Hanger Institute
FOR CLINICAL RESEARCH & EDUCATION

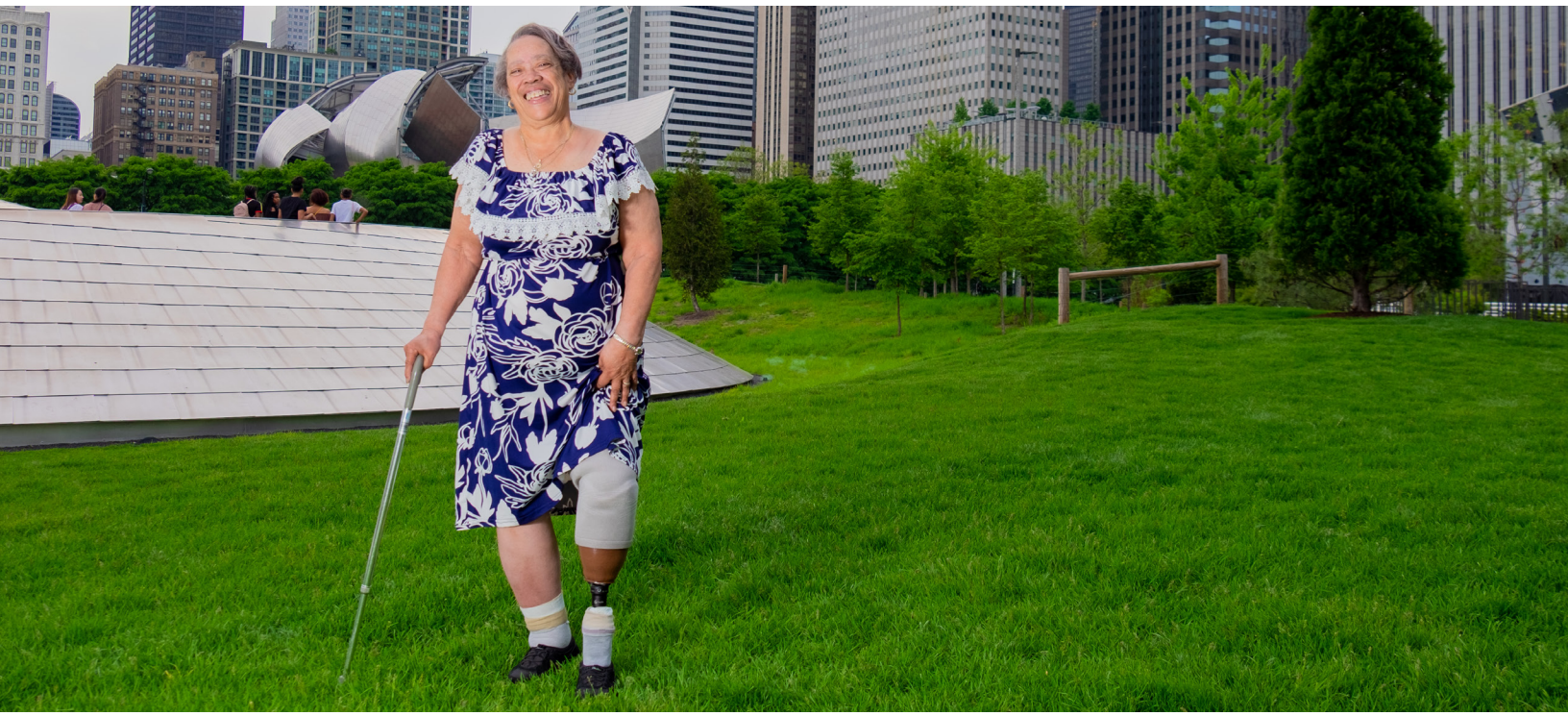
Hanger Clinic®

# Restoring mobility and building a patient-focused future driving quality of life and holistic care

## RESEARCH REVIEW:

Mobility Analysis of AmpuTees

WHITEPAPER | 2022



# OVERVIEW

The prevalence of lower limb amputations in the United States continues to rise with a projected population of 3.6 million by 2050, up from 1.6 million in 2005.[1] Accompanying the rise in patients is a shift in healthcare policies that place increased emphasis on patient-centered outcomes as they relate to prosthetic mobility.[2,3] While prosthetic rehabilitation has traditionally focused on restoring functional mobility, there is now a need to go beyond that and better understand the impact of improved mobility on the holistic care of patients with lower limb loss.

The Mobility Analysis of AmpuTees (MAAT) series is comprised of seven separate landmark studies that represent one of the largest multi-center retrospective analyses of mobility among users of lower limb prostheses. The series seeks to further our understanding of prosthetic mobility as it relates to such considerations as satisfaction, quality of life, comorbid health conditions, and prosthetic component choices.

MAAT stems from the adult lower limb prosthetic clinical outcomes work being conducted at Hanger Clinic. Utilizing a number of validated collection instruments, clinicians collect patient outcomes as part of their standard of care. Lower limb prosthetic outcomes are collected using the Prosthetic Limb Users Survey of Mobility (PLUS-M™) developed by the University of Washington, led by Brian Hafner, PhD. The well-being subsection of the Prosthesis Evaluation Questionnaire (PEQ-WB) is used to collect data on patient satisfaction and quality of life.

Led by the Hanger Institute for Clinical Research and Education, this outcomes initiative, which began in 2016, demonstrates the value of implementing outcome measures as a standard of care for all patients with lower limb loss.

# MAAT I

## Quality of Life and Satisfaction are Strongly Related to Mobility for Patients with a Lower Limb Prosthesis

PROSTHETICS AND ORTHOTICS INTERNATIONAL | OCTOBER 2017

It is essential that we understand and analyze the overall effect of prosthetic rehabilitation and the impact it has on a patient's mobility and quality of life following amputation.

Using one of the largest data sets at the time, the MAAT I study begins the series by underscoring the importance of maximizing mobility in patients with lower limb loss, both for the associated immediate functional benefits as well as its influence on quality of life and satisfaction. In the first study, researchers analyzed the constructs of quality of life and satisfaction in correlation to the mobility of 509 patients with a lower limb prosthesis. The analysis validates our assumption that mobility has a positive correlation with quality of life and satisfaction (r values of 0.511 and 0.475, respectively).

### CLINICAL IMPACT

These results highlight that restoring and maximizing mobility through prosthetic rehabilitation is an important part of providing holistic care and positively impacting a patient's quality of life and satisfaction.

*Wurdeman SR, Stevens PM, Campbell JH. Mobility Analysis of AmpuTees (MAAT I): Quality of life and satisfaction are strongly related to mobility for patients with a lower limb prosthesis. Prosthet Orthot Int. 2018 Oct;42(5):498-503.*

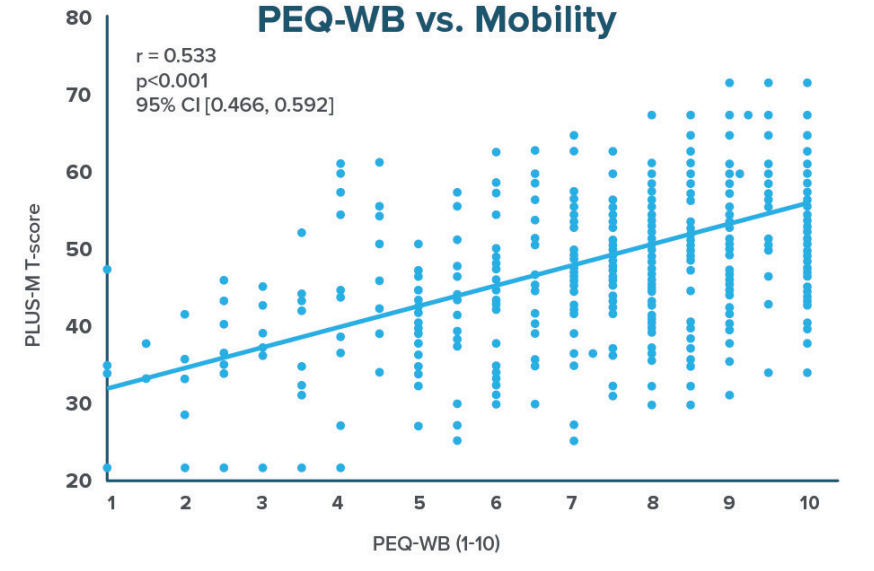



**Figure 3.** For patients with a lower limb prosthesis, there is a strong, significant relationship between the Prosthesis Evaluation Questionnaire—Well-Being subsection (PEQWB) and mobility. The positive relationship indicates patients reporting greater mobility tend to report higher quality of life and satisfaction. The PEQ-WB comprises the arithmetic mean of individual questions of quality of life and satisfaction and has been previously validated to be administered separate from the entire PEQ. Mobility was measured through the Prosthetic Limb Users Survey of Mobility (n = 509).

# MAAT II

## Comorbidities and Mobility in Lower Limb Prosthesis Users

### AMERICAN JOURNAL OF PHYSICAL MEDICINE & REHABILITATION | NOVEMBER 2018

Some patients are denied access to prosthetic rehabilitation due to assumptions that are tied to certain comorbidities, and often times those assumptions hurt those who may otherwise benefit from prosthetic mobility. In MAAT II, the second study in the series, researchers aimed at determining the impact of comorbidities and multi-comorbidities on mobility in patients with lower limb prostheses. The questions considered were:

**1.** What role does comorbid health or multi-comorbidities play on mobility?

**2.** Which comorbidities are significant predictors for increased mobility?

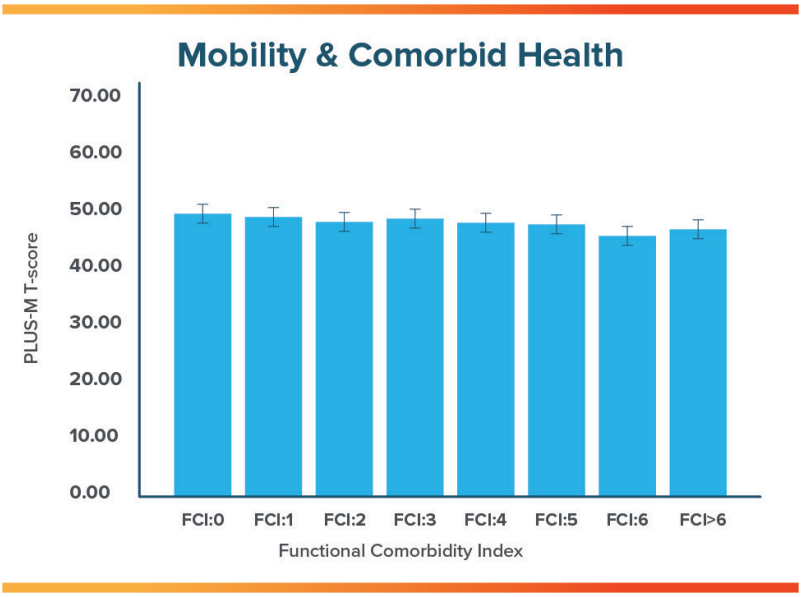



**Figure 1.** Group estimated marginal means for each FCI cohort after removing effects of covariates. There was a lack of significant differences between groups.

The study included a cohort database chart review examining mobility in lower limb prosthesis users. Patients were grouped according to comorbidities, and regression models were used to determine significant predictor comorbidities for mobility. A general linear univariate model was also used to investigate differences in mobility among those cohorts (N=596). Mobility was assessed utilizing the PLUS-M, while comorbid health was evaluated by collecting data on 18 possible conditions as reported by each patient. Comorbidities are commonly associated with a decrease in physical function (including mobility), so it was important to include a multitude of conditions that limb loss patients deal with every day. Common comorbidities in the data set were: diabetes, peripheral vascular disease (PVD), heart disease, forms of arthritis, upper gastrointestinal disease, depression, anxiety, degenerative disc disease, and obesity. Patient demographics included a wide age range from 19-95 years and a gender distribution of 448 males vs 148 females, with the largest conditions noted within the vascular disease/diabetes group (267) and the injury/trauma group (138). With a far more robust data set to analyze than in previous published studies, researchers were able to generate a weighted value for a specific Functional Comorbidity Index (FCI) that helped analyze mobility while accounting for comorbidities and begin to identify predictors.

Researchers identified only three comorbidities that ended up being significant predictors for decreased mobility: history of stroke, peripheral vascular disease (PVD), and anxiety/panic disorders, in addition to advancing age.

Following the identification of the four significant predictors, researchers were able to compare the groups with multi-comorbidities and determined there was no significant differences when comparing overall comorbid health after adjusting for covariates.

## CLINICAL IMPACT

Clinicians should consider patient age and history of stroke, peripheral vascular disease, or anxiety/panic disorders when optimizing a lower limb prosthesis users' mobility as these variables may be predictive of modest but clinically meaningful decreased prosthetic mobility. Rehabilitation plans that account for these conditions can further optimize patient mobility. By contrast, common comorbid health conditions such as diabetes, obesity, arthritis, chronic obstructive pulmonary disease, congestive heart failure, and others do not seem as influential to decreased mobility among lower limb prosthesis users.

*Wurdeman SR, Stevens PM, Campbell JH. Mobility Analysis of AmpuTees II: Comorbidities and Mobility in Lower Limb Prosthesis Users. Am J Phys Med Rehabil. 2018 Nov;97(11):782-788.*

# MAAT III

## Matching Individuals Based on Comorbid Health Reveals Improved Function for Above-Knee Prosthesis Users with Microprocessor Knee Technology

ASSISTIVE TECHNOLOGY | DECEMBER 2018

Increased function is a commonly-asserted benefit of below-knee (BK) amputation compared to above-knee (AK) amputation. Better control of the knee leads to increased stability for individuals with a BK amputation. With stability comes the ability to counter falls, one of the biggest factors impacting a patient's rehabilitation plan and cost of care. Now, using big data, researchers can improve the narrative for patients with an AK amputation, providing them with the opportunity to improve their stability and control through advancements in technology.

The MAAT III study evaluated the impact of microprocessor knee (MPK) technology on AK prosthesis users when matched with individuals with similar comorbid health conditions. A matching process was feasible by pulling from a database that included 2,300 patients, allowing for matching similar overall health profiles, and most importantly, comorbidities. They were analyzed in the real world, doing real activities, and interacting in their own communities rather than more common analyses within a lab, doing only restricted activities based on prescribed design variables.

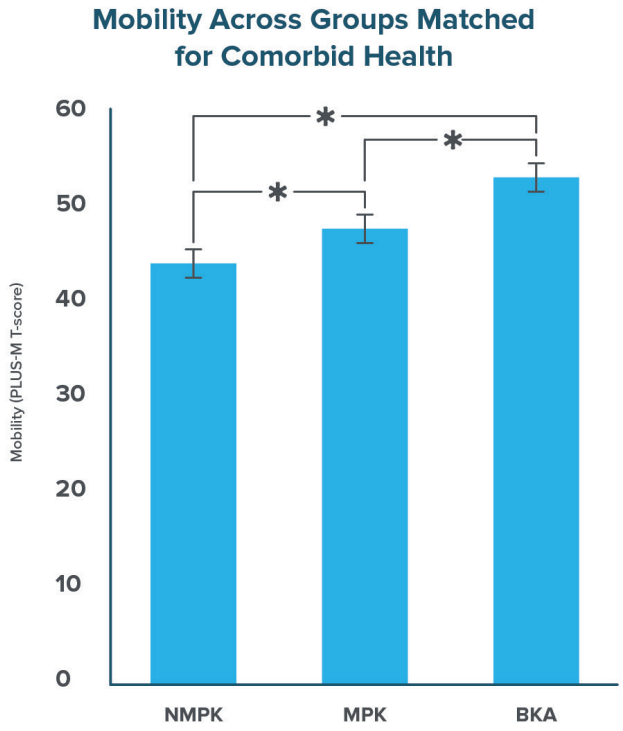



**Figure 2.** Group differences for mobility calculated from the Prosthetic Limb Users' Survey of Mobility (PLUS-M). Significant differences were found between the matched above-the-knee prosthesis users with a NMPK and those with a MPK. These differences were also observed while accounting for potential confounding effects of age, body mass index, cause of amputation, and comorbid health status. Other significant group differences are noted ($p < 0.05$). *, Sig. at $p < 0.05$. NMPK, nonmicroprocessor knee group; MPK, microprocessor knee group; BKA, below-the-knee amputation group.

In MAAT II, the correlation between mobility and comorbid health status was reported. With MAAT III, we were able to go one step further and analyze from within that dataset MPK and Non-MPK (NMPK) users. The matching process based on comorbid health also facilitated a third group, a biological knee group comprised of patients with a BK prosthesis. Three cohorts of 150 patients each were analyzed, all with a similar functional comorbidity index. When looking at three cohorts: AK NMPK users, AK MPK users, and BK prosthesis users, we

found that even though we did see a difference in mobility for AK vs BK prosthesis users, generally, AK MPK users had a significant increase in mobility as compared to their AK NMPK counterparts. Researchers concluded that not only would a MPK improve mobility for the NMPK group, but it practically cuts the functional gap between BK and AK limb loss patients in half.

## CLINICAL IMPACT

Understanding that it may be costlier and may require increased documentation, this study provides continued evidence that patients receive the benefits of improved mobility and reduced functional limitations from advanced knee technology.

We look at this study as a message of continued hope for patients—hope that with the right technology, functional limitations can be overcome and mobility can be improved, and ultimately so can their quality of life.

*Shane R. Wurdeman, Phillip M. Stevens & James H. Campbell (2018): Mobility Analysis of AmpuTees (MAAT 3): Matching individuals based on comorbid health reveals improved function for above-knee prosthesis users with microprocessor knee technology. Assist Technol. 2020 Sep 2;32(5):236-242.*

# MAAT IV

## Classification Tree Analysis for Probability of Lower Limb Prosthesis User Functional Potential

ASSISTIVE TECHNOLOGY | FEBRUARY 2019

Lower limb prosthetic rehabilitation within the United States currently relies on the Medicare Functional Classification Level (K-Level) system to provide reimbursement eligibility guidelines for prostheses. Subsequently, a patient's K-level assignment often has a large impact on his or her prosthesis prescription, with some commentary going so far as to note "K-level designation is important because it is the driving factor in the decision on what prosthetic device to provide."

The increase in computing power and statistical insights has provided the ability to synthesize big data into complex, predictive models to inform evidence-based decision trees. With K-level designation having a large impact on determining a patient's prosthesis prescription, our goal with MAAT IV was to develop a decision tree that can effectively inform the probability of a patient's functional potential. It was hypothesized that the ending nodes within the decision tree would provide probabilities for functional potential determination greater than random determination.

With the goal of bringing evidence-based decision making into every day clinical practice,

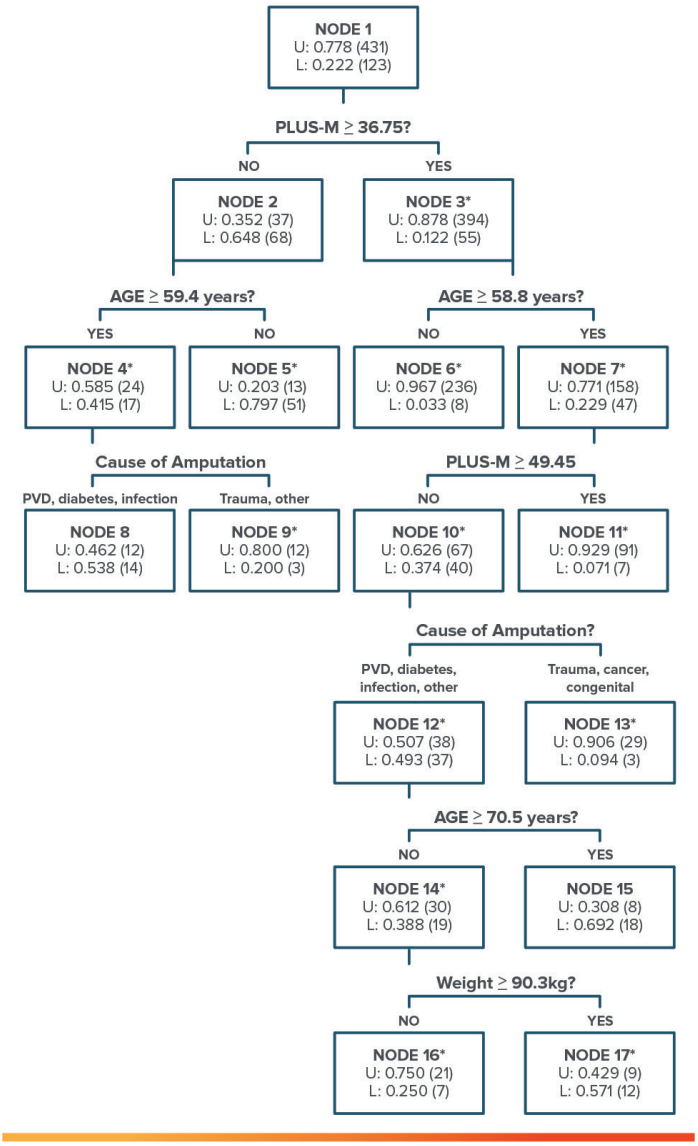



**Figure 3.** Classification tree developed and tested based on data from 2770 patients. The overall correct classification rate was 87.4%, with a risk of 12.6% and standard error 1.4% when training the model. Correct classification for limited community/household ambulators was 77.2% and 90.3% for unlimited community ambulators. Each node displays class probability and membership in parentheses for training sample. U: unlimited community ambulator, in Medicare Functional Classification System would be K3 or K4; L: limited community/household ambulator, in Medicare Functional Classification System would be K2 or K1. *node classification significantly different than random assignment process, clinicians should obtain more information for patients not ending in these nodes when making functional potential determination.

researchers perfomed a retrospective review of an outcomes database featuring 2,770 lower limb prosthesis users to inform a classification and regression tree analysis.

Using the potential predictive variables (gender, age, height, weight, body mass index adjusted for amputation, amputation level, cause of amputation, comorbid health status, and functional mobility score [PLUS-M™]), a classification tree was successfully developed and was able to accurately classify 87.4% of individuals within the model's training group (standard error 1.4%), and 81.6% within the model's testing group (standard error 0.82%). Age, PLUS-M T-score, cause of amputation, and body weight were retained within the tree logic.

## CLINICAL IMPACT

A classification tree analysis was developed to effectively predict the probability of a lower limb prosthetic patient's functional potential and inform K-Level designation. This simple and quick analytical tool can be used to provide predictive models for patients with a lower limb prosthesis, helping clinicians to make evidence-based care decisions based off a patient's functional potential.

*Wurdeman SR, Stevens PM, Campbell JH. Mobility Analysis of AmpuTees (MAAT 4): classification tree analysis for probability of lower limb prosthesis user functional potential. Disabil Rehabil Assist Technol. 2020 Feb;15(2):211-218.*

# MAAT V

## Impact of Five Common Prosthetic Ankle-Foot Categories for Individuals with Diabetic/Dysvascular Amputation

JOURNAL OF REHABILITATION AND ASSISTIVE TECHNOLOGIES ENGINEERING | FEBRUARY 2019

Diabetes and vascular disease represent the most common etiologies resulting in lower limb amputations. Understanding the impact of these diseases is crucial to providing important insight to the patient's medical team. While it has been shown that technological advances in prosthetic rehabilitation give patients the opportunity to improve outcomes, studies incorporating such a large data set are far and few between.

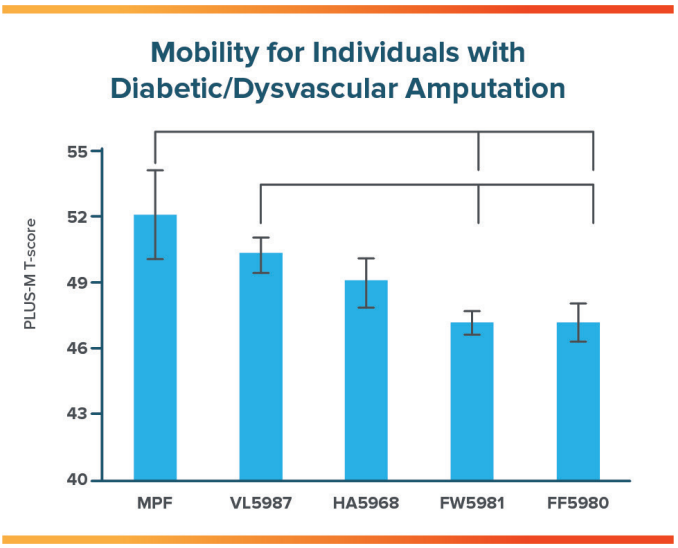



**Figure 2.** Mobility (PLUS-M T-score) for five different groups of prosthetic ankle-foot users (total sample, n¼738). Columns (from left to right) correspond to microprocessor ankle-foot (MPF), shank-foot systems with vertical loading pylons (VL5987), hydraulic ankle-foot systems (HA5968), flex-walk ankle-foot systems (FW5981), and flex-foot type ankle-foot systems (FF5980). Significant differences were noted after removing potential confounding effects of age, body mass index, comorbid health status, time since amputation, and amputation level. Black bars indicate group differences at $p<0.05$.

MAAT V examined the impact of five common prosthetic ankle-foot mechanisms on functional mobility in a large sample of individuals with amputation due to diabetes/vascular disease. In lower limb loss rehabilitation, the prosthetic ankle-foot mechanism is the most common major component needed to restore function to patients impacted by these diseases. From a retrospective analysis of the PLUS-M captured in the patient care setting, a total of 738 individuals were included and subsequently subdivided into five groups based on the ankle foot mechanism of their current prosthesis. Groups were compared using a general linear univariate model with age, body mass index, comorbid health status, time since amputation, and amputation level entered as covariates.

The microprocessor ankle-foot group had the highest mobility ($F_{4,728}=3.845$, $p=0.004$), which was followed by the vertical loading pylon-type ankle-foot, the hydraulic ankle-foot, the flex-walk-type ankle-foot, and lastly the flex foot-type ankle-foot.

### CLINICAL IMPACT

These results demonstrate the selection of different prosthetic ankle-foot technology directly impacts functional mobility for patients with an amputation due to diabetes and/or vascular disease. As all individuals that experience a lower limb amputation at or proximal to the ankle joint will require a prosthetic ankle-foot mechanism, this

component category impacts the lives of more individuals with amputation than any other prosthetic technology.

*Wurdeman SR, Stevens PM, Campbell JH. Mobility Analysis of AmpuTees (MAAT 5): Impact of five common prosthetic ankle-foot categories for individuals with diabetic/dysvascular amputation. J Rehabil Assist Technol Eng. 2019 Feb 13;6:2055668318820784.*

# MAAT VI

## Mobility, Satisfaction, and Quality of Life among Long-Term Dysvascular/Diabetic Prosthesis Users–Results of a Cross-Sectional Analysis

JOURNAL OF PROSTHETICS AND ORTHOTICS | FEBRUARY 2020

Irrespective of the cause, amputation brings a dramatic change in the life situation of an individual in almost all aspects of daily living and functioning. The most common cause of lower-limb amputation in the United States is vascular disease typically with associated diabetes. Recent articles on the long-term prognosis of those individuals who undergo major lower-limb amputation due to vascular disease and diabetes have emphasized mortality rates.

Long-term mobility levels among individuals with amputation due to vascular disease have generally been reported in a binary fashion, distinguishing only between those who sustain or lose their ability to walk. The aim of MAAT VI was to establish the mobility, satisfaction, and quality of life among prosthesis users with dysvascular/diabetic amputation at both acute and long-term phases of prosthetic rehabilitation. As part of the routine standard of care, patients' satisfaction and quality of life were assessed using the Prosthesis Evaluation Questionnaire- Well Being (PEQ-WB).

### CLINICAL IMPACT

Patients with vascular disease/diabetes who remained actively engaged in prosthetic rehabilitation as far

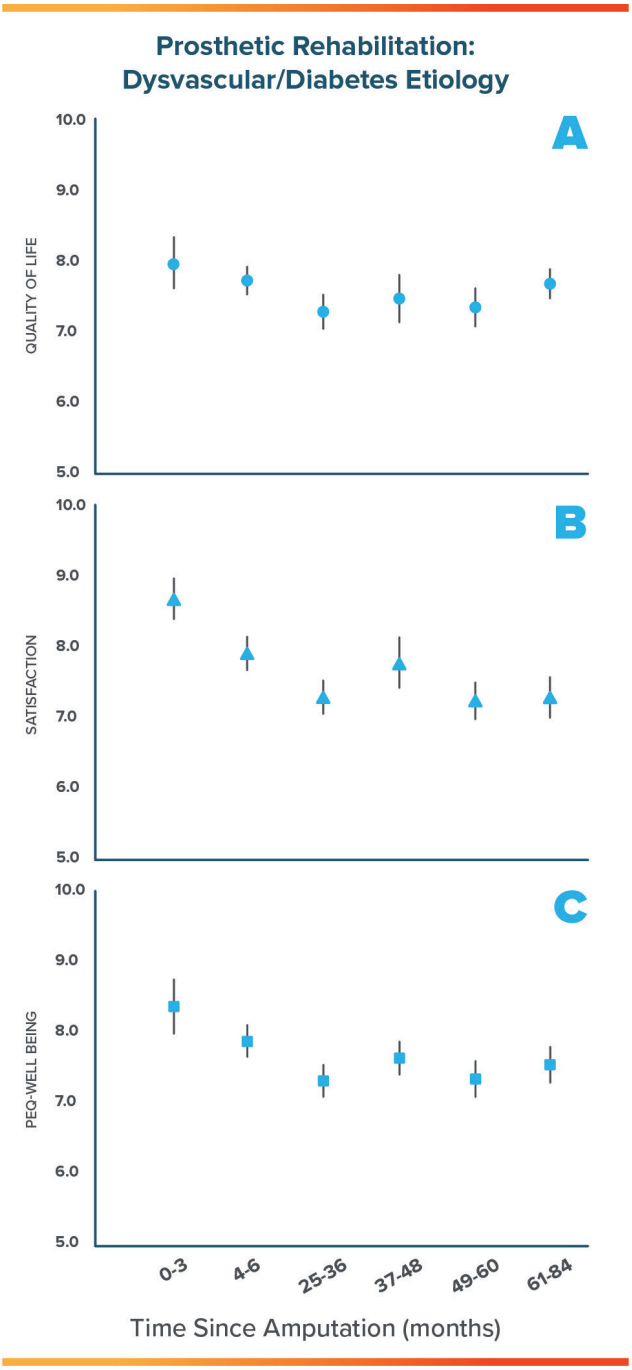



**Figure 3.** Quality of life, satisfaction, and well-being scores were analyzed across groups at different time points post-amputation. Only satisfaction had any differences, with early satisfaction (0–3 months) levels postamputation being inflated, which subsequently led to similar trends in Prosthesis Evaluation Questionnaire–Well-Being (PEQ-WB) composite score, but this was not significant. Mean ± S.E.

out as 7 years post-amputation experienced high levels of quality of life, satisfaction, and sustained mobility. The results underscore the value of continued prosthetic rehabilitation into the post-amputation care plan and sustained utilization of a prosthesis. Not only do individuals with a prosthesis continue to experience elevated quality of life and satisfaction values, but their use of a prosthesis and continued mobility may contribute to their ability to continue to thrive in light of the elevated mortality rates observed in this population.

*Wurdeman SR, Stevens PM, Campbell JH. Mobility Analysis of AmpuTees (MAAT 6): Mobility, Satisfaction, and Quality of Life among Long-Term Dysvascular/Diabetic Prosthesis Users-Results of a Cross-Sectional Analysis. J Prosthet Orthot. 2021 Jul;33(3):161-167.*

# MAAT VII

## Normative Mobility Values for Lower Limb Prosthesis Users of Varying Age, Etiology, and Amputation Level

AMERICAN JOURNAL OF PHYSICAL MEDICINE & REHABILITATION | DECEMBER 2021

The final study in the series, MAAT VII, analyzed data from nearly 12,000 lower limb prosthesis users, who were grouped by age, amputation etiology, and AK vs. BK amputation. MAAT VII established normative values for each group, ultimately expanding known benchmarks from two etiologies across four age groups, to four etiologies (cancer, congenital, trauma, and diabetes/dysvascular) across seven age groups. The awareness of differences across amputation etiologies extending across the lifespan of ages can assist the goal-setting process as part of prosthetic rehabilitation. Additionally, refined normative values provide the ability to benchmark new and innovative changes in clinical practice.

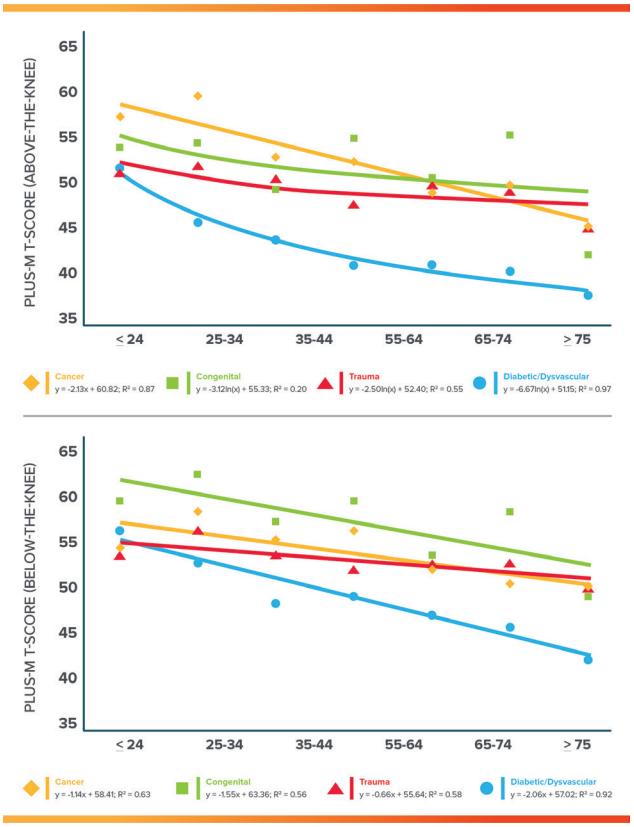



**Figure 2.** The optimal best fit line across age group medians was plotted for cancer, congenital, trauma and diabetic/dysvascular (DV) etiologies for both individuals with above-the-knee (figure 2A) and below-the-knee amputation (figure 2B). DV shows greatest decline with age.

The findings of this study are valuable and insightful because mobility seems to decline at different rates across amputation levels for cancer, congenital, and trauma compared to diabetes/dysvascular. Older individuals with above-knee or below-knee amputations reported reduced mobility across the four primary etiologies. As expected, the oldest age group had the lowest mobility across amputation level and etiology. The diabetes/dysvascular etiology had the lowest median mobility scores across amputation levels and was significantly different from trauma, cancer, and congenital disease. With an understanding of the general decline in mobility due to aging, future longitudinal studies may now have the ability to benchmark intervention performance in reducing the rate of decline in mobility associated with age.

### CLINICAL IMPACT

Individuals with amputation can struggle to understand realistic goal setting, which is also dependent on the underlying cause of amputation. Understanding the magnitude in the differences among the four etiologies may

aid in the allocation of targeted interventions, and allows for a more nuanced discussion at the patient-clinician level for goal setting during the rehabilitation process. Clinicians can help patients set goals based on how well individuals that are similar to them are able to perform when achieving their highest reported mobility, subsequently preventing unrealistic goals as well as encouraging attainable goals.

Additionally, refined normative values provide the ability to benchmark new and innovative changes in clinical practice.

*England DL, Miller TA, Stevens PM, Campbell JH, Wurdeman SR. Mobility Analysis of AmpuTees (MAAT 7): Normative Mobility Values for Lower Limb Prosthesis Users of Varying Age, Etiology, and Amputation Level. Am J Phys Med Rehabil. 2021 Dec.*


# IN CLOSING

The MAAT series has worked to further the profession, advancing outcomes-based care and revolutionizing the way we leverage clinical research to discover best practices for our patients. This work underscores the importance of empathy of care, and ultimately helps us to better meet patients where they are on their journey. It will undoubtedly serve as a springboard that continues to drive advances in evidence-based practice within orthotic and prosthetic care.

## REFERENCES

**1.** *Ziegler-Graham K, MacKenzie E, Ephraim P, et al: Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med Rehabil 2008;89:422–9.*

**2.** *Patient Centered Outcomes Research Institute, http://www.pcori.org (accessed July 2017).*

**3.** *Patient-reported outcomes measurement information system. National Institutes of Health Office of Strategic Coordination—the common fund, https://commonfund.nih.gov/promis/index (accessed July 2017).*

Review the full, individual **MAAT Studies.**

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