

PATIENT PERFORMANCE AND OUTCOMES: A COMPARATIVE ANALYSIS OF
MICROPROCESSOR AND MECHANICALLY CONTROLLED PROSTHETIC KNEE
JOINTS

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The advantages and the medical necessity of a microprocessor-controlled knee over a mechanical-controlled knee (conventional) are unclear, in terms of clinical outcomes. The predominant issue is the absence of fact that a microprocessor-controlled knee may not yield clinically detectable functional improvement(s) relative to a conventional knee. There is a lack of objective research in the industry to substantiate claims that a microprocessor-controlled knee would improve a patient's function and confidence. However, if a microprocessor does enhance performance, it will encompass a larger scope of patients that would benefit from its capabilities. Therefore, there is a need to establish a protocol for prosthetists to follow that provides clinically objective information. The patient's subjective perspective should also be accounted for, in a comparison. In short, it is important to determine if the patient is benefiting from a knee's capabilities. This study compares the functional difference between a patient's conventional knee and a microprocessor-controlled knee. The study will determine if the knee improves function, perception, performance, and is a medical necessity.

This is an independent twenty patient study that analyzes the actual (objective) and perceived (subjective) performance of the microprocessor-controlled knee (C-Leg) when compared to a conventional knee. The twenty subjects are a convenience sample that range in age from 19- 83. The subjects use conventional components for a period of at least ninety days. They are then tested on an obstacle course. The course includes timing various distances on a level surface and an uneven surface, the measuring of heart rate, and the ability to descend stairs and a ramp. Following physical testing, two subjective tests are administered. One subjective test rates their confidence, stability, and performance on their components. The other subjective test is a patient evaluation questionnaire (PEQ), which rates their perception of confidence, stability, performance, and achievement of activities of daily living with their prosthesis. The patient is then fit into a C-Leg for a period of at least ninety days. The obstacle course test, subjective questionnaire, and PEQ are then retested with the C-Leg. Both tests are videotaped for comparison, documentation, and presentation. The results are compared, contrasted, and evaluated in this study.

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There is a clear difference in performance between the microprocessor-controlled knee and a conventional knee. The microprocessor knee did significantly reduce gait deviations, falls, and stumbles in most patients. It also allowed greater efficiency in ramp and stair descent, although most patients did not utilize its full capabilities (as described by the manufacturer). The walking speeds did increase on the timed distances. The research protocol did help establish a clear difference between the two knees, and assisted the prosthetist and patient in the decision of knee selection. Some patients showed an increase in energy and a decrease in heart rate in the microprocessor-controlled knee. Most patients preferred the microprocessor-controlled knee.

This study clinically establishes if, in fact, the microprocessor-controlled knee improves function and is a medical necessity for most patients. Some patients did not improve in all fields. However, most patients made dramatic improvements. The study contrasts and differentiates the two knees, while providing a template for prosthetists to determine the performance of one knee to another in their own practice. It establishes a protocol to determine whether or not a patient is a candidate for a microprocessor-controlled knee. The materials and method are designed to be used in any clinical situation. This type of instrument, to determine a component's validity, is essential to the process of justifying the medical necessity and a patient's need.

REFERENCES

Walter Reed Army Medical Center Microprocessor Knee Forum/ Patient Evaluation Protocol 2003

Gailey The Amputee Mobility Predictor *Archives of Physical Medicine and Rehabilitation*. May 2002

Legro PEQ study in the *Archives of Physical Medicine and Rehabilitation*. 1998

PROSTHETIC KNEE JOINT PERFORMANCE QUESTIONNAIRE

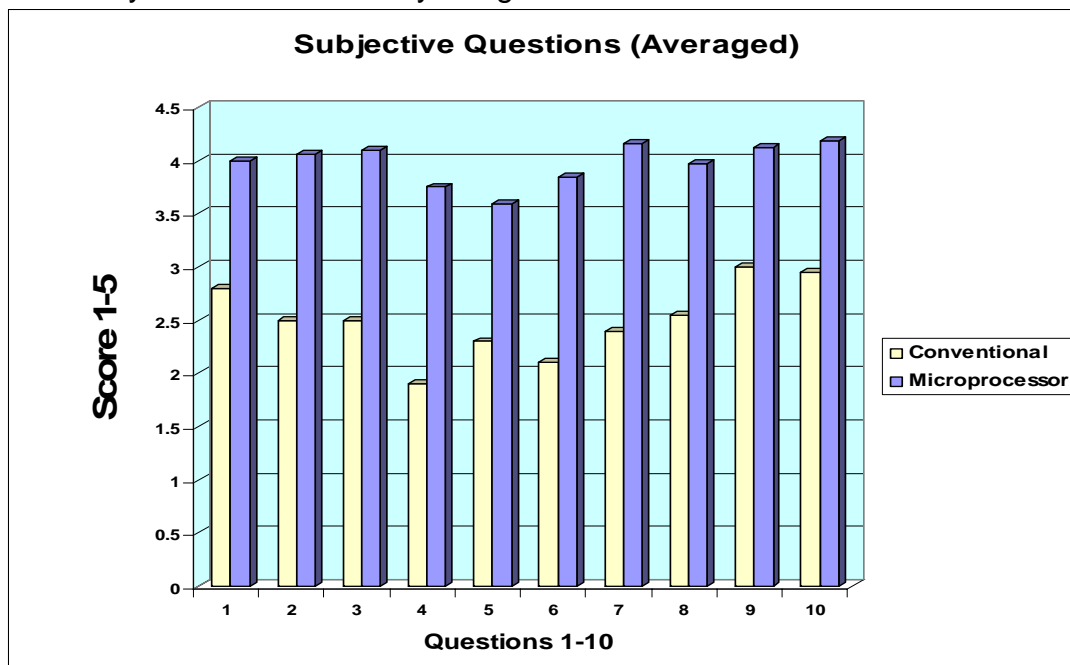
Objective Performance

1. Can the subject descend stairs step over step (1-6 scale on ability)?
2. Can the subject descend ramps step over step (1-6 scale on ability)?
3. What is the subject's normal/ baseline walking speed (timed) for 250 ft.?
4. What is the subject's fast walking speed (timed) for 250 ft.? Rate of perceived exertion?
5. What is the subject's walking speed (timed) on uneven terrain for 125 ft.?
6. How fast can the subject walk twenty ft.?
7. How many times has the subject fallen in the last 60 days?
8. How many times has the subject stumbled or has the knee buckled in the last 60 days?

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Subjective Questions 1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent

1. Rate your confidence with the existing components? 1 2 3 4 5
2. Rate your stability with the existing components? 1 2 3 4 5
3. Rate your balance with the existing components? 1 2 3 4 5
4. Rate your confidence, stability, and balance on uneven surfaces with the existing components? 1 2 3 4 5
5. Rate the amount of energy you have at the end of the day with the existing components? 1 2 3 4 5
6. Rate your ability to descend ramps, stairs, and slopes with the existing components? 1 2 3 4 5
7. Rate the ability of the existing components to keep up with your walking speeds? 1 2 3 4 5
8. Rate your ability to walk at a faster than baseline pace with the existing components? 1 2 3 4 5
9. I would rate the performance of my existing components? 1 2 3 4 5
10. Rate the extent to which your existing components help you achieve your activities of daily living. 1 2 3 4 5



Prosthetic Evaluation Questionnaire 1-100 scale

1. The fit of your prosthesis. *From terrible (1) to excellent (100)*
2. The comfort of your prosthesis while standing still when using your Prosthesis. *From terrible (1) to excellent (100)*

3. How much you have perspired in your prosthesis. *From an extreme amount (1) to not at all (100)*
4. The appearance of your prosthesis. *From terrible (1) to excellent (100)*
5. Your ability to walk in close spaces when using your prosthesis. *From cannot (1) to no problem (100)*
6. Your ability to walk on slippery surfaces. *Cannot (1) to no problem (100)*
7. Your ability to get in and out of a car when using your prosthesis. *From cannot (1) to no problem (100)*
8. How often the desire to avoid strangers' reactions to your prosthesis makes you avoid doing something you otherwise would have done. *From all the time (1) to never (100)*
9. How a family member (other than your partner) has responded to your prosthesis. *From very poorly (1) to not at all (100)*
10. How much a burden your prosthesis has been on your partner or a family member. *From extremely burdensome (1) to not at all (100)*
11. Your ability to take care of someone else. *Cannot (1) to no problem (100)*
12. How frequently you were frustrated with your prosthesis. *From all the time (1) to not at all (100)*
13. Think of your most frustrating event and rate what you felt at that time. *From extremely frustrated (1) to not at all (100)*
14. How satisfied you have been with how things have worked out since your amputation. *From extremely dissatisfied (1) to extremely satisfied (100)*
15. Your quality of life. *From worst possible life (1) to best possible life (100)*

