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OASIS 2: Mobility differences with specific prosthetic feet across procedure codes

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Abstract

Introduction: Recently, many prosthetic devices were subjected to reimbursement coding review. Several prosthetic feet that were historically coded with the shock-attenuating function were recoded. The purpose of this analysis was to compare patient-reported functional mobility across a range of prosthetic feet using real-world clinical outcomes data.

Methods: A retrospective, observational review. A univariate generalized linear model was used to assess mobility across foot categories and between different prosthetic feet coded as L5987 or L5981.

Results: The final sample analyzed comprised of 526 individuals and four mutually exclusive categories of feet examined across a total of 10 different prosthetic foot types. The comparison of prosthetic foot categories were significantly different from the control category (i.e. historically L5981).

Conclusions: The current data suggest the development of some prosthetic foot designs using advanced materials and geometric designs can provide comparable functional benefits as those with distinct shock absorbing mechanical features. Emphasizing functional performance over visible features may be a pathway towards higher performance for the end user.

Keywords

prosthetic feet, outcomes, amputees, mobility, prosthesis foot type

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Introduction

Shock absorption to mitigate the impact of ground reaction forces during initial contact has been identified as one of the primary locomotor functions during ambulation.[1,2] Anatomic strategies for shock absorption include the compression of the calcaneal fat pad with its shock absorbing tissues, eccentric lengthening of the ankle dorsiflexors, pronation of the foot through stance phase, and stance phase knee flexion.[3] For users of lower limb prostheses, the lack of these anatomical body segments and more critically, the disruption of these eccentric joint movements compromise this foundational element of locomotion. In the absence of these mechanisms, the impact forces incurred with each step are translated proximally into the residual limb and through the body.[4] It has been suggested that one of the reasons lower limb prosthesis users walk slower than their able-

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bodied peers may be to decrease the impact forces of weight acceptance to comfortable, manageable levels.[5,6] This appears especially relevant in environmental ambulation, particularly during slope and stair descent.[5] The restoration of sufficient shock absorption to lower limb prosthesis users may enable faster gait across a broader range of environmental elements.[5]

In addition to the associated discomfort, users of lower limb prostheses risk the development of a number of injurious, overuse symptoms including osteoarthritis and low back pain.[7] The repeated impact forces also make the limb itself vulnerable to increased socket pressures, pain and skin breakdown.[8,9] Such socket issues have been linked to decreases in function and mobility among prosthesis users.[10]

As part of the effort to restore safety, comfort and mobility for lower limb prosthesis users to levels experienced prior to amputation, there have been a number of prosthetic components developed with shock absorbing functionality. This includes shock absorbing pylons (SAP). SAPs have been the subject of several studies, and while the majority of such studies have failed to confirm objectively measured reductions in shock attenuation,[11] patient-reported assessments have noted increased comfort across a range of ambulatory environments.[5,12]

Following the development of SAPs, alternative approaches were sought out to replicate SAP function through integrated designs using composite materials and thoughtful geometry rather than separate, distinct components for shock absorption. The goal of such attempts was to replicate the functionality of SAPs without the additional weight and height associated with additional componentry. The success of such efforts was illustrated in a recent analysis in which transtibial prosthesis users navigating a military obstacle course expressed a preference for such a lightweight composite foot with shock absorbing functionality over both a heavier foot with a distinct proximal shock attenuation unit or a similarly lightweight foot lacking the shock absorption functionality.[13]

The introduction of prosthetic feet with vertical shock absorption componentry was an advancement in care for individuals with lower limb amputation that was acknowledged by the Centers for Medicare and Medicaid Services (CMS) through issuance of a new reimbursement code, L5987. The descriptor for L5987 describes a "shank foot system with vertical loading pylon". As innovation drove towards a focus on patient performance through enhanced materials science, vertical shock absorption was obtained through integrated designs with reduced height and weight as described above.

Recent years, however, have seen an expanded discussion as to whether distinct, visible shock attenuation units should be required to justify the functional performance of a given foot and ankle mechanism. In 2020, this issue was central when the CMS contractor for Pricing, Data Analysis and Coding (PDAC) asserted that the L5987 describes a prosthetic foot in which "all components are integrated as a single product," rather than an assembly of separate products or components, but stipulated that "this code does not describe vertical loading or shock absorption achieved from the inherent flexibility of the J-shaped keel section".[14] Subsequently, a number of prosthetic feet were submitted to PDAC for review and L-code determination. Consistent with their statement, a number of prosthetic feet that were developed to achieve vertical shock absorption through advanced geometry and materials science, but lacking a distinct vertical loading mechanism, were recoded to an L5981. Notably, the L5981 procedure code carries lower reimbursement for clinicians providing this level of care. The feet submitted for review which featured a distinct, easily visible shock absorption component and are generally taller and heavier than the recoded feet, retained the L5987 code.[14]

The L5981 descriptor of the recoded feet notes a "flex-walk system or equal", and is considered to be a lower function foot than the L5987. These feet are not associated with enhanced shock absorption characteristics. Indeed, it was the historical need and practice to combine distinct shock absorption units with these feet that encouraged the creation of the L5987 code. Notably, a previous analysis among patients with lower limb amputation due to diabetes confirms increased functional mobility among patients with the shock absorbing elements of L5987 feet compared to L5981 that lack this additional functionality.[15]

The assertion and subsequent re-coding by PDAC raises a pivotal question of whether healthcare interventions, and systems such as CMS that reward high quality of care, should be focused on distinct features or incentivize improved functionality and patient outcomes regardless of the underlying mechanism or material. Thus, the purpose of this analysis was to compare real-world evidence of functional mobility across a range of prosthetic feet designed to provide shock-attenuating functionality. In particular, it was hypothesized that prosthetic feet with distinct proximal shock absorption units would perform similar to those designed to provide similar functionality without the added build height and weight that purport to achieve functionality through innovated geometry and materials engineering. However, both of these categories were hypothesized to function higher than a group of prosthetic feet that were originally and historically coded by PDAC as L5981. Finally, upon understanding differences at the categorical level, a more detailed investigation into performance of specific make and model prosthetic feet was performed. This includes an analysis of prosthetic feet currently coded as L5987 that have not yet been re-reviewed by PDAC.

Methods

Data source

This study utilized patient outcomes data from a large prosthetics provider with clinics across the US. The outcomes database contains patient-level data linked from clinical records and self-reported outcomes that are collected as part of routine clinical practice. A retrospective analysis of those who received the selected prosthetic feet from January 2016 through December 2020 was performed. This study was approved by ethics review XX *blinded for review* XX (Protocol #XXXXXX). Per IRB review the study was exempt from obtaining informed consent. Study reporting follows STROBE guidelines.

Population

Outcomes were included for analysis if the patient was a current prosthesis user determined by receipt of a prosthesis, was age 18 or older, had a major amputation (i.e. transtibial, knee disarticulation, or transfemoral), and had completed mobility outcomes after confirmed delivery of a new prosthetic foot. Symes amputations or distal (i.e. partial foot) were excluded. Outcomes collected after December 2020 were not included because coding changes went into effect as of January 2021.

Measures

Mobility as the outcome of interest, was measured using the PLUS-M self-reported outcome,[16] which was collected as part of routine clinical practice. The PLUS-M instrument is described in detail in prior work, but briefly, the instrument was administered in the 12-item short form (v1.2).[17,18] The instrument assesses mobility on 12 different tasks. The result is a raw score that is converted to a calibrated T-Score on a continuous scale ranging from 0–100, with 50.0 representing the population average score.[16] The PLUS-M has been demonstrated to have a strong positive relationship to the Activities-specific Balance Confidence (ABC) Scale (rho = 0.81, $p < .001$) and moderate negative correlation with the Timed-Up and Go (TUG) (rho=−0.56, $p < .001$).[16] Mobility must have been measured between 4 and 12 weeks after the patient received the new prosthetic foot to reduce potential bias.

The specific prosthetic foot (i.e. brand and model) was extracted from the patient's chart, and confirmed with appropriate accompanying L-code used upon receipt of the prosthesis. 10 different prosthetic feet were selected for inclusion in this analysis based on their manufacturer recommended coding, subsequent PDAC coding recommendations, and utilization volume within the clinics. Prosthetic feet were collapsed into mutually exclusive groups for further analysis. The groups were (Table 1): 1) "Sustained-87"- contains prosthetic feet which underwent recent PDAC review and remained coded as L5987 base code, 2) "Modified" group-contains prosthetic feet which were previously considered within the field with the L5987 base code but as of 1 January 2021 are PDAC recommended for L5981, 3) "Not-Reviewed" contains prosthetic feet which have not yet been submitted for PDAC review, and 4) "Original-81" contains prosthetic feet that have previously been reviewed by PDAC and assigned code L5981. This group (Original-81) served as the control group for comparison. Prosthetic foot type or category were entered as exposure variables.

Analysis

Descriptive statistics were applied to the sample. Continuous variables were assessed using means with standard deviation, whereas categorical variables were represented with counts (n) and percentages. To compare patient mobility for the different foot categories, a univariate generalized linear model (glm) was applied. In the event of a significant effect, Tukey post-hoc tests were performed to assess specific group differences by foot category. A second model was run and adjusted for amputation level based on significant differences within descriptive statistics table. Both SQL and R were used for data management. All analyses were conducted with R version 3.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Of the 2104 observations that met initial outcomes criteria, the final analytic sample included 526 unique observations (Table 2). The sample was 83% male (n = 438) and 78% of the sample had a transtibial amputation (n = 412). Overall age was an average of 52.5 ± 13.9 years old. The cause or

Table 1. Number of individuals based on prosthetic foot type (brand and model) per foot category.

Category	Count		Type of foot
Sustained 87	79	—	Ottobock Triton VS and Proteor Rush Rogue
Modified	83	—	Fillauer all-Pro and Blatchford Elite 2
Not reviewed	250	—	Proteor Agilix, Ottobock Maverick Xtreme and Ottobock Renegade
Original 81	114	—	Proteor Highlander, Ossur Vari-flex LP, Ottobock Triton LP

Table 2. Sample characteristics, means and counts presented based on foot type grouping. Significance indicates whether or not differences across groups occur.

	Sustained-87	Modified	Not-reviewed	Original-81	Significance
Total n = 526	n = 79	n = 83	n = 250	n = 114	$p < .05$
Mobility T-score, mean (SD.)	55.0 (8.66)	52.9 (9.94)	51.3 (10.6)	48.1 (10.3)	~
Age, mean (SD.)	49.7 (14.4)	49.6 (15.8)	52.4 (12.9)	56.5 (13.6)	.13
Cause of amputation (n/%)					
Vascular disease/Diabetes	19 (24.1)	26 (31.3)	109 (43.6)	43 (37.7)	.19
Trauma	27 (34.2)	25 (30.1)	64 (25.6)	26 (22.8)	—
Other/Unknown	33 (41.8)	32 (38.6)	77 (30.8)	45 (39.5)	—
Amputation level					
Transtibial/Below the knee	61 (77.2)	75 (90.4)	211 (84.4)	65 (57.0)	.02
Transfemoral/Above the knee	18 (22.8)	8 (9.6)	39 (15.6)	49 (43.0)	—
Gender					
Male	71 (89.9)	68 (81.9)	213 (85.2)	86 (75.4)	.23
Employment status					
Not employed/retired/disabled	39 (49.4)	48 (57.8)	184 (73.6)	88 (77.2)	< .0001
Employed	40 (50.6)	35 (42.2)	66 (26.4)	26 (22.8)	—

Table 3. Analysis of variance model results.

ANOVA results	F-value	p-value
Unadjusted mobility foot group[b]	$7.91_{3,522}$	< .0001
Mobility by foot group[a]	$22.04_{9,419}$	.0001
Unadjusted mobility by each foot[b]	$3.79_{9,516}$	< .0001
Mobility by each foot type[a]	$13.76_{15,413}$	< .0001

[a]Adjusted/controlling for: amputation level.
[b]Tstrok; One way ANOVA.
Reference = Original-81 or Triton LP.

etiology associated with amputation was varied with 37.4% attributed to vascular disease and/or diabetes (n = 197), 27.0% reported trauma to be the cause (n = 142) and the other 35.6% contains a combination of etiologies including cancer, congenital, and/or not reported (n = 187). Most participants were categorized in clinical notes as K-3 ambulators (n = 523) the remaining three were K-2.

The unadjusted results demonstrated that significant differences occurred by foot category ($F_{3,522}$ = 7.91, $p < .0001$) (Table 3). Of note, the Sustained-87 group and Modified group were not statistically different based on the post-hoc pairwise comparison (p=0.55). However, the post-hoc comparisons showed that all the foot groups significantly improved over the Original-81 foot group in terms of patient mobility (Figure 1). Furthermore, the Sustained-87 was significantly different from the Not-Reviewed. When comparing categories while adjusting for amputation level, results persisted ($F_{4,521}$ = 8.98, $p < .0001$) (Table 3).

The predicted mobility scores while adjusting for amputation level were similar and statistically different from the Triton LP for the Triton VS, Rogue, and All Pro. The remaining feet were not statistically different from the Triton LP based on the glm model (Figure 2). Across specific foot types, there appeared consistency within groups with exceptions observed which may be influencing category means (Figure 2).

Discussion

The prosthetic foot is a unique tool provided to patients as part of their overall prosthetic rehabilitation following limb loss. There is a category of prosthetic foot in particular, coded as L5987, which was predicted to enable higher functionality by integrating vertical shock absorption. Originally, this functionality was achieved through additional mechanical components attached to the foot, adding both build height and weight. However, improvements in geometries and materials science allowed these feet to evolve to the point that they could potentially provide similar functional benefit without the added weight and height of the visible vertical shock absorption units.

Recently the organization that assigns prosthetic components their categorical codes, i.e. PDAC, re-classified several L5987 feet to an L5981 code due to the lack of an obvious, visible additional vertical shock absorption unit. This was done without consideration for the performance or observed function of the feet. Rather, the decision was informed by the presence of distinct mechanical features. The purpose of this analysis was to investigate real world evidence on several highly utilized prosthetic feet that were previously coded as L5987, and compare this to those that retained their L5987 coding as well as those that were and remain L5981 coded feet. Results showed there was no significant difference in functional mobility for those

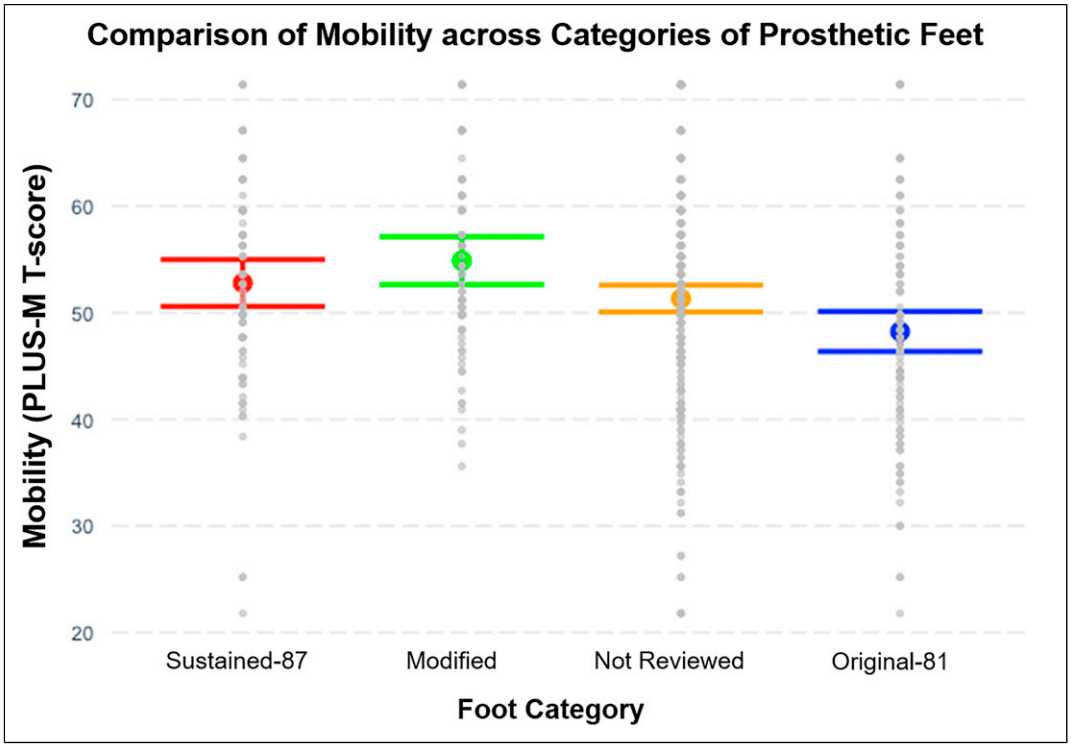

Figure 1. There was a significant effect for foot category when comparing mobility estimates while controlling for covariates predicted applying a linear regression model. Post-hoc analysis showed the Sustained-87 category to be significantly greater than the Original-81 category ($p < .0001$). Notably, there were no statistical differences between the Sustained-87 and Modified categories ($p = .55$), or between the Modified and Not-Reviewed ($p = .62$).

individuals with the feet that had their coding modified compared to those that retained their L5987 designation. Consistent with previous work,[15] outcomes associated with these feet were greater than those measured in patients with L5981 feet.

These results call into question as to whether prosthetic feet and componentry should be categorized based on the appearance of the mechanisms and materials used or the functional benefits they provide. Under the current approach that categorizes, and subsequently reimburses, based on appearance and visible mechanisms used, there is less incentive to create lighter weight devices that afford increased functional benefit.

The relevance of the availability of shock absorbing feet in lower profile, shorter build-height options can be seen in the gender distribution of the study sample. The percentage of women from our sample using the Modified feet was nearly twice those who were able to be fit using the higher profile, heavier Sustained-87 feet.

The resulting inequity of the new PDAC position can be seen in the forced response of prosthetic feet such as the Fillauer All-Pro. The All-Pro was previous L5987 and is now re-categorized as L5981. The result is a redesign whereby the All-Pro is now sold with an additional vertical shock unit bolted onto it and provided under the name All-Pro DS. As a result, the same foot which already provided strong benefit to patients now has additional weight and height, excluding its use with longer transtibial limbs or patients of a shorter stature such as females.

It is unclear how CMS has incentivized better care versus wasteful material use. This analysis considered several L5987 feet that at the time of this analysis have yet to submit to PDAC for coding review and consideration. These feet were grouped as Not-Reviewed and found to perform without statistical difference in terms of functional mobility as those that sustained their L5987 coding and those that were modified to the L5981 status. Subsequently, at a categorical level, the historical L5987 feet all performed better than the historical L5981 feet. The Not-Reviewed group of feet, however, do not have the separate units attached for vertical shock absorption. Rather, these feet rely on geometry and materials science similar to the feet whose coding was modified. As a result, these manufacturers should not be confident on the conclusion of any potential PDAC review of their feet.

Lastly, specific make and model of the feet included were analyzed to understand how specific make and models were affecting the categorical average performances. When looking at this data (Figure 2), there were three prosthetic feet that stood out-the Fillauer All-Pro, the Blatchford Elite2 and Ossur Vari-Flex LP.

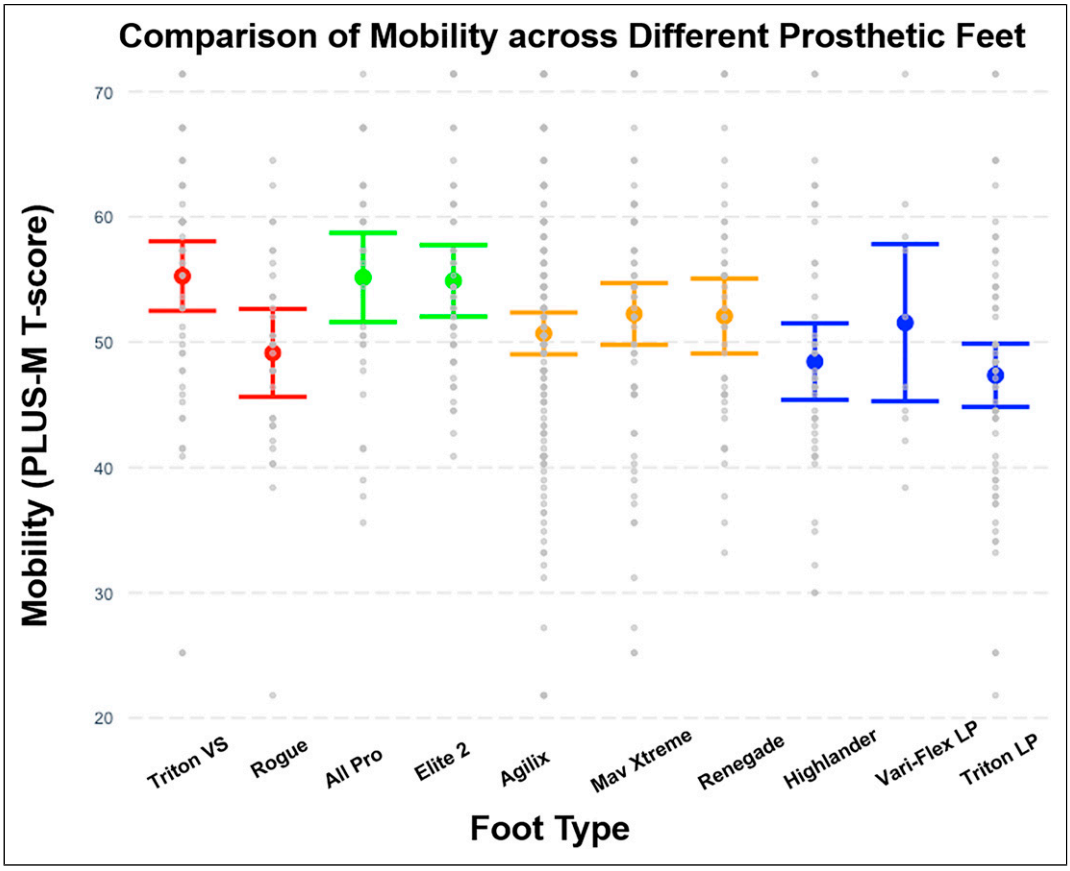

Figure 2. Effect plot visualizes the predicted values of mobility while controlling for covariates, estimates generated from linear regression. Specific make and model of feet within each category performed fairly consistent although there were exceptions. The Fillauer All-Pro within the Modified category performed similar to the feet within the Sustained-87 category and seemed to overall increase the average performance of the feet grouped in the Modified category. The Ossur Vari-Flex LP, although there was large variability, seems to be performing better than the other feet within the Original-81 category.

First, the All-Pro, which was among the feet whose category was modified, was associated with a functional mobility comparable to the Sustained-87 foot, suggesting that the added height and weight of a distinct shock absorption mechanism is not necessary to avail the functional benefits of current advanced foot design.

Second, the Blatchford Elite2, which was also modified, was performing on average lower than both the All-Pro and the Sustained-87 feet. Subsequently, these results provide a level of functional justification for considering the change in coding status of the Elite2 rather than what should be considered an inappropriate approach when focusing on mechanical features rather than functional benefits to the patient.

A third foot that requires comment is the Ossur Vari-Flex LP. This foot was part of the original L5981 group labeled Original-81. The Vari-Flex LP on average performed well-above the other two feet within the Original-81 group. More specifically, the average mobility for Vari-Flex LP user was consistent with the L5987 category feet (Figure 2). This would indicate that the outcomes with the L5981 category as a whole are likely lower without the influence of the Vari-Flex LP, and subsequently the functional gap between L5987 and L5981 is more than was reflected in the categorical analysis. This would indicate that the Ossur Vari-Flex LP, despite its historical classification as L5981, may be more appropriately classified as L5987. However, it should be noted there was a greater amount of variability in mobility with the Vari-Flex LP that warrants further examination.

Limitations

There are limitations to consider with the current analysis. First, the data provided the ability to examine only whether or not patients received the prosthetic foot but not the patient's actual use or time wearing the prosthesis. However, since mobility is captured at a follow-up appointment, this increases the likelihood the patient is using their prosthesis as non-prosthesis users tend to stop further interaction with their prosthetist. Second, above-the-knee and below-the-knee amputation levels were included. For

above-the-knee, the type of prosthetic knee was not controlled due to limitations in the data, and subsequently functional mobility may be enhanced or impaired based on the prosthetic knee. However, inclusion of these individuals allowed for a broader understanding and generalizability for lower limb prosthesis users with the specific feet assessed.

Conclusion

The restoration of sufficient shock absorption to lower limb prosthesis users may enable faster gait across a broader range of environmental elements yielding increased reported mobility. In practice, policy positions that limit the associated reimbursement to those feet that contain distinct shock absorbing elements, necessitating additional build height and weight to the foot, may exclude users with shorter, smaller frames from access to these benefits. The current data suggest the development of some prosthetic foot designs lacking an overt shock absorption mechanism can result in similar mobility achieved by the patient provide associated benefits as those observed in more obvious shock absorbing designs. Emphasizing the therapeutic benefit associated with prosthetic componentry integrated into the patient's rehabilitation can reinforce optimal patient outcomes. A focus on the patient functional outcomes achieved over visible features appears to be the pathway towards higher performance for the end user and thus perhaps a consideration in reimbursement structure.

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Author contributions

JHC and SRW conceived the study. TAM, PMS, SRW researched literature and drafted the manuscript. DE was involved with study design and managing/cleaning the data. TAM designed the study and conducted data analysis. All authors discussed the results and reviewed/edited the manuscript and approved the final version of the manuscript.

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