

# The Impact of Using a Unilateral Microprocessor Prosthetic Knee for Individuals with a Transfemoral Amputation on Function: A Systematic Review

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# Overview

- Purpose
- Definitions
- C-Leg vs. Genium
- Introduction
- Materials and Methods
- Search Terms
- Inclusion/Exclusion Criteria
- PRISMA
- Minors Scale
- Results
- Conclusion
- Clinical Relevance
- Limitations
- Future Research
- Acknowledgements

# Purpose

- To investigate the impact of using a microprocessor knee (MPK) prostheses for individuals with a unilateral transfemoral amputation (TFA) on functional mobility.

# Definitions

- Non-Microprocessor Knee (Non-MPK)<sup>1</sup>
  - Mechanical Hinge
  - Variations to control speed and swing
    - Free swing
    - Manual lock
    - Constant friction
    - Weight-activated friction
    - Geometrically locking
    - Hydraulics

# Definitions

- Microprocessor Knee (MPK)<sup>2</sup>
  - A device that controls friction of the knee joint via a computer chip
  - The computer chip automatically adjusts to changes in velocity for a smooth transition between speeds
  - No assistance provided with knee motion
  - Examples: the C-Leg and the Genium knee

## C-Leg MPK<sup>3</sup>



## Genium MPK<sup>3</sup>



# C-LEG VS. GENIUM <sup>4</sup>

Parameter	Characteristics	C-Leg	Genium
<b>Swing Phase Control</b>	Effect of different shoe length	Affected, heavier shoe means slower swing phase. Requires programming	No effect, electronics compensate by automatically adjusting the hydraulics
<b>Stance Phase Control</b>	Swing characteristics when not walking	Stance control is active with knee relatively stiff	Knee swings freely—better!
<b>Aspects for everyday use</b>	Maximum knee angle	Only up to 120°	>120°
	Kneeling down	O.K. with knee protector mounted	No knee protector, slips on hard surfaces. Can result in scratches in the knee frame

# Introduction

- ~Two million people living with limb loss in the United States<sup>5</sup>
- ~185,000 amputations occur in the United States each year<sup>5</sup>
  - Among those living with limb loss, the main causes are:
    - Vascular disease (54%)<sup>5</sup>
      - Including diabetes and peripheral artery disease
      - Of persons with diabetes who have a lower extremity amputation, up to 55% will require amputation of the second leg within 2-3 years
    - Trauma (45%)<sup>5</sup>
    - Cancer (<2%)<sup>5</sup>



# CLASSIFICATION (K) LEVELS:<sup>6</sup>

<b>Level 0: Non-ambulatory</b>	No ability/potential to ambulate or transfer safely with or without assistance; prosthesis will not increase QOL
<b>Level 1: Limited or unlimited household ambulator</b>	Has ability/potential to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence
<b>Level 2: Limited community ambulator</b>	Has ability/potential for ambulation with ability to transverse low level environmental barriers (curbs, stairs, and uneven surfaces)
<b>Level 3: Moderate community ambulator</b>	Has ability/potential for ambulation with variable cadence and able to navigate most environmental barriers and have vocational, therapeutic or exercise activities that demand prosthetic use beyond locomotion
<b>Level 4: Child, active adult, or athlete</b>	Has ability/potential for prosthetic ambulation that exceeds basic ambulation skills exhibiting high impact, stress, or energy levels.

# Materials and Methods

- A literature search was conducted included:
  - CINAHL
  - PubMed
  - ProQuest
  - ScienceDirect
  - Cochrane Library
- Two Reviewers independently assessed each study
  - MINORS scale



# Search Terms

- (transfemoral amputation) AND (microprocessor OR c-leg OR genium)

# Inclusion Criteria

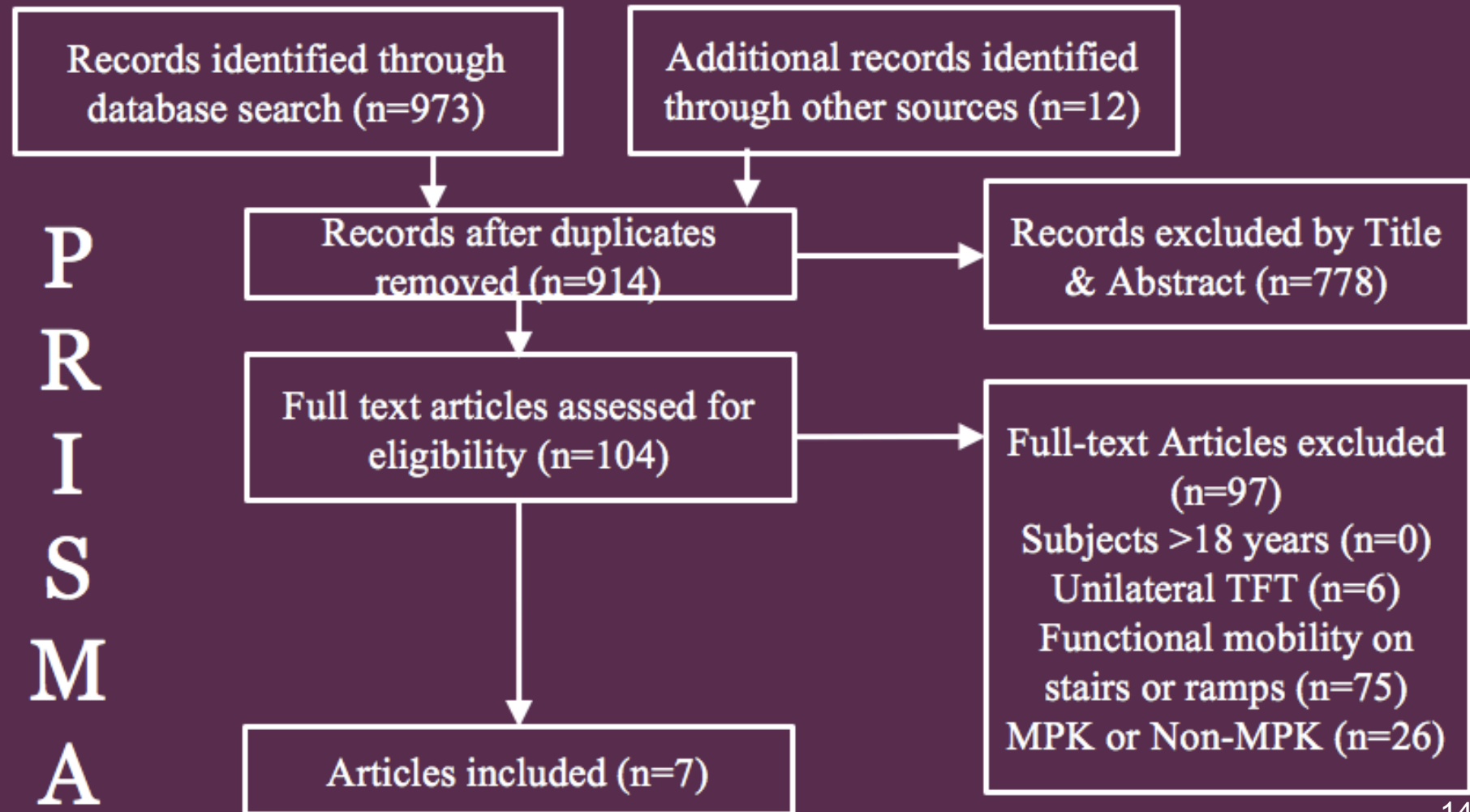
- Human subjects
- Adult ( $\geq 18$ )
- Unilateral
- Transfemoral
- Microprocessor knee prosthetic
- Non-microprocessor knee prosthetic
- Outcomes related to functional activities/mobility including stairs and ramps



# Exclusion Criteria

- Children (<18 years)
- Not a transfemoral amputee (transtibial or lower)
- Bilateral amputees
- Powered knee prosthetic
- Outcomes not related to functional activities or mobility





<b>Article</b>	<b>MINORS</b>	<b>Average</b>
<b>Kahle J<sup>4</sup></b>	<b>17/24</b>	<b>= 18.7/24</b>
<b>Kannenbergh A, et al<sup>5</sup></b>	<b>17/24</b>	
<b>Swiontkowski M<sup>6</sup></b>	<b>17/24</b>	
<b>Theeven P, et al<sup>7</sup></b>	<b>18/24</b>	
<b>Highsmith M, et al<sup>1</sup></b>	<b>20/24</b>	
<b>Highsmith M, et al<sup>2</sup></b>	<b>21/24</b>	
<b>Highsmith M, et al<sup>3</sup></b>	<b>21/24</b>	

# Results

- Total of 973 articles were screened for eligibility resulting in:
  - 7 comparative studies:
    - 6 cohorts
    - 1 case-control
- Minors scores ranged from 17-21 (average 18.7/24)
- Sample size ranged from 10-41 subjects (N=156)
- Age ranged from 21-83 y/o (average 39.2 y/o)
- Prosthetic experience ranged from none to >1 year
- Accommodation period ranged from  $\geq 2$  weeks to  $\leq 3$  months





# Results

- Four of the 7 studies found that the Genium had statistically significant improvements in:
  - Stair ascent/descent
  - Slope and ramp navigation
  - Gait speed
  - Safety
- One study found that the Genium scored significantly higher on the Prosthesis Evaluation Questionnaire (PEQ) when compared to the C-leg in:
  - Perceived response
  - Social burden
  - Utility and well-being scales

# Results

- Four studies showed the majority of individuals had a preference for the Genium when performing ADLs
- One study examined physical performance (CS-PFP10) and found the Genium was not significantly different from non-amputee controls
  - C-leg users showed significantly lower function
- Three of 7 studies showed improved outcomes with the use of a MPK compared to non-MPK users, specifically in:
  - Stair and ramp negotiation
  - Decrease in fall frequency

# Conclusion

- There is moderate evidence to support the use of MPK over a non-MPK in individuals with unilateral TFA when examining functional mobility
- Genium resulted in improved safety and better performance on uneven terrain vs. C-leg and non-MPK devices, decreasing fall risk



# Clinical Relevance

- The use of a MPK can significantly impact independence with ADLs and participation in work/leisure activities in individuals with unilateral TFA
- The Genium appears to be the best option compared to C-leg and non-MPK to promote the highest level of functional mobility and patient satisfaction

# Clinical Relevance

- When providing input on a prosthetic prescription in patients with TFA, clinicians should consider the patient's:
  - Current and potential functional mobility (K level 3-4)
  - Work/play/leisure activities
  - Cost (Genium 3x cost of C-leg)
  - Insurance coverage

# Limitations

- Several articles were published by the same authors
- Fairly novel technological advancements
- Lack of RCTs
- Short accommodation periods
- Small sample size
- Subjects and researchers were not able to be blinded
- Lack of longitudinal studies

# Future Research

- Future research is needed on different age groups and activity levels using both MPK and non-MPK prosthesis with long-term follow-up to determine optimal outcome measures and training parameters to maximize functional mobility in this population.



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# Questions or Comments?



# References

1. Prosthetic FAQs for the New Amputee. Amputee Coalition. <http://www.amputation-coalition.org/resources/prosthetics-faqs-for-the-new-amputee/>. Accessed October 11, 2017
2. C-leg. Sisson Mobility. <http://www.sissonmobility.com/c-leg/>. Published February 23, 2017. Accessed October 11, 2017
3. Prosthetic Knees. Prosthetic & Orthotic Care - St. Louis & Fairview Heights. <http://www.pandocare.com/prosthetic-knees/>. Accessed October 11, 2017
4. Compare Prosthetic Knees. Amputee Prosthetic Leg Tips. <https://ampulife.com/compare-vgk/>. Published September 19, 2017. Accessed October 11, 2017.
5. Limb Loss Statistics. Amputee Coalition. <http://www.amputee-coalition.org/limb-loss-resource-center/resources-filtered/resources-by-topic/limb-loss-statistics/>. Accessed October 11, 2017

# References

6. What are K Levels? Ottobock. <http://www.ottobockus.com/therapy/resources-for-prosthetics/what-are-k-levels.html>. Accessed October 11, 2017.
7. Highsmith MJ, Kahle JT, Wernke MM, et al. Effects of the Genium Knee System on Functional Level, Stair Ambulation, Perceptive and Economic Outcomes In Transfemoral Amputees. *Technol Innov.* 2016;18(2):139-150. doi:10.21300/18.2-3.2016.139.
8. Highsmith MJ, Kahle JT, Miro RM, et al. Functional performance differences between the Genium and C-Leg prosthetic knees and intact knees. *J Rehabil Res Dev.* 2016;53(6):753-766. doi:10.1682/jrrd.2014.06.0149.
9. Highsmith MJ, Kahle JT, Miro RM, et al. Perceived Differences Between The Genium And The C-Leg Microprocessor Prosthetic Knees In Prosthetic-Related Function And Quality Of Life. *Technol & Innov.* 2014;15(4):369-375. Doi:10.3727/194982413x13844489091297.

# References

10. Kahle JT. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *J Rehabil Res Dev*. 2008;45(1):1-14.doi:10.1682/jrrd.2007.04.0054
11. Kannenberg A, Zacharias B, Mileusnic M, Seyr M. Activities of Daily Living: Genium Bionic Prosthetic Knee Compared with C-leg . *J Prosthet Orthot*. 2013;25(3):110-117. doi:10.1097/jpo.0b013e31829c221f.
12. Hafner B, Willingham L, Buell N, Allyn K, Smith D. Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Arch Phys Med Rehabil*. 2007; 88: 207-217.
12. Theeven P, Hemmen B, Rings F, et al. Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. *J Rehabil Med*. 2011;43(10):906-915. doi:10.2340/16501977-0861.

