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Original Research

PROClass: The Development and Validation of a Novel Prosthetic Component Sophistication Classification System

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KEYWORDS
Accuracy;
Classification system;
Lower limb amputation;
Lower limb prosthesis;
Rehabilitation;
Reliability

Abstract *Objective:* To develop a lower limb prosthesis (LLP) sophistication classification system that categorizes prosthetic component prescriptions into "basic," "intermediate," and "advanced" and assess its content validity, reliability, and accuracy.
Design: Classification development and validation study.
Setting: The Veterans Affairs (VA) Corporate Data Warehouse database and National Prosthetics Patient Database were used to identify patients undergoing their first amputation at the transtibial or transfemoral level due to diabetes or peripheral artery disease and to identify the associated codes for each LLP.
Participants: An expert panel of 6 nationally recognized certified prosthetists, a national expert in VA prosthetics data and coding, a physical medicine and rehabilitation physician, and an epidemiologist developed an LLP classification system (*PROClass*) using 30 transfemoral and transtibial lower limb amputees.
Main Outcome Measures: The expert panel reviewed 20 consecutive participants meeting study criteria for the development of the *PROClass* system and a subsequent 30 consecutive cases for assessing the inter- and intra-rater reliability and accuracy.

List of Abbreviations: CI, confidence interval; HCPCS, Healthcare Common Procedure Coding System; LLP, lower limb prosthesis, PMR, physical medicine and rehabilitation; TF, transfemoral; TT, transtibial; VA, Veterans Affairs.

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Results: The interrater and intrarater reliability was almost perfect with Gwet's AC1 values ranging from .82 to .96 for both expert panel members and research assistants. The accuracy of the research assistant's classifications to the "criterion standard" was excellent with Gwet's AC1 values ranging between .75 and .92.
Conclusions: PROClass is a pragmatic, reliable, and accurate prosthetic classification system with strong face validity that will enable the classification of prosthetic components used for large data set research aimed at evaluating important clinical questions such as the effects of sophistication on patient outcomes.

One of the most important decisions to be made during lower limb amputation rehabilitation is the determination of patient suitability for a lower limb prosthesis (LLP), and if appropriate, what type and level of prosthetic componentry sophistication will best optimize functional outcomes. These decision-making requirements have been identified as a significant challenge in current clinical practice.[1] Clinical practice guidelines suggest that the currently available level of evidence to guide prosthetic componentry prescription decisions is weak,[2] and that there is inadequate evidence to support the benefit of specific prosthetic prescription components necessary to maximize ambulation function and quality of life or to minimize abandonment.[3] For individuals who have undergone traumatic amputation, there is increasing clinical consensus about the benefits of prosthetic componentry with more sophisticated design characteristics,[4] while the potential benefits of more sophisticated prosthetic foot/knee units on functional recovery in patients who have undergone amputation secondary to diabetes or peripheral artery disease continues to be controversial.[5] This lack of adequate evidence has led to a reluctance for third-party payors to fund these more costly components.[5]

The necessary evidence to support prosthetic sophistication as an important contributor to patient outcomes requires the availability of a valid prosthetic componentry classification system. Considering the large number of available prosthetic foot designs and knee units, it is not feasible to study the effect of every potential combination of components in a transtibial (TT) or transfemoral (TF) prosthesis; therefore, a parsimonious classification system is the first step in assisting future researchers in evaluating the effect of prosthetic sophistication prescriptions on patient outcomes.

The purpose of this study was to develop an LLP sophistication classification system (aka, *PROClass*) that categorizes prosthetic component prescriptions based on their sophistication and assess its content validity, reliability, and accuracy. The ultimate goal of this research is to use the system to address important research questions that require large data set analyses, such as whether prosthetic sophistication is associated with future mobility in specific demographic or comorbid patient populations.

Methods

This development and validation study for the *PROClass* system is part of a larger study to develop a prediction model for predicting 12-month prosthetic mobility at the time of prosthetic prescription assessed through patient-reported outcomes.[6]

As part of the larger study, a Department of Veterans Affairs Corporate Data Warehouse database was used to identify patients who were aged 40 years and older, undergoing their first amputation at the TT or TF level. Only amputations performed because of diabetes or peripheral artery disease were included. For each identified amputation, we looked back 5 years to determine if there was a prior procedure code for a previous amputation or reamputation to ensure that only patients who had undergone a single incident amputation were included. Subjects were excluded if they died within 12 months of prosthetic prescription (as we were unable to obtain patient-reported mobility outcomes for the parent study), were undergoing a bilateral amputation, were paraplegic, quadriplegic, had a diagnosis of spinal cord injury or dementia, or a BMI<15 or >52. Patients were included if they met all study criteria and received a qualifying prosthetic prescription between March 1, 2018, and November 30, 2020. Qualifying Healthcare Common Procedure Coding System (HCPCS) codes included all L51xx-L53xx, as well as all codes listed in table 1. Patients were excluded if the only prescription found was for an initial post-operative rigid dressing or evidence of a repair to or supplies for a previous prosthesis. The first 20 consented consecutive participants meeting study criteria were used for the development of the *PROClass* system. The next 30 consecutive cases were used for the reliability and accuracy assessment. All participants provided informed consent and this study was approved by the local Internal Review Board.

Data source and key variables

The Department of Veterans Affairs Corporate Data Warehouse was used to access the National Prosthetics Patient Database to identify patients who received a qualifying prosthetic prescription, the date of that prescription, and the associated HCPCS codes for each LLP prescribed within 12 months after incident amputation. The National Prosthetics Patient Database was established as a central database of prosthetics data, to enable clinical reviews to increase quality, reduce costs, and improve efficiency of the prosthetics program.[7] All prosthetic records and relevant data variables were organized in a summary table including the following variables: *IncidentAmpLvl* (amputation level and laterality), *ConsultEIN* (record number), *date_rx_written* (date prescription was written), *hcpcs code, AppReq_Description* (free text to describe the

Table 1 Prosthetic sophistication designation based on HCPCS codes

Prosthetic Sophistication	Amputation Level	Prosthetic Description	HCPCS Descriptions and CMS designation if provided
BASIC	Transtibial	• Foot/Ankle assemblies: Flexible keel, SACH feet or single axis	L5970: solid ankle cushion heel (sach) L5971: solid ankle cushion heel (sach) (replacement) L5972: Flexible Keel L5974: Single Axis foot L5975: Single Axis with flexible keel
	Transfemoral	• Knee unit: Constant friction knees; may include manual lock	L5611: 4 bar, friction swing phase control L5616: Universal multiplex, friction swing phase control L5810: Single axis Manual lock L5811: Single axis manual lock ultra-light L5812: Single axis, friction swing, stance phase control (safety knee) L5816: Polycentric, mech. Stance phase lock L5818: polycentric, friction swing, stance phase control
INTERMEDIATE	Transtibial	• Foot/Ankle assemblies: Energy storing feet and multi- axial ankle/feet	L5976: Energy storing foot (Seattle Carbon Copy II or Equal) L5978: Multiaxial ankle/foot L5979: Multiaxial ankle/Dynamic response foot L5980: Flex foot system L5981: Flex-Walk system
	Transfemoral	• Knee units: Fluid controlled mechanical knees	L5613: 4 bar linkage, hydraulic swing phase control L5614: 4 bar linkage, pneumatic swing phase control L5814: polycentric, hydraulic swing phase control, stance phase lock L5822: single axis, pneumatic swing, friction stance L5824: single axis, fluid swing control L5826: single axis, hydraulic swing phase, miniature high active frame L5828: single axis, fluid swing and stance control L5830: single axis, pneumatic/swing phase control L5840: 4 bar linkage or multiaxial, pneumatic swing phase control
ADVANCED	Transtibial	• Foot/Ankle assemblies: Vertical loading pylon feet, Microprocessor controlled ankle/foot system and power assist system	L5969: Ankle foot Power assist system L5973: Microprocessor controlled ankle/foot system L5987: shank foot system with vertical loading pylon
	Transfemoral	• Knee units: Microprocessor control knees and knee/foot system allowing ankle dorsiflexion	L5610: Hydracadence system L5856: Microprocessor, swing and stance phase control L5857: Microprocessor, swing phase only L5858: Microprocessor, stance phase only L5859: Powered, Programmable, flex/Ext assist Control

item), *PORemarks* (free text for purchasing staff to describe the item), and *ConsultReason* (details of prescription).

PROClass system and algorithm developed by expert panel

The *PROClass* system was developed by an expert panel of 6 nationally recognized certified prosthetists, a national expert in Veterans Affairs (VA) prosthetics data and coding, a physical medicine and rehabilitation (PMR) physician with 35 years of prosthetic rehabilitation experience, and an epidemiologist with 20 years of amputee outcomes research experience. The classification system assigns each prosthetic foot and knee HCPCS code to a functional sophistication category including "basic," "intermediate" and "advanced" (table 1). These assignments were based on the design and features described by the HCPCS language.

The "basic" sophistication included feet with a simple design of a foam shape foot with a structure of plastic, wood, or inexpensive flexible material. In addition, feet that have a simple single axis pivot for allowing plantarflexion and dorsiflexion were considered "basic" by design and function. The "basic" designed knees include a mechanical friction-controlled knee joint, which often has a manual lock. "Basic" knees are often used for limited walking on level ground with a single speed of walking.

The "intermediate" sophistication includes feet with energy storing forefoot keels and feet with a toe and heel spring design. Also included in the "intermediate" sophistication are feet with multi-axial ankle units. The "intermediate" sophistication knees included designs with a mechanical fluid-controlled knee joint. "Intermediate" feet and knees are often used for community ambulation on uneven ground with varied walking speeds.

The "advanced" sophistication included feet with a complex design involving a vertical loading pylon to absorb impact loads. Also included in the "advanced" sophistication are feet with microprocessor-controlled units or power assist-controlled systems. The microprocessor and power assist systems are often used for community ambulation with a need for increased toe clearance from the ground and improved safety while walking on uneven terrain by absorbing the ground reaction forces. There are additional components that can be added to a foot that would increase the sophistication and function of the foot by 1 grade. The components include a hydraulic ankle unit, rotational unit, or a shock pylon and are described by L5968, L5984, and L5988.[8] The L5986 was not used to increase the sophistication because many manufacturers have strongly recommended this code for split keel and heel springs when it should not be applied. In addition, the L5986 provides minimal motion in all 3 planes and does not add to the complex sophistication of a prosthetic foot. The "advanced" sophistication includes knees with a complex design using a microprocessor-controlled knee joint or complete knee and foot system allowing for ankle dorsiflexion. The microprocessor monitors and controls the knee joint during the swing and stance phase of gait. The "advanced" knees are often used for variable walking speeds with quick speed adjustments and users who need increased stability with varying terrain changes.

Development of the *PROClass* algorithm and content validity

An algorithm for reviewing the prosthetic records and assigning the prosthetic sophistication classification was developed by a smaller expert panel of 3, including a research prosthetist, the PMR physician, and the epidemiologist, with frequent consultation from the national expert. The algorithm underwent several iterations before the panel arrived at the final *PROClass* algorithm to be evaluated for reliability and accuracy. The classification was based on the first qualifying prescription after incident amputation. The compendium of commercially available prosthetic feet and knees prepared by 1 of the research prosthetists was used to assign the HCPCS codes identified for the prosthetic sophistication (supplemental tables S1-S2).[8,9] Table 2 describes the steps in the classification algorithm, which underwent a reliability and accuracy assessment.

Interrater and intrarater reliability of the *PROClass* algorithm

Interrater reliability of the classification algorithm was established by having 3 independent reviewers from the expert panel and a research assistant who participated in the development of the algorithm classify 30 new consecutive cases by following the algorithm and assigning a

Table 2 Four step algorithm to classify prosthetic functional sophistication*

Step 1	a) The amputation level was determined by reviewing the *IncidentAmpLvl* variable. This was used to guide the reviewer as to whether to classify the foot or the knee. b) The HCPCS code used for the prosthetic sophistication classification was based on the following criteria: if a transtibial amputation was the defined amputation level, the classification was based on the prosthetic foot type. If a transfemoral amputation was the defined amputation level, the classification was based on the prosthetic knee type. c) If the amputation level did not agree with the prosthetic limb prescribed in steps 2-4 below (eg, a transtibial amputation included a prosthetic knee in the prescription), then the sophistication was classified based on the HCPCS code rather than the *IncidentAmpLvl* and it was assumed the amputation level was misclassified (this rarely happened). d) If the first record (*CONSULTIEN=1*) did not include an initial prosthesis, the reviewer moved to the next *CONSULTIEN* to identify the initial foot or knee classification.
Step 2	If a specific foot or knee (eg, "Variflex" or "Plié") was specified in the *ConsultReason, AppReqDescription,* and *PORemarks* variables (reviewed in this order) then the classification was based on this prosthesis corresponding HCPCS code from the VA compendium (see Table in supplemental material). Generic system descriptions (eg, "Variflex type," "flex foot system," or "flex foot or similar") were not relied on in this step.
Step 3	If a specific foot or knee was not listed, but *the ConsultReason, AppReqDescription,* and/or *PORemarks* variables indicated a "microprocessor" foot or knee should be prescribed, these were classified as "advanced" without requiring a named prosthetic component.
Step 4	If a specific foot or knee was not prescribed but rather a generic foot or knee system (eg, " Variflex type," "flex foot system," or "flex foot or similar") was in the *ConsultReason, AppReqDescription,* and/or *PORemarks*, the classification was based on the corresponding HCPCS code.

* If a classification could not be determined by this algorithm due to sparce data, the prosthetic was deemed non classifiable. This occurred in less than 5% of cases.

sophistication level based on table 1. Based on prior research evaluating interrater reliability among 3 raters, to achieve correlation coefficients above 0.7, 13-18 cases would have beenequireed.[10] These classifications were compared between the 3 expert panel reviewers. After independently classifying each case, the "criterion standard" was established based on consensus among the 3 reviewers, and when there was not consensus, at least 2 out of 3 agreeing on the sophistication.

Accuracy of the *PROClass* algorithm

The accuracy of the system was assessed by having a research assistant without prior experience in prosthetics, but who participated in the development of the classification system, classify these same records and comparing their classification sophistication to the "criterion standard." To ensure that the algorithm was equally effective for a "novice" research assistant, a research assistant with no prior experience in prosthetics nor involved in the algorithm development classified the first 10 of the 30 cases after 1 hour of training in the algorithm. Three weeks after the assessment, the cases were randomly reorganized and evaluated again by the same research assistants to assess intrarater reliability. The decision to evaluate 10 cases was pragmatic and based on the high level of agreement between the 3 independent reviewers.

Statistical analysis

To determine agreement between and within reviewers (ie, inter- and intrarater reliability) and accuracy (comparing research assistant classifications to the "criterion standard") we calculated agreement using Gwet's AC1 (with 95% confidence intervals [CI]). Gwet's AC1 has been shown to provide more stable reliability coefficients than Cohen's Kappa which is known to have some limitations that can lead to paradoxical results (eg, low Kappa even in the presence of strong agreement), and in certain circumstances,[11,12] is less affected by prevalence and is therefore recommended for use with reliability analyses.[13,14] Because of the smaller sample of TF amputees, we performed the analysis on the entire population and then repeated the intra-tester reliability and accuracy assessment in just the TF amputees by pooling the 2 research coordinator assessments. Data were analyzed using Stata 16.0.[a]

Results

Prosthetic characteristics

Among the 30 cases, 6 of the participants received a TF amputation (20%) and the remaining 24 received a TT amputation (80%). The "criterion standard" classifications for the 30 cases were as follows: 3 (10%) classified as Basic, 20 (66.7%) classified as Intermediate, 6 (20%) classified as Advanced, and 1 (3.3%) deemed unclassifiable (table 3).

Interrater reliability

Among the expert reviewers, the interrater reliability of the 30 consecutive cases was almost perfect (Gwet's AC1 round 1=.86; 95% CI [.75-.98]); after case order was randomized and a 3-week washout period was observed it remained almost perfect (Gwet's AC1=.92; 95% CI [.83-1.00]), table 4. There was no appreciable difference in strength of agreement between feet and knee classifications; therefore, we did not present these separately.

Intrarater reliability

Intrarater reliability was also almost perfect within each of the expert reviewers, with Gwet's AC1 values ranging from .82 to .96. The research assistant who participated in the algorithm development also had almost perfect intrarater reliability (Gwet's AC1=.92; 95% CI [.80-1.00]). The research assistant who did not participate in algorithm development that received 1 hour of training showed almost perfect intrarater reliability, with Gwet's AC1=.88; 95% CI (.60-1.00), table 4.

Accuracy

The "criterion standard" classification was established from the first round and agreed 100% of the time with the second round. The accuracy of the research assistant's classifications to the "criterion standard" who participated in the development of the algorithm was also almost perfect (Gwet's AC1=.92; 95% CI [.80-1.00] for both rounds 1 and 2). The research assistant with 1 hour of training also demonstrated nearly perfect and substantial accuracy to the "criterion standard," with Gwet's AC1=.88; 95% CI [.60-1.00] and .75; 95% CI [.38-1.00], in rounds 1 and 2, respectively, table 4.

Table 3 Prosthetic functional sophistication distribution by amputation level and category (N=30)

Amputation Level	Transtibial (n=24)	Transfemoral (n=6)
Prosthetic sophistication	N (% for amputation level)	N (% for amputation level)
Basic	1 (4.2%)	2 (33.3%)
Intermediate	18 (75.0%)	2 (33.3%)
Advanced	4 (16.7%)	2 (33.3%)
Unclassifiable	1 (4.2%)	0 (0.0%)

Table 4 Reliability and accuracy statistics summary of the prosthetic classification system algorithm

Intra-rater Reliability	Gwet's AC1	95% Confidence Interval
Expert reviewer 1	.96	.88-1.00
Expert reviewer 2	.88	.74-1.00
Expert reviewer 3	.96	.88-1.00
Research assistant	.92	.80-1.00
Research assistant without prior experience	.88	.60-1.00
Inter-rater reliability		
Round 1	.86	.75-.98
Round 2	.92	.83-1.00
Accuracy (Research assistant)		
Round 1	.92	.80-1.00
Round 2	.92	.80-1.00
Accuracy (research assistant without prior experience)		
Round 1	.88	.60-1.00
Round 2	.75	.38-1.00

Pooled assessment of the research coordinators in transfemoral amputees only

Among the 40 combined assessments performed by the research coordinators (30 by the one involved in the development of the system and 10 by the one not involved), 8 assessments were among TF amputees only. The intrarater reliability among these assessors was perfect (Gwet's ACI=1.00) and the accuracy was strong (Gwet's ACI=.84; 95% CI=.45-1.00).

Discussion

Using an expert panel, which included 6 nationally recognized prosthetists, a national expert in VA prosthetics data coding, a PMR physician, and an epidemiologist, the *PROClass* system was created. The experience of the development team and the iterative effort met necessary criteria for achieving face and content validity. The algorithm used to assign the "basic," "intermediate," and "advanced" classification to the corresponding prosthetic prescription was found to demonstrate almost perfect interrater and intrarater reliability and accuracy when used by both clinical experts, and research assistants with and without any clinical training. This suggests that for future use, prosthetic sophistication classification can be successfully accomplished without the need for clinician expertise or knowledge of HCPCS coding. This feature enables its potential use in larger data set studies of amputee populations without the need for reliance on skilled clinical personnel.

Prior work related to the development of prosthetic component classification systems has largely relied on quantitative mechanical characterization,[15-18] particularly in the case of prosthetic foot classification.[19] This approach, although having merit, would require the characterization of potentially hundreds of prosthetic feet that are currently available in the marketplace, which would pose significant limitations for larger data research methodologies. These methodologies are critically important when addressing clinical questions related to the association of prosthetic componentry sophistication and prescription practices with patient demographic characteristics or comorbidities and their ultimate effects on patient outcomes.

This *PROClass* system is not intended to replace other systems such as the Medicare Functional Classification Levels "MFCL," or "K-levels." The Medicare Functional Classification Levels system is not a prosthetic sophistication classification system but a mobility classification system that has evolved into a tool that drives prosthetic prescription practices. It relies on the clinical provider determining the most appropriate level of sophistication of a prosthetic device to achieve a given anticipated level of mobility. The *PROClass* system can be used as a tool in future research to evaluate the potential relation between mobility outcome and prosthetic sophistication as well as other important questions related to bias in prosthetic prescription, as well as the relation between patient characteristics and the role of sophistication on outcome.[3]

Study limitations

The *PROClass* system does not include mechanical characterization in the classification. Therefore, it will not differentiate a foot/ankle mechanism that allows for multidimensional movement, which is typically prescribed for a patient walking on complex terrain, from a moderately sophisticated energy storing prosthetic component, which is typically designed for mobility optimization of linear gait activities. Future research using this classification system should be cognizant of this when interpreting the results of any potential associations between the degree of prosthetic sophistication and mobility outcome. In addition, for TF amputees, the system classifies using prosthetic knee characteristics—not both knee and foot.

Incorporating both knee complexity and foot complexity would expand the number of TF categories to 9 (3^2) reducing its practicality for research purposes. In hindsight, though we based our sample size on precedence from other studies, the sample size of 30 rendered relatively large confident intervals around our coefficients, despite very high agreement. In addition, because of the normal distribution of TT to TF amputations in this population, the sample size for

classifying knees in the TF group was small. Fortunately, the intratester reliability and accuracy among the research coordinators was equally as strong as the assessments among the TT amputees. However, this small sample size makes the results for the TF knee prosthesis less precise. To ensure sustainability of the system as componentry evolves over time, future work will reevaluate the accuracy and consistency of the system and will also include purposive sampling of TF amputees to ensure an equitable number of TT and TF amputees in the analysis. Finally, this study was conducted using data from the Veterans Health Administration. These data have a specific structure that was used to acquire the prosthetic prescription data elements; therefore, the extent to which it can be replicated with other large non-VA databases, such as those available through the Center for Medicare and Medicaid Services, remains unknown. However, with the HCPCS systems consistent across all databases, the application of the classification algorithm should not need to be altered. With a reliable and accurate system for classifying prosthetic sophistication available, the next steps will be to evaluate the *PROClass* system's ability to predict future prosthetic mobility, controlling for a host of variables that may influence both outcomes.

Conclusions

In summary, we have developed a pragmatic, reliable, and accurate prosthetic classification system with strong face and content validity that will enable both expert and non-clinical personnel to classify prosthetic components based on the sophistication of the mechanical control system into "basic," "intermediate," and "advanced" sophistication. This classification system can be used in future research to evaluate the effect of foot and knee prosthetic sophistication on a myriad of patient outcomes.

Suppliers

a. Stata 16.0, StataCorp.

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