with C-Leg use (5). Increased activity level with C-Leg utilization is uncorroborated through step-counting, which does not consider stepping intensity such as sloped terrain ambulation, leaving this assertion unresolved (5).

Using dynamic posturography, the project's second phase determined that balance improved with C-Leg use (7). Furthermore, many studies corroborate improved safety with utilization of this device (5). Yet, a mechanistic explanation for these safety and balance improvements was lacking until this study was performed.

This study demonstrates that somatosensory system dependence increases significantly with C-Leg use. Vrieling et al. indicated that prosthetic side somatosensory input can increase with the weight-bearing aspect of balance maintenance (14). As subjects used the C-Leg and experienced fewer falls, confidence likely increased, contributing to increased prosthetic reliance. This is further corroborated by Kaufman et al.'s findings that weight-bearing symmetry improved while walking with a C-Leg compared to NMPKs in this same cohort (6). Nederhand et al. explain that an amputee's continued weight-bearing symmetry improvement is attributable to central reorganization, including decreased reliance on active cognition and visual input (11). Our results confirm decreased visual reliance because we did not find significant increases in visual or vestibular dependence. Ultimately, balance improved as evident by previously reported improved SOT scores and further substantiated by a grade B recommendation of the C-Leg as a safer prosthetic knee (5,7).

Potentially confounding is the prosthetic foot/ankle. Nederhand et al. indicate that amputees can use passive prosthetic ankle stiffness to “fine-tune” ankle torque as an ankle strategy during balance (11). Prosthetic feet were not standardized in this experiment. Nevertheless, ankle kinetic gait symmetry improved with C-Leg use (6). Perhaps weight-bearing confidence was improved, and, as Vrieling et al. indicate, an ankle strategy may be employed by micromanaging ankle moments via axial weight bearing (14).

Confidence also plays an important role by increasing axial prosthetic loading and thus somatosensation (14). We believe increased confidence comes from utilizing the stumble recovery feature and subjects’ knowledge that their knee is more stable. This can be partially corroborated because stumble recovery was effective when subjects were tripped and had fewer stumble events (1,5). There is presently not a clear and direct linkage between stumble recovery proficiency and increased confidence, although one study demonstrated improved Activities-Specific Balance Confidence scores with C-Leg utilization (12).

Several authors report improved balance may result from a learning effect associated with repeated postural control assessments when time between tests ranged from days to a month (4,15). Our subjects were only tested twice with a mean accommodation of 4.5 ± 2.0 months between tests. Further, the two prosthetic knee mechanisms differ considerably, requiring different stump motor strategies. Therefore, a learning effect can be ruled out.

Limitations

We attempted to optimize external validity in order to answer an important clinical question to determine if balance improved. The experimental conditions’ sequence was not randomized. The NMPK was tested first because subjects were already accommodated to it and because this sequence best mimics clinical situations where amputees transition from NMPK to MPK. Unfortunately, there was no opportunity for long-term follow-up to determine if sensory inputs and activity levels stabilize, because studies with lesser quantities of training show structural cortical changes relative to balance performance (13). Finally, differing component properties may impact balance and activity levels so future studies should consider controlling them (11).

CONCLUSION

This study provides a mechanistic explanation for improved balance performance following C-Leg accommodation. Subjects increased reliance on somatosensory input, resulting from increased activity associated with C-Leg utilization, leading to improved balance.

Acknowledgments

This project was partially supported by grant number M01 RR000585 from the National Institutes of Health (NIH). Partial funding also came from Otto Bock HealthCare, Inc. The contents are solely the responsibility of the authors and do not necessarily represent the official view of the NIH or Otto Bock HealthCare, Inc. We certify that no party with a direct interest in the results of this research has or will confer a benefit on us or on any organization with which we are associated, and we certify that all financial and material support for this research and work are clearly identified.

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Figure 1. Sensory preference scores during Sensory Organization Tests. SOM, somatosensory system; VIS, visual system; VEST, vestibular system; PREF, preference score; NMPK, nonmicroprocessor prosthetic knee. * $p < 0.05$, significantly different between C-Leg and NMPK.

Table 1**Enrollment Criteria and Sample Descriptive Data**

Inclusion criteria				
1	Unilateral transfemoral amputees aged 18 and older			
2	Amputation for any reason			
3	A minimum of 2 years postamputation			
4	Medicare functional classification level 3 or 4*			
5	Current use of a nonmicroprocessor, hydraulic control mechanical prosthetic knee			
Exclusion criteria				
1	Chronic residual limb skin breakdown			
2	Any additional partial foot, ray, or toe amputation on the sound side			
3	Secondary medical conditions that would prevent participation in or completion of the study			
4	Acute or chronic illness			
5	Required assistive aids for ambulation			
6	Self-reported history of significant volume fluctuation in the past 6 months			
Sample's descriptive data (<i>n</i> = 15) [†]				
	Mean(+SD)	Range	NMPKs	Etiology
Age (years)	42(9)	26–57	Mauch SNS ^B 11	Trauma 7
Years of prosthetic use	20(10)	3–36	CaTech ^C 2	Cancer 6
Body mass index (kg/m ²)	25(4)	17–28	Black Max ^D 1	PVD 1
Time to accommodate to C-Leg (weeks)	18(8)	0–39	Century 2000 ^B 1	Congenital 1

^{*} HCFA Common Procedure Coding System (HCPCS) 2001. Washington, DC: U.S. government Printing Office; 2001: Chap. 5.3.

[†] Descriptive data regarding the subjects who completed the study ($n = 15$). One male subject was withdrawn for administrative reasons.

The superscripts B, C, and D refer to devices by Ossur (Reykjavik, Iceland), Endolite (Hampshire, England), and Trulife (Dublin, Ireland), respectively.

Table 2

Calculations Utilized to Differentiate a Particular Afferent System's Contribution to Balance

System Score	The Score Represents	How the Score Is Calculated
Somatosensory (SOM) score	Subjects' ability to utilize SOM with vestibular input or the supporting surface with vestibular input to maintain balance	$\text{SOM score} = \text{SOT condition 2 score} \div \text{condition 1 score}$
Visual (VIS) score	Subjects' ability to utilize VIS with vestibular input to maintain balance	$\text{VIS score} = \text{SOT condition 4 score} \div \text{condition 1 score}$
Vestibular (VEST) score	Subjects' ability to utilize VEST input to maintain balance	$\text{VEST score} = \text{SOT condition 5 score} \div \text{condition 1 score}$
Preference (PREF) score	The extent a subject relies on VIS with vestibular input, regardless of its accuracy	$\text{PREF score} = \text{SOT condition 3 score} + \text{condition 6 score} \div \text{condition 2 score} + \text{condition 5 score}$