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Considering passive mechanical properties and patient user motor performance in lower limb prosthesis design optimization to enhance rehabilitation outcomes

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Abstract

Background—Selection of prosthesis mechanical characteristics to restore function of persons with lower-limb loss can be framed as an optimization problem to satisfy a given performance objective. However, the choice of a particular objective is critical, and considering only device and generalizable outcomes across users without accounting for inherent motor performance likely restricts a given patient from fully realizing the benefits of a prosthetic intervention.

Objectives—This review presents methods for optimizing passive below-knee prosthesis designs to maximize rehabilitation outcomes and how considerations on patient motor performance may enhance these outcomes.

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Major Findings—Available literature supports that considering patient-specific variables pertaining to motor performance permits a multidimensional landscape relating device characteristics and user function, which may yield more accurate predictions of rehabilitation outcomes for individual patients. Moreover, the addition of targeted physical therapeutic interventions that encourage user self-organization may further improve these outcomes. We note the potential of existing paradigms to address these additional dimensions, and we encourage investigators to consider the many different performance objectives available for prosthesis optimization.

Conclusions—By considering user motor performance in combination with prosthesis mechanical characteristics, a staged optimization approach can be formulated which acknowledges that device modifications may only improve outcomes to a certain extent and user self-organization is a critical component to complete rehabilitation. An iterative process that can be integrated within existing rehabilitative practices accounts for changes in patient status through combined targeted prosthetic solutions and physical therapeutic techniques, and embodies the concept of personalized intervention for patients with lower limb-loss.

Keywords

prosthesis; biomechanics; design; optimization; motor control; locomotion

1. Introduction

Worldwide, there is a large and growing number of persons with lower-limb loss ^{1–3}. Amputation causes vary widely from traumatic injuries and military conflicts to complications stemming from vascular diseases and cancer. For individuals with access to clinical care, a common rehabilitation goal is to restore the highest level of independence and ambulation ⁴. A major component of this care involves fitting and use of a prosthesis to realize an individual's full rehabilitation potential.

Prosthesis users commonly develop compensatory gait mechanisms following prosthetic intervention that lead to secondary conditions which challenge their mobility. For example, they commonly develop chronic pain in the back and lower limbs ^{5–7}, degenerative joint diseases ^{8–10}, altered psychological states ¹¹, and elevated metabolic costs of movement ¹². Thus, the efficacy of rehabilitation interventions is multifactorial. An essential component to rehabilitation is the selection of prosthetic componentry to meet a patient's needs as influenced by their capabilities and desire to function with the definitive prosthetic system ^{13–17}. A prescribing clinical team must often consider amongst many commercially-available components to maximize long-term rehabilitation outcomes while also having the prosthesis remain cost-effective. Historically, restoring function through prosthetic intervention was largely accomplished via subjective and experience-driven decisions of clinicians, as opposed to scientifically-rigorous quantitative information and evidence-based practice ^{13–19}. However, the component selection process is adapting as health practitioners become more familiar with evidence of how prosthesis designs influence rehabilitation outcomes ^{17, 18, 20, 21}.

In current clinical practice, selection of a prosthesis and its associated mechanical function can be framed as an optimization problem in which device characteristics are chosen to satisfy a given objective. However, the choice of an objective as decided by the patient and clinical team is critical for enhancing patient quality of life, especially when considering the inherent capabilities of the user. These capabilities which drive self-organization, or identification and implementation of effective motor control strategies, when using the prosthetic intervention are dependent on motor performance. We define motor performance in this context as the neuromotor response and capacity (i.e., inherent neural and musculoskeletal structure) that underlie prosthetic ambulation^{22–24}. Additionally, objectives depend on the importance patients place on certain aspects of ambulation (e.g., comfort, mobility, appearance, safety, and fatigue)^{14–16, 18, 19, 24–28}. As an example, normalizing elevated metabolic energy expenditure or reducing asymmetric bilateral joint mechanics are objectives supported by the literature for unilateral lower-limb prosthesis users. Persons with lower-limb loss between the ankle and hip walk with metabolic energy expenditure that range from one to two times greater than able-bodied individuals (depending on amputation level, etiology and walking speed)^{12, 29} and develop chronic joint disorders like osteoarthritis thought to be linked to asymmetric loading of their sound limb^{8–10}. Accordingly, feedback on exertion and comfort of the patient are normally considered during the clinical fitting of prostheses. However, those individuals who have a fear of falling¹¹ or impaired balance may value locomotor stability or even maneuverability more so than improved metabolic cost or able-bodied joint mechanics. Patients may be willing to prioritize certain objectives over others that are most relevant to their specific state. Essentially, a patient's physical and psychological response to a prosthesis and ultimately their rehabilitation outcomes may be heavily influenced by their inherent motor performance and the value they place on particular functional objectives.

To satisfy patient-specific objectives, it is important to consider not only recently-developed active devices that drive joint rotations for generating assisted propulsion or ground clearance, but also purely passive devices that require loading to produce motion. Perhaps the most sensible reason to continue use and development of passive prostheses are availability and cost. To date, there are limited commercially-available active prostheses, including the emPOWER foot (Otto Bock, Germany), and the PowerKnee (Össur, Iceland) which provide powered joint plantarflexion/extension, and the Proprio foot (Össur) which provides powered dorsiflexion when unloaded during swing phase. The manufacturing cost of passive systems will likely always be lower than active systems due to simplifications of materials and components, which suggest a consistent economic benefit to limited-resource countries or financially-challenged populations. Less expensive devices can also help reduce healthcare costs in developed countries such as the USA where component reimbursement policies aim to control spending³⁰. Importantly, support for passive devices is centered on their contribution to locomotor mechanics. The most consistent compensatory gait mechanisms of passive lower-limb prosthesis users occur during the prosthetic limb loading phase when musculotendon units spanning the ankle and knee have been shown to act in a primarily eccentric manner, in contrast to terminal stance when ankle power is generated^{31, 32}. Compensations may then still occur during a different period of the gait cycle than targeted by the interventions which add net ankle power during terminal stance.

Consequently, the passive properties of prosthetic feet/ankles which contribute to prosthesis function during the majority of stance can have just as large an effect on user outcomes as active contributions^{33, 34}.

For the purpose of optimizing passive prosthesis design and function to maximize a user performance objective, design criteria can be formulated from generalized relationships between prosthesis properties and ‘average user’ outcomes. However, as suggested earlier, patient-specific variables pertaining to motor performance may be critical to maximize outcomes for an individual user. Accordingly, physical therapeutic interventions delivered by the rehabilitation team to facilitate user self-organization can play a critical role in the optimization process. The purpose of this review is to discuss methods for optimizing passive below-knee prosthesis designs and how considerations on motor performance may enhance rehabilitation outcomes by considering the human element. This narrative will be presented through the following structure:

1. Review methods of parametric optimization of passive prosthesis mechanical properties based on experimental relationships between device properties and user outcomes for a given mobility scenario.
2. Discuss methods that: consider patient motor performance for constructing a multidimensional landscape defining relationships between device properties, motor performance, and user outcomes; and encourage user self-organization to a prosthetic intervention for enhancing rehabilitation outcomes.
3. Propose an iterative optimization strategy that integrates prosthesis design, clinical fitting, and physical therapeutic intervention to facilitate consistent achievement of a patient’s full rehabilitation potential by leveraging both prosthesis mechanical properties and user motor performance.

Importantly, this review is not intended to critique prior approaches. Rather, we hope to urge ongoing and future studies to consider that user motor performance is an equally-important dimension as device characteristics, and to acknowledge therapeutic techniques that can be implemented by physical therapists to address this dimension. As a matter of scope, although the concepts described in this review can be applied to passive devices for all levels of amputation, we focus on below-knee prostheses with the discussion centered on components distal to the prosthesis suspension system.

2. Optimizing Passive Prosthesis Design through Parametric Studies

2.1. Relating Prosthesis Properties and User Performance Outcomes

Passive below-knee prostheses have become more advanced and numerous over the past several decades partly resulting from developments in materials science to enhance their mechanical function^{18, 20, 35}. For example, carbon fiber reinforced polymers now incorporated in many energy storage-and-return (ESAR) and dynamic prosthetic feet (e.g., Flex-Foot series, Össur), can demonstrate decreased net energy loss relative to other feet constructed of conventional composites and polymers (e.g., Solid Ankle Cushion Heel (SACH) series, Otto Bock, or Seattle Lightfoot, Seattle Systems, USA)^{35–39}. The hypothesis was that modifications in mechanical function would be reflected in user

performance^{18, 20}, such as reduced metabolic cost of gait^{35, 36}. Addressing such hypotheses generates evidence to inform the clinical goal of selecting the prosthesis design(s) that yields the best patient outcomes, and this is accomplished through exploring effects of prosthesis characteristics on user outcomes.

The traditional model of human subject comparative studies involves testing multiple prostheses, often defined by commercial trade names and/or type such as conventional non-articulated, dynamic, ESAR, and articulated (Figure 1)^{17, 20, 40}. This approach is limited as outcomes are only attributable to arbitrary device classifications, which historically resulted from subjective evaluations on topology, modular components, and material composition. Without knowledge of the device's user-independent mechanical properties, it is impossible to establish relationships between objective device characteristics and user outcomes⁴¹. Although there are notable exceptions when commercial prostheses characterization is included to correlate mechanical function with user outcomes^{42–44}, these studies are constrained within the range of prosthesis properties available through commercial devices. Recently, standardized bench tests were proposed to classify prosthetic feet based on mechanical properties such as stiffness and energy loss^{38, 45}, which could enhance objectivity of device classification.

To liberate from traditional study constraints and further define relationships between user outcomes and device function, investigators began to pursue experimental designs incorporating systematic adjustments in mechanical properties. These parametric studies can be separated into: human subject *in-vivo* testing that employ experimental prostheses^{34, 47–57} (Figure 2), and numerical *in-silico* simulations incorporating physics-based prosthesis models^{58–64} (Figure 3). To facilitate *in-vivo* testing, standardized methods for reliably characterizing the mechanical properties of commercial and experimental prostheses, including combinations of stiffness, damping, and roll-over geometry, have been developed^{41, 65–67}. There are benefits and limitations to both types of studies. For example, numerical simulations allow for rapid and extensive systematic exploration as they are not directly reliant on human subjects, but require validation of sometimes complex musculoskeletal models to lend confidence in the results^{58, 59}. Conversely, although human subject testing accounts for biological variability, they are practically limited in terms of possible test conditions, sample size and hence, statistical power and external validity^{47, 48}. Consequently, both forms of studies are needed to inform understanding of how device properties influence user outcomes⁴¹.

Parametric studies enable control of prosthesis mechanical properties and generation of mappings between physics-based definitions of mechanical function and clinically-relevant user outcomes. The resolution and range of this mapping is dependent on the modular adjustments of the experimental devices, but exceeds that obtained by testing commercial devices. Specific examples of this mapping for *in-vivo* and *in-silico* studies include defining relationships between: ankle rotational stiffness and lower-limb joint range-of-motion (ROM) during fast level walking⁴⁷ (Figure 4); ankle rotational stiffness and bilateral swing time symmetry across different mobility scenarios⁴⁸ (Figure 5); overall foot stiffness on foot and muscle function⁵⁸ (Figure 6); and overall foot damping on intact knee abduction moments during level walking at different speeds⁶⁹. These results help populate the vast map

relating prosthesis properties and user outcomes for different scenarios (e.g., level ground and slope walking at different speeds), and inform on how fine adjustments in prosthesis properties can maximize rehabilitation outcomes. However, these data also emphasize that much of the experimental mapping remains incomplete, and concerted research efforts are required to fill the gaps in knowledge.

2.2. Prosthesis Optimization using Experimental Mapping, the Role of Clinical Fitting, and Limitations of Generalized Models

The utility of human-prosthesis interaction mapping is that generalized models can be created to predict user performance outcomes from prosthesis properties. When considering multiple objectives, a system of models would include clinically-relevant performance outcomes, such as minimizing metabolic cost or kinematic deviations, or maximizing residual limb health/comfort or locomotor stability, as the dependent (outcome) variables and prosthesis mechanical parameters as the independent variables. This modelling process represents a form of optimization where the prosthesis is designed to yield the best outcomes for a given patient state. We recognize the possibility of relationships between prosthesis properties and user outcomes that are more complex than a U-shape with a single min/maximum, thereby permitting the possibility of multiple designs with equally-valid function.

The definitive below-knee prosthesis is composed of modular components, including the foot-ankle mechanism, pylon, suspension system (often including a residuum socket and liner), and footwear⁴, each contributing to overall prosthesis mechanical function⁴¹. For example, footwear may substantially affect regional and overall stiffness and damping of prosthetic feet, in some instances normalizing the mechanical function across designs^{35, 37, 39, 70}. Additionally, the choice of suspension system and constituent components⁷¹ will play a role in determining the residuum-prosthesis interface properties and behavior^{72, 73}, and this is especially relevant with the advent of bone-anchored prostheses (osseointegration)⁷⁴. Therefore, a first application of the optimization process relates to evidence-based practice. Human-prosthesis maps inform clinicians to make educated selections of commercial components with which to build the definitive prosthesis while accounting for patient-specific factors. The second application of the optimization process is the identification of a set of prosthesis mechanical parameters that produces a desired performance outcome as a means to drive research and development (R&D) (Figure 7)⁴¹. Following identification of the optimized prosthesis properties, exploration of different topologies, modular component designs, and material composition can be conducted through simulation (e.g., finite element analysis and/or forward dynamics simulation) and physical prototyping to yield tuned components for maximizing the desired performance outcome(s).

Applying to both clinical prescription and R&D, the decision to select one or more objectives is a matter of prioritizing performance outcomes, and these outcomes may interact positively or negatively. For example, optimizing for metabolic efficiency may also affect locomotor stability as physical fatigue has associations with fall risk^{75–77}. When selecting to optimize for multiple objectives, prioritizing through a weighting scheme may be appropriate. Simulations provide a powerful and expedient platform of optimization for multiple objectives concurrently, such as identifying prosthesis stiffness distributions that

minimize metabolic cost and intact knee joint loading⁵⁹ (Table 1) to identify trade-offs in performance.

When considering clinical applicability, prosthesis fitting plays a complementary role to design optimization from R&D contributions and is an important step after device selection. The definitive prosthesis delivered to the patient incorporates tuning from both processes as prosthetists select, assemble, fit, and align the device. Alignment relies on subjective evaluations from clinician observation and patient feedback to satisfy relevant clinical goals^{4, 78}, broadly defined as “*maximum comfort, efficient function, and cosmesis*”⁴. Clinical objectives then reasonably include minimization of leg length discrepancy and limb discomfort, smooth and controlled stance-phase shank progression, bilateral symmetry of temporal-spatial parameters, and prosthetic structural stability^{4, 78, 79}. As evidence suggests that lower-limb prosthesis users can tolerate a range of alignments⁷⁸, the R&D optimization process may also need to consider designing for a range of alignments.

We would be remiss to not emphasize that prosthesis optimization may be less than straightforward due to some key features of generalized models. *In-vivo* parametric study results are derived from using experimental prostheses and isolated adjustments in specific properties, such as dorsiflexion rotational stiffness while holding plantarflexion stiffness constant⁴⁷ or overall foot damping while holding stiffness constant⁶⁹. Furthermore, experimental mappings are generated for isolated mobility scenarios, most commonly walking at a self-selected speed over level ground^{34, 47–52, 58, 59, 69}. These experimental designs are needed for practical, easy-to-interpret, and valid experimentation. However, there may be important interaction effects between mechanical parameters (e.g., stiffness and damping), regional structures (e.g., heel and keel), and mobility scenarios (e.g., level and slope walking) that can be included in the inferential statistical approach^{48, 69}. For example, the effects of keel stiffness on metabolic cost may be different for different values of heel stiffness, or as illustrated in Figure 5, the effects of ankle rotational stiffness on gait symmetry may be different for different mobility scenarios (although not significant in the referenced study⁴⁸). Not accounting for interactions means the optimization process operates on an incomplete model and may result in suboptimal outcomes in the broader context of daily ambulation. Of course, consideration of multiple independent variables increases analytical and interpretation complexity.

Importantly, optimizing a set of passive properties for unlimited community ambulation involving different mobility scenarios of walking speed and terrain characteristics⁸⁰ is challenging. Prior parametric studies are useful when designing for a specific mobility scenario, but each scenario may require different prosthesis properties to achieve the same level of performance. This concept has been supported through studies that have characterized the quasi-static stiffness and roll-over geometry of the physiological foot-ankle complex across various mobility scenarios to inform biomimetic prosthetic foot designs^{81–87}. Similar to optimizing for multiple performance-based cost objectives, the process should consider tuning for multiple mobility scenarios which may require reconciliation of parameters to achieve the best balance of real-world outcomes. Alternatively, the design space is open to passive devices that can modify properties to adapt to a given scenario, such as different walking gradients^{88, 89}.

Despite their challenges, current parametric study designs account for some of the most important variables defining the human-prosthesis interaction, but a limitation of generalized models is that they are based on ‘average user’ performance. Consequently, they neglect patient-specific motor performance which impacts the user’s ability to exploit the prosthetic intervention as they self-integrate with the device. This limitation is partially an artifact of common experimental designs that rely on data from convenience samples of willing and able participants⁹⁰. These data may then be derived from a sample of relatively homogenous motor performance, thereby not accounting for a range of motor control strategies. Although a prosthesis user theoretically has the luxury of selecting from multiple solutions to achieve ambulation due to motor abundance/redundancy, the range of solutions are likely limited by their neuromotor capacity as affected by neural and musculoskeletal structural properties (e.g., levels of joint ROM, muscle strength, reaction time, and sensory feedback)^{31, 91–95}. The optimal prosthesis design to maximize a given performance outcome may reasonably be different for patients of dissimilar motor performance, such as young individuals of traumatic etiology versus older individuals of dysvascular etiology^{22, 23}.

Although generalized models can account for the majority of prosthesis users via targeted and diverse subject recruitment strategies, the ultimate goal is to provide personalized interventions through inclusion of patient-specific variables. We propose that aspects of motor performance can and likely should be considered in the optimization process to account for neuromuscular constraints underlying movement. In a sense, this is already included in clinics in the USA and other countries that classify patient mobility level using the Medicare Functional Classification Level (MFCL) system³⁰, where component designs are reserved for each level as rationalized through medical necessity. However, we emphasize that considerations on motor performance should be included in R&D and clinical optimization processes in a standard way to accurately and reliably define the intended user. A logical next step is to incorporate the motor performance variable in parametric studies to expand the experimental mapping landscape. As this discussion is focused on optimization for a given outcome, we are operating on the position that users are ‘self-organizing’ to converge on a selection of motor strategies that stabilize performance for a given ambulatory task in ways that leverage their own neuromotor capacity^{93, 95}.

3. Motor Performance as a Patient-Specific Variable for Design Optimization

3.1. Accounting for Motor Performance of Lower-Limb Prosthesis Users

An equally important factor as device characteristics impacting lower-limb prosthesis user performance outcomes is the patient. When considering the user as their own system, they have the ability to respond and adapt to device characteristics in non-intuitive ways. The potential contributors to individual self-organization to a prosthetic intervention are many. However, there exist practical methods to incorporate user neuromotor response and capacity in the prosthesis optimization process. Perhaps the most straightforward are parametric studies that, in addition to studying the relationships between prosthesis mechanical properties and performance outcomes, consider the heterogeneous nature of the patient pool. So, analogous *in-vivo* parametric studies on the effects of mechanical

properties can be extended in new investigations or analyzed retrospectively with quantification of motor performance. Measures used to quantify the multidimensional construct of motor performance can be either categorical (e.g., discrete subgroups of neuromotor capacity) or continuous, and require consideration of desired levels of resolution, reliability, and validity.

We can first consider basic measures that share relationships more broadly with motor performance but are often overlooked due to small subject cohorts or unevenly distributed subgroups. These variables include, but are not limited to, age, amputation etiology/level/number, duration of prosthesis use, presence and severity of comorbidity as defined by established indices^{96–98}, and mobility capability level as defined by the MFCL system³⁰. Evidence suggests that each of these variables can serve to characterize motor performance and would influence a user's self-organization or ability to benefit from a device intervention. For example, increasing age is known to influence muscle coordination, strength and response time characteristics of lower-extremity movements^{99–103}, and individuals with dysvascular-related amputation may suffer from reduced sensory feedback compared to those with trauma-related amputation that could affect general mobility^{104, 105}. Although these simple measures of characterization can be readily collected or assigned in clinical and research environments, their shortcomings include: 1) assuming that a given patient follows generalized trends, and 2) limited resolution and accuracy. Practically, a patient of traumatic etiology may have similar neuromotor capacity to their dysvascular counterpart. Additionally, although the MFCL system is a commonly used taxonomy for classifying mobility capability, it is not an outcome measure by design and its resolution is considered insufficient by prosthetic practitioners who prefer clinical outcome measures for improved characterization accuracy³⁰.

Therefore, for the purpose of prosthesis optimization, it may be of greater advantage to characterize motor performance through continuous measures of neuromotor capacity. Several of the neural and musculoskeletal structural properties which influence performance, such as joint ROM, muscle strength, proprioception, and tactile sensation, can be measured through common physical therapy techniques¹⁰⁶, possibly with some adaptation specific to persons with lower-limb loss^{22, 23, 107–112}. Additionally, performance-based or self-report clinical outcome measures that assess physical capabilities such as balance and mobility^{30, 113, 114}, provide additional means for functional characterization. As such, a physical therapist trained in administration of manual muscle testing, passive ROM assessment, proprioceptive and touch sensation examinations¹⁰⁶, and clinical outcome measures can play an integral role in characterizing patient motor performance status. There is also the potential to estimate the baseline level of coordination or compensatory mechanisms of a patient using their current device, prior to applying a new prosthetic intervention. For example, factors such as the degree of asymmetry of muscle excitation¹¹⁵, anterior/posterior ground reaction forces¹¹⁶, hip extension muscle moment^{116, 117} and/or knee mechanical loading¹¹⁸ could be considered to glean insights into compensatory methods a patient may employ with a new intervention (if such factors are not the primary user outcomes). Therefore, when considering the construct of motor performance, there exists a multidimensional landscape for describing each user outcome as a function of a set of prosthesis properties and motor performance measures. In the simplest case where only a

single prosthesis property and motor performance measure is considered, the landscape can be reduced to a three-dimensional profile (Figure 8).

Although the complexity of this map has increased, *in-silico* parametric studies offer a powerful tool to perform systematic investigations where variations in motor performance can be modeled. Techniques to model aspects of the neuromotor capacity do exist, thereby extending musculoskeletal simulation frameworks that have coupled the modeling of device mechanical properties and user coordination^{58, 59, 119}. Prior approaches have used generic models that include modifiable musculoskeletal factors such as across-user variations in muscle strength, lines of action, and/or a preference for relying on proximal or distal mechanisms to mediate changes in locomotor scenario. So for example, as evidence suggests that aging in the general population impacts these factors^{120–122}, it would be possible to simulate and control the effects of progressing age on user outcomes in combination with changes in prosthesis properties.

Overall, the populated multidimensional map of relationships yielded from these parametric studies would estimate the prosthesis properties that maximize performance outcomes in the context of motor performance and mobility scenario. Consequently, the prosthesis can be optimized prior to delivery to the patient through appropriate clinical selection of commercial devices or tuning the prosthesis design in the R&D stage (Figure 7).

It is worth acknowledging that in contrast to development of generalized relationships, recent subject-specific investigations have applied more personalized approaches that customize device characteristics directly to an individual in real-time. For example, there exist “tuning” studies that alter the passive and active control parameters of knee and ankle prostheses to allow each patient to perform a number of ambulatory and non-ambulatory activities^{123–125}. Particular strengths of these studies are that feedback from clinicians were incorporated to select the “optimal” device parameters and that the resulting user biomechanical outcomes were objectively reported^{123–126}. These studies note subject training and accommodation times and partition results based on novice or experienced users of the respective device for a wide range of mobility scenarios^{124, 125}. This technique relies on an interdisciplinary clinical team with contributions from rehabilitation engineers, prosthetists, and physical therapists. Furthermore, a concept that has been proposed in active orthoses is “user-in-the-loop” tuning. In this scenario, devices are constrained to explore a defined range of some parameter to populate the experimental map of relationships. A subsequent optimization routine then “pushes” the user toward their optimal device tuning in a gradient-descent or semi-automated co-adaptation fashion^{127–129}. Using such approaches, the patient’s motor performance is theoretically accounted for as the optimization operates on the combined human-prosthesis system. Although promising, these concepts require refinement for clinical applicability. First, clarification is needed on clinician involvement for such approaches, and how the technique can be applied in the multifactorial space of device characteristics. Additionally, the time required for a patient to perform these optimizations may limit applicability to lower-functioning patients. Finally, validation tests with lower-limb prostheses users need to be performed to evaluate this form of tuning for identifying optimal prosthesis parameters.

3.2. Physical Therapeutic Interventions to Encourage Patient User Self-Organization

Although we have argued that design considerations are important, there is an additional step that may best address motor performance for maximizing rehabilitation outcomes: subjecting users to physical therapeutic interventions in the form of training that facilitates integration of the optimized prosthetic system. In this scenario, the capacity of the neuromotor system to self-organize for enhanced benefit could be exploited.

The simplest form of physical training to encourage self-organization is community-based free accommodation. This method is of course integral to the experience of any prosthesis user. Following clinical fitting of the prosthesis, the user is naturally permitted to explore the range of possible locomotor mechanics and converge on a motor strategy that satisfies some inherent objective (e.g., minimizing effort or maximizing stability). This free accommodation is important as the user must learn to integrate the device, as well as appraise the values they place on particular ambulatory objectives. For example, bilateral below-knee passive prosthesis users tend to display exaggerated medial-lateral trunk sway to possibly facilitate limb advancement but at the cost of reducing locomotor stability at faster walking speeds¹³⁰. However, there is a risk that an experienced prosthesis user may automatically and prematurely limit their self-organization to a new prosthetic intervention as derived from their behavior with a previously used prosthesis. Consequently, the patient may be unable to take full advantage of the capabilities of an upgraded system, and methods to detrain old mechanisms of movement would be an important consideration. As such, if a prosthesis has been optimized for some performance objective, then it is reasonable and perhaps necessary that physical training interventions be employed as complementary to free accommodation.

There are various means to consider when addressing the integration of physical training interventions, and this component of the optimization process would primarily be the responsibility of physical therapists with specialization in implementing these strategies. Prior studies have proposed general training recommendations to allow the user to explore and engage the functional capabilities of themselves and the prosthesis^{105, 131–134}. A review on therapeutic interventions to improve prosthetic gait performance identified five categories: supervised walking, specific muscle strengthening, balance training, (part-to-whole) gait training, and functional mobility training¹³². More specifically, a recent prosthesis comparative investigation involved training as implemented by a physical therapist “*to minimize gait deviations...and to maximize the appropriate use of each foot based on its mechanical design*”, which involved single-limb balance, resisted gait training to maximize toe load and restore torso and pelvis kinematics, and exercises to enhance knee and hip muscular contraction speed¹³¹. Such methods would activate the self-organization principal, but are simple enough to perform in an out-patient clinical environment.

Another technique is to employ training paradigms that target specific performance objectives. To illustrate this concept, we will focus on the objective of locomotor stability in which the prosthesis user can be subjected to destabilizing environments (disturbed feedback or perturbations). In this situation, the user would select the motor strategies that complement the prosthesis design to maximize stability-related outcomes. Grabiner and Kaufman¹³⁵ developed a means to simulate trips during level walking by rapidly

accelerating the speed of a treadmill, while Shirota et al.¹³⁶ used a cable and clutch-driven device to induce trips during walking to study the selection of biomechanical strategies for recovery. Curtze has also implemented clinically-accessible methods to test postural control through setups that subject prosthesis users to environments simulating waist-level perturbations (push/pulls)¹³⁷, forward falls¹³⁸, and walking over uneven terrain¹³⁹. In order to prompt responses in frontal plane postural control, prosthesis users have been subjected to medial-lateral perturbations at the waist^{140, 141} and foot¹⁴². Finally, virtual environments that provide visual and surface perturbations have been used to test locomotor stability^{143, 144}. When considering stability as an objective, all of these paradigms provide features that could be employed as physical therapeutic training interventions to better prepare prosthesis users for independent and safe community ambulation.

Extending beyond more intuitive techniques, there are other promising forms of training that have been suggested to engage self-organization or motor learning separate to assistive devices. To encourage recovery of motor function post-stroke, “*high-intensity step training*” has been used to subject patients to challenging obstacles and perturbations during high speed walking¹⁴⁵. Other methods directly target restoration of step symmetry in post-stroke patients by slowly and differentially adapting the speed of a split-belt treadmill at an unperceivable rate¹⁴⁶. Finally, there are gait retraining paradigms that have been investigated to help offload the knee joint such as walking with a “medial thrust” pattern^{147, 148}. All of these paradigms target objectives (stability, symmetry, joint loading) that are clinically relevant given the elevated prevalence of: fall risk and fear of falling¹¹, back and lower-limb pain^{5–7, 149}, and knee joint disorders like osteoarthritis and osteoporosis^{8–10} among persons with lower-limb loss.

By considering the many different performance objectives, and linking these prior works within and outside the field of prosthetics, new opportunities may emerge for physical therapeutic interventions to provide the greatest clinical benefit to prosthesis users. For the purpose of guiding self-organization and enhancing motor performance, the definitive therapeutic intervention program may consist of some (ordered) combination of the presented modalities: free accommodation, functional training, and objective-specific targeted paradigms. Future work is warranted to identify the feasibility and efficacy of various approaches.

4. Maximizing Performance Outcomes through an Integrated Optimization Approach

When considering factors that are independent (mobility scenario) and inherent (motor performance) to the patient user, this review suggests that an integrated and holistic approach is preferred when considering optimization of the human-prosthesis system. Through incorporation of the techniques described in this review, an integrative optimization sequence for maximizing desired performance outcome(s) could involve the following stages (Figure 9):

1. Prosthesis design (*sections 2.1, 2.2, and 3.1*)– The objective of this stage is to maximize performance outcomes through selection of definitive prosthesis

mechanical properties via device tuning (with contributions from R&D) and/or clinical prescription of commercial components that considers mobility scenarios (i.e., desired activity level) and patient-specific variables (inherent motor performance);

2. Clinical fitting (*section 2.2*) – The objective of this stage is to perform adjustments in the prosthesis setup through assembly and alignment based on feedback from clinician observation and user perception to satisfy relevant clinical outcomes (e.g., comfort, appearance, and gait quality);
3. Physical therapeutic intervention (*section 3.2*) – The objective of this stage is to encourage user self-organization (i.e., integration of the prosthetic system and selection of effective motor strategies) through free accommodation and general or targeted physical training paradigms that aim to maximize performance outcomes.

This sequential process would begin following selection of the desired performance outcomes to serve as the rehabilitation, and hence optimization, objectives through shared decisions between the clinical team and patient user. However, as the user continues this process of self-organization, they may likely experience state changes in patient-specific variables that would influence motor performance (e.g., body mass, sensory feedback, and muscle strength). Consequently, acute and longitudinal evaluation of the patient user's motor performance status by the interdisciplinary rehabilitation team would be essential to this process as results may suggest that the prosthesis design undergo iterations of (re)optimization to sustain the desired level of performance (represented by the optimization iterative loop of Figure 9). More specifically, as the user's motor performance changes, the prosthesis should be able to accommodate this change such that users are consistently achieving their full rehabilitation potential and are not hindered by prosthesis mechanical properties that could limit ability. Furthermore, as selection of the desired performance outcome(s) is multifactorial, it may be likely that evaluation results suggest the need for reconsideration of these outcomes as rehabilitation priorities change for both the clinical team and patient user. Once reconsideration of performance outcomes and/or prosthesis design is deemed appropriate, the three-stage optimization sequence restarts, otherwise the patient user continues to undergo longitudinal evaluation to monitor their status. In summary, optimization in this context represents a best solution and outcome for a characterized patient state, but as this is fundamentally an organic process, state changes may be sufficiently large to necessitate periodic refinements.

5. Conclusions

By considering patient-specific variables pertaining to motor performance, the landscape that maps prosthesis mechanical properties to user outcomes for the purpose of prosthesis optimization could be expanded to additional dimensions. Evidence suggests that this enhancement would benefit rehabilitation by generating more accurate predictions of individual patient outcomes. We have argued that physical training interventions to encourage user self-organization are an equally important optimization component, and the proposed integration of targeted prosthetic solutions and physical therapeutic techniques into

an iterative rehabilitation strategy embodies the concept of personalized intervention. This process, when refined and standardized, may better satisfy the purpose of rehabilitation to consistently and fully restore safe and independent ambulatory function of prosthetic patients. A major driver of this view is that the multitude of available performance objectives can be accounted for through combined efforts of rehabilitation engineers, prosthetists, physical therapists, and patients alike in the optimization of the human-prosthesis system.

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Figure 1. Examples of a A) conventional non-articulated (SACH), B) dynamic (Impulse®), and C) articulated (Single Axis) prosthetic foot. Images of products adopted from The Ohio Willow Wood Company (Mt. Sterling, Ohio, USA) ⁴⁶.

Figure 2.

Experimental prostheses used for systematic modulation of mechanical function: A) overall prosthesis stiffness through rapid prototyping ³⁴, B) roll-over geometry through a cut-out scheme ⁵⁷, and C) ankle rotational stiffness through a pivot and spring system ⁴⁷.

A **B** **Figure 3.**

Numerical simulation models used for systematic modulation of prosthesis mechanical function: A) a low-dimensional model (left) incorporating roll-over geometry (right)^{60, 68}, and B) a musculoskeletal model (left) incorporating localized prosthesis stiffness (right)^{58, 59}.

Figure 4.

Effects of four prosthetic ankle stiffness conditions (represented by four distinct lines) on stance-phase (0%=initial contact; 100%=toe-off) ankle and knee joint kinematics during self-selected fast walking on the level ⁴⁷.

Figure 5.

Effects of four prosthetic ankle dorsiflexion (DF) and plantarflexion (PF) stiffness conditions (LO/HI DF/PF) on gait symmetry (symmetry ratio=sound/prosthetic limb swing time) during self-selected walking speed on the level (SSWS), fast walking speed on the level (FWS), self-selected walking speed on 5% incline (UP) and self-selected walking speed on 5% decline (DOWN) ⁴⁸.

Figure 6. Effects of three overall prosthetic foot stiffness conditions (Stiff, Nominal, and Compliant) on *in-vivo* (temporal profiles) and simulated (horizontal bars) muscle excitation timing of 8 lower-extremity muscles for both limbs during self-selected walking speed on the level ⁵⁸.

Figure 7. Proposed process of using experimental mapping to inform prosthesis research and development. *AIPP* refers to “amputee-independent prosthesis properties”, or the mechanical properties of the prosthesis (stiffness, damping, roll-over geometry) that influence user performance outcomes ⁴¹.

Figure 8.

The multidimensional experimental mapping landscape for a given mobility scenario to include motor performance as an additional factor of optimization.

Figure 9.
Proposed iterative optimization process for maximizing performance outcomes including sequential stages of prosthesis design, clinical fitting, and physical therapeutic intervention.

Table 1

Estimated metabolic cost, knee joint impulse, and knee joint load resulting from foot stiffness optimizations for one (columns 2 and 3) or both (column 4) of these performance outcomes ⁵⁹.

	Minimize Metabolic Cost	Minimize Knee Joint Contact Force	Minimize Metabolic Cost and Knee Joint Contact Force
Metabolic Cost (J)	307	315	481
Intact Knee Impulse (N*s)	1389	1130	1062
Intact Knee Peak Load (N)	3473	2424	2480