Design Optimization in Lower Limb Prostheses: A Review

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***Abstract*—This paper aims to develop a knowledge base and identify the promising research pathways toward designing lower limb prostheses for optimal biomechanical and clinical outcomes. It is based on the literature search representing the state of the art in the lower limb prosthesis joint design and biomechanical analysis. Current design solutions are organized in terms of fulfilling four key functional roles: body support, propulsion, task flexibility, and loading relief. Biomechanical analyses of these designs reveal that the hypothesized outcomes are not consistently observed. We suggest that these outcomes may be improved by incorporating tools that can predict user performance metrics to optimize the device during the initial design process. We also note that the scope of the solution space of most current designs is limited by focusing on the anthropomorphic design approaches that do not account for the person's altered anatomy post-amputation. The effects of the prosthetic joint behavior on whole-body gait biomechanics and user experience are likewise underexplored. Two research paths to support the goal of better predicting the user outcomes are proposed: experimental parameterization of designs and model-based simulations. However, while work in these areas has introduced promising new possibilities, connecting both to improve real-world performance remains a challenge.**

***Index Terms*—Design optimization, prosthetics, user-centered design.**

I. Introduction

LOWER limb prosthesis design has evolved from creating devices that solely provide weight-bearing support to devices that perform specific behaviors to aid locomotion. The continuing improvement of prosthesis functionality has the potential to impact the quality of life of millions of people in the coming decades. Statistically, the number of persons living with limb loss in the United States is projected to number approximately 3.6 million by 2050 [1]. 65% of people living with limb loss in the US in 2005 had undergone a lower limb amputation, 61% of which removed at least the foot [1]. People who have had a lower limb amputation typically experience significantly reduced mobility and experience several impediments when completing the basic activities of daily life [2].

A major objective of prosthesis design research is to minimize both immediate and long-term detrimental effects. The evolution of prostheses driven by this research has led to quantifiable improvements in user performance metrics such as metabolic cost [3] and joint loading [4]. Researchers have investigated ways to improve a user's ability to walk on level ground [5]–[7], traverse inclines and declines [6], [8], [9], navigate stairs [6], [7], [10], turn while walking [11]–[13], transition between sitting and standing [14], [15], and run [16]. Efforts are ongoing by researchers to parameterize, quantify, and correlate the design factors of prostheses to desired user outcomes, thereby improving our understanding of what makes prosthetic devices effective. However, knowledge gaps between intended and actual user outcomes remain that require further exploration to more effectively address the needs of the prosthesis user [17]–[20].

The objective of this paper is to act as a resource for current and prospective prosthesis designers and researchers interested in future directions to best fill these knowledge gaps. In this review, we highlight the biomechanical challenges intrinsic to lower-limb prosthesis design, contextualize and summarize the major works to-date, identify key knowledge gaps, and highlight research paths which we expect to enable designers to meet user outcome-based functional needs. Literature for this review was obtained by investigating related papers on prosthesis design, modeling and simulation of human biomechanics with prostheses, and evaluation of prostheses with users. To this end, reference databases including IEEExplore, ScienceDirect, PubMed, and Google Scholar databases were searched and analyzed.

II. Biomechanical Challenges

Problems resulting from a lower limb amputation can manifest as immediate effects (i.e., asymmetrical gait compensations) and progress into long-term consequences

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(i.e., secondary impairments or other co-morbidities) [2], [21], [22]. This section discusses the causes of these problems and their interactions with prostheses.

A. Gait Compensations and Asymmetry

Lower limb amputation significantly alters the mechanics of walking from able-bodied mechanics. Muscle-tendon units interact with the skeletal system by generating, storing, dissipating, and transferring energy between segments [23]–[25], stabilizing joints [26], and enforcing compressive loading in individual bones through external tension [27]. These functions are critical for performing motor tasks, and they are removed with the amputation of a biological joint. Further, the use of a prosthesis adds an additional passive “joint” to the limb at the socket-residuum interface [28]–[31]. Methods to directly integrate the prosthesis into the residual bone exist and are becoming more common, but conventional sockets are still prevalent [32].

As a consequence, people walking with the aid of a prosthesis develop compensatory habits for the lost functionality which alters their dynamics. The resulting motion and muscle engagement changes can cause asymmetrical joint loading [33], [34]. These trends typically manifest as minimization of weight-bearing time for the prosthesis, increased work performed by the muscles on the sound side limb, and increased muscle work at the hip of the residual limb to compensate for lost distal muscle function [2], [33]. Widely used conventional passive prostheses are designed with elastic foot segments to restore some of the energy storage and return capability that the biological muscles once provided. However, elastic energy storage and return prostheses release less than half of the mechanical energy of intact biological muscles during level walking [35]. Depending on the age and physical condition of the user, walking with a passive prosthesis typically requires more metabolic energy when compared to walking with intact biological limbs [19], [36]. The development of powered prostheses has resulted in devices capable of restoring or even exceeding power output produced by biological muscles [3], [20]. However, these devices do not necessarily reduce the metabolic cost of walking to able-bodied levels for all users, nor do they restore symmetry to the motion [20]. This suggests that lost muscle power is not the only factor in causing gait abnormalities. Powered devices also have greater distal mass relative to passive devices. Increased distal mass has been shown to contribute to reduced metabolic efficiency [37], which may mitigate some of the benefits of added power. This increased mass is similar to the biological limb mass, however – commonly between 2 and 2.5 kg for powered transtibial prostheses [3], [38], [39] compared to between 2.5 and 5 kg for the average full shank and foot [40].

The loading of the residual limb via the non-rigid socket interface can also be a significant cause for discomfort and energy losses [2], [3], [27], [41]. The socket interface introduces loads to the residual soft tissue and bone that are not experienced during walking with an intact limb [27]. Inefficient energy transfer caused by losses due to socket motion or tissue absorption may also limit desired prosthesis contributions to whole body mechanics [3]. Socket fit and alignment are also largely qualitative measures and not typically assessed when evaluating prosthesis performance. Without deterministic analyses of socket fitment, it is difficult to assess the effect of fitment on user outcomes. However, these parameters are strongly associated with walking ability and user discomfort [2], [17], [41].

B. Secondary Impairments and Co-Morbidities

People who have received an amputation are at risk for several secondary impairments. For example, the prevalence of knee osteoarthritis in the intact limb of unilateral lower extremity amputees has been observed to be significantly higher than experienced by able-bodied persons [2], [21], [42]. Symptomatic knee osteoarthritis has been observed to be 17 times more common in unilateral amputees than in age-matched non-amputees [42]. This painful degeneration of the intact joints further detracts from one’s quality of life beyond the original amputation. Additional secondary conditions associated with lower limb loss include a reduction of bone density in the residual limb [2], muscle atrophy [2], [22], weight gain [2], chronic back pain [2], [22], [43], skin irritation [43], [44], and pressure ulcers [44]. Mitigating the risk of developing secondary impairments is an important design goal for a prosthesis to fulfill its purpose of restoring a user’s quality of life.

Many of these impairments result simply from a reduced level of physical activity overall due to discomfort, pain, or difficulty walking. Loss of bone density, muscle atrophy, and weight gain post-amputation are all linked to a decline in physical activity [2]. Back pain, some skin problems, and osteoarthritis are linked to another phenomenon: loading conditions for both the residual limb and sound limb which are not experienced by able-bodied persons. Prosthesis users tend to increase loading of the sound limb to make up for lost muscle power and reduce discomfort associated with loading the socket [2]. The development of back pain, for example, has been linked to an increased anterior pelvic tilt common in people with lower limb amputation [2]. The development of osteoarthritis has been linked to increased sound knee loading after heel-strike [2], [4]. Specifically, people with unilateral lower limb loss tend to have a large peak knee external adduction moment (EAM) in the sound side limb after heel-strike [4]. Knee EAM typically has a “double hump” profile after heel strike, the first of which is more closely associated with the development of osteoarthritis due to its higher loading rate and typically higher magnitude [45]. Poor socket fit and alignment have also been proposed to exacerbate the causes of many of these impairments, if not cause them directly [2].

A few dominant approaches have emerged to address the challenges described in this section. The next section identifies these approaches with representative examples, the hypotheses behind them, and the common metrics used to assess designs and user outcomes.

III. Current Design Approaches and Methods

The primary design goal of most current lower limb prostheses is to restore gait symmetry and effort to able-bodied

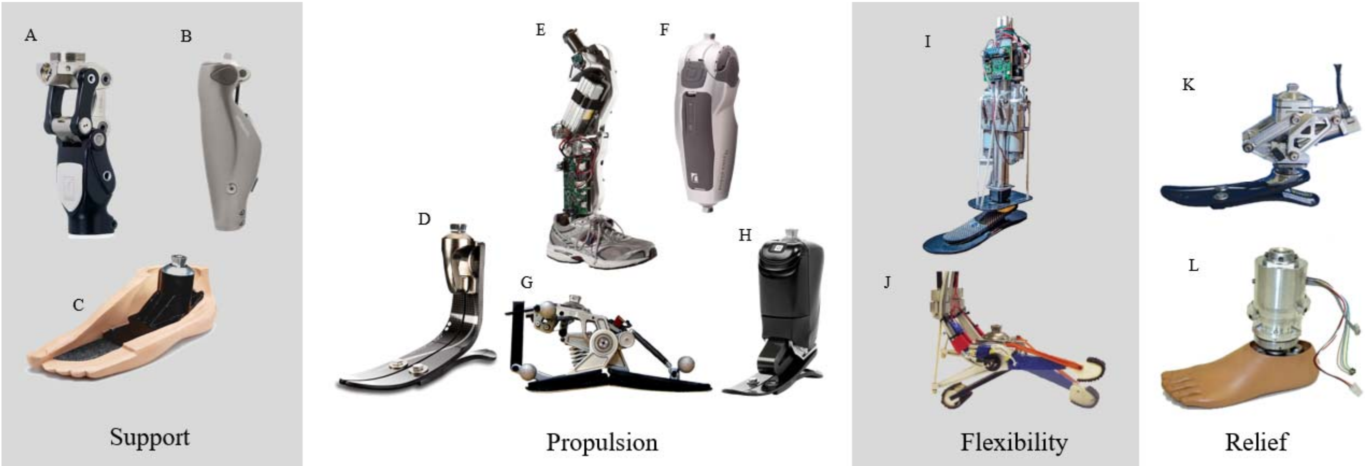

Fig. 1. An overview of commercial and research lower limb prostheses categorized by functional emphasis. A) Total Knee® 1900, Össur [49]: Passive polycentric knee prosthesis. B) C-Leg 4®, Ottobock [46]: Microprocessor-controlled hydraulically damped knee prosthesis. C) SACH, Ohio Willow Wood [69]: Passive ankle-foot for low-activity users with a cushioned heel and minimal energy return. D) Vari-Flex®, Össur [68]: Passive ankle-foot for low- to high-activity users with elastic energy storage and return. E) Vanderbilt Leg [5], [6], [8], [16]: Motor powered knee and ankle prosthesis which injects propulsive energy during walking. F) Power Knee®, Össur [100]: Motor powered knee joint prosthesis. G) CESR foot [62], [71]: Semi-active ankle-foot with actively controlled clutch mechanism for release of stored elastic energy at toe-off. H) Empower®, Ottobock [3], [7], [85], [90]: Motor powered ankle-foot prosthesis which generates positive ankle flexion work at toe-off. I) Michigan Tech 2-DoF ankle-foot [11], [103]: Motor powered ankle-foot with control over dorsi-/plantarflexion and inversion/eversion joint angles. J) 2-DoF ankle-foot prosthesis emulator [101]: Powered ankle-foot test platform with offboard motor actuation to control over dorsi-/plantarflexion and inversion/eversion joint torques. K) UMass Adaptive Alignment Prosthesis [27], [110]: Motor powered ankle-foot prosthesis with ankle flexion coupled with sagittal plane translation to reduce socket moment loads. L) TU Darmstadt & Blatchford shank adapter [13]: Motor powered parallel elastic actuator controlling shank torsion stiffness and foot alignment to reduce socket loads during turning maneuvers.

levels. Targets such as reducing abnormally high loads in the joints or the residual limb, improving the ability to perform specific tasks, and increasing balance and stability are also considered, however. The design approaches corresponding with these various desired outcomes can generally be categorized according to what the prosthesis is being designed to functionally provide: a) Support, b) Propulsion, c) Flexibility, and/or d) Relief. Examples of prostheses and research prototypes are illustrated according to these categories in Figure 1.

A. Support

Providing weight-bearing support is a fundamental function of a lower limb prosthesis. This function is performed by replacing the missing skeletal structure with a mechanical surrogate which provides static structural support. However, there are other design features which specifically serve to provide active support for balance or stability, almost all of which are commercially available. For example, active damping is commonly used in joints of both ankle and knee prostheses to stabilize the joint under load in hydraulic [46], pneumatic [47], and magnetorheological forms [48].

Prosthetic knees have also been designed to have a polycentric joint trajectory using linkages, rather than a revolute joint (Figure 1A) [49]. This motion more accurately mimics the range of motion of the biological knee and can be designed to allow the knee to naturally lock at full extension, offering more reliable support [50]. However, the addition of the ability to passively lock the knee during stance removes the ability of the knee to flex at heel strike, as the biological knee typically does. Semi-active devices use active components to vary the passive properties of the prosthesis, aiding the function of support when it is most needed. Microprocessor knees, the most notable examples being the introduction of the Ottobock C-Leg® and Össur Rheo Knee®, are a now common example of this approach to dynamically alter the viscous damping of the artificial knee (Figure 1B) [51]–[53]. The ability of microprocessor knees to adjust to task-specific behaviors such as variable stride cadences, knee joint stiffness requirements for traversing slopes or stairs, and transitioning between sitting and standing has been associated with increased balance and confidence with users [54]. A similar principle has been demonstrated for a prosthetic ankle-foot in [55], which changes the rollover shape of the foot from a locked, shallow curve while standing to a more flexible curve while walking. This design attempts to address the task-dependent stability needs inherent in the loss of feedback and control from the foot and ankle.

Support design features are primarily dissipative in nature. Design elements which prioritize work produced at the joint tend to focus on providing propulsion.

B. Propulsion

The loss of "push-off" torque provided by the ankle plantarflexors during the step-to-step transition in the biological ankle has been hypothesized to be the primary factor driving asymmetrical muscle compensations, increased metabolic cost of walking, and reduced preferred speed [56], [57]. This hypothesis is based on observations of the high percentage of the mechanical work required during gait being generated at the ankle joint during gait, the magnitude of which increases with walking velocity [56]–[58]. The loss of propulsion work is also hypothesized to lead to a compensatory increase in leading limb collision work to provide the necessary forward and up acceleration to the center of mass, and thus be responsible for abnormally large joint loadings in the sound side limb [4], [59]. Under this hypothesis, mitigating the risk of developing secondary impairments and restoring gait efficiency are goals which can both be achieved by restoring ankle push-off to able-bodied levels.

Designs which provide propulsion use passive, semi-active, or fully active approaches. Fundamental to the passive and semi-active approaches is the concept of energy recycling [53], [60]. Active approaches focus on energy injection but also use energy recycling design elements to improve efficiency [61].

1) Energy Recycling: Designs employing an energy recycling approach attempt to recapture some of the energy that would otherwise be dissipated through friction, damping within the joints, or inelastic collision with the ground [62], [63]. This energy is used to provide some of the positive work during the step-to-step transition that the biological ankle would normally provide, as well as generally reduce the amount of energy dissipated to the environment [62], [63]. This principle is applied primarily to passive and semi-active prostheses, but is also used in active prostheses to improve the overall energy efficiency of the design [64], [65].

Design work on passive prostheses primarily focuses on the efficient recovery of energy absorbed after heel-strike [66]. The typical approach is to incorporate elasticity into the design so that the user can store energy with their body weight, and then release it at toe-off [66]. Energy storage and return (ESAR) prostheses apply this by containing elastic heel and keel (hindfoot and forefoot) sections that each store and release energy at various stages during stance (Figure 1D) [67], [68]. These are prescribed as an alternative to solid ankle-cushioned heel (SACH) prosthetic feet, which offer cushioned heel-strike shock absorption with little energy recovery (Figure 1C) [67], [69]. The bulk of commercially available lower limb prostheses are implementations of these basic designs. Due to an aesthetic demand for anthropomorphic appearance, the geometry of these devices is limited to a similar size and shape of the biological foot. While these devices do restore some energy to the residual limb during walking, it is substantially less than is provided by the plantarflexor muscles during walking [35], [60]. However, running prosthetic feet represent specialized passive energy recycling designs exist which do not fully comply with anthropomorphic norms. These devices use high amounts of elastic displacement and a comparatively small base of support to maximize energy storage and return efficiency during running. This design style, while being impractical for heel-toe walking due to the lack of a heel, allows users to run while expending similar metabolic energy costs to able-bodied runners, and reach comparable sprint times to able-bodied runners at high levels of competition [70].

It is possible to increase the amount of energy provided during push-off using semi-active devices. Such devices control the storage and release of energy using motorized clutches and springs (Figure 1G) [4], [71], actuated pneumatic cylinders [72], or powered lead screws to modify the active length of a leaf-spring [73]. Commercially, semi-active devices are used to assist with propulsion by modifying the static angle of the prosthetic ankle to different set points for different scenarios [74], [75]. While passive and semi-active prostheses are capable of recycling a percentage of energy, they cannot produce net positive work over the entire gait cycle.

Active prostheses can also be designed to recycle energy through passive springs or clutches that supplement the active elements. Series and parallel elastic elements have been shown to decrease the peak power requirements of the actuator and biological joints [64], [76]. However, these benefits come with trade-offs in the form of reduced control bandwidth [77] and increased system complexity contributing to higher fault sensitivity [78]. It is common practice to use series-elastic as well as parallel elastic elements in powered prostheses to reduce demands on the actuator [5], [7], [65], [79]–[81]. ESAR prosthetic feet have also been used in conjunction with powered prosthetic joints [3], [5], [27]. In these cases, energy recycling is used as a supplementary feature to the primary contribution active prostheses provide: an injection of external energy.

2) Energy Injection: The biological ankle produces a net positive work over the gait cycle, the magnitude of which increases with walking speed [57]. The inability of passive and semi-active designs to replicate biological muscle work at the ankle joint has been hypothesized to be the cause of gait deficiencies in people walking with passive prostheses and is based on the importance of the step-to-step transition for overall energy cost of walking in dynamic walking models [82], [83]. Researchers have been motivated to inject power into the artificial joint from an external source. Most commonly used are electromechanical motors [61], but power has been also sourced using pneumatic artificial muscles [84]. Positive network is achieved by engaging the prosthesis actuators at the end of the stance phase, providing push-off force and torque to the residual limb. A standard approach is to produce a plantar-flexion torque about a revolute joint, and mimic the active and passive dynamics of the biological ankle [5], [7], [79], [81], [84]–[86]. However, alternatives exist which do not depend on strictly recreating the biological ankle function in the sagittal plane. For example, linkages are used to achieve polycentric rotational motion to increase efficiency and alter the passive impedance [87], [88], or to align the residual limb with ground reaction forces [27]. A device also exists which is explicitly designed to vary the amount of propulsion work above and below biological levels to test the hypothesis that reduced propulsion work is the cause for gait deficiencies in people with lower limb amputation [89]. Commercial availability of powered ankles is limited, with only one on the market (Empower® - formerly BiOM®, Ottobock [3], [90] – Figure 1H) and another undergoing commercialization (Walk-Run Ankle®, SpringActive, Inc. [91]). Other commercial ankles with active elements ultimately perform semi-active functions to modulate the behavior of the passive elements.

Active energy injection approaches have been developed for the knee joint as well. Most of the propulsive work in able-bodied walking is performed by the ankle, but some net positive work is also required at the knee [92]. Other activities such as running, jumping, upslope walking, and stair climbing require significant amounts of net positive knee work in able-bodied individuals [33], [93], [94]. Active knee prostheses in research have similar dominant characteristics to active ankles – flexion-extension actuation with an emphasis on emulating able-bodied biomechanics, often leveraging passive elements for efficiency purposes (Figure 1E) [5], [80], [95]–[99]. Polycentric linkage joints, common in passive and semi-active knees due to their natural locking properties, are not seen in these powered designs. This is likely due to the presence of linkage singularity points which cause the joint to lock - a feature in passive designs which becomes a complex control problem in active designs. The primary design focus for these examples is to actively control the knee torque and generate net positive work. Commercially, one propulsive powered knee is currently available (Power Knee®, Össur - Figure 1F [100]).

C. Flexibility

Prostheses that are designed to provide flexibility attempt to restore the range of capabilities that the biological limb could provide, or increase robustness to variability in the environment. For example, some designs include passive or powered degrees of freedom in the inversion/eversion axis of the ankle, targeting walking stability as a design objective. It is hypothesized that controlling this additional degree of freedom can reduce side-to-side sway, improve balance confidence [101], and improve a user's ability to perform walking tasks like turning, which is accompanied by ankle inversion/eversion rotations in able-bodied individuals [11]. For example, a prosthesis has been designed with active control of the inversion/eversion of the foot by using a four-bar linkage mechanism, with a passive spring providing plantarflexion torque [102]. By actuating a prosthesis emulator with two separate toes, inversion/eversion can be controlled (Figure 1J) [101]. A cable-driven prototype which can steer the entire foot in the flexion axis, as well as the inversion/eversion axis, has also been developed (Figure 1I) [11], [103]. Passive compliance non-flexion axes are also used in commercial prostheses to assist with walking on uneven ground [104], [105].

D. Relief

Reaction moments and soft tissue loading between the socket and residual limb are believed to be a major cause of reported discomfort and decline in mobility over time [2], [41]. Relief from undesirable loads on the residual limb and on the body as a whole is conventionally provided at the socket-limb interface. Soft cushioned gel socket liners are used to reduce peak loads [106], but may also reduce a user's sense of stability and sensory feedback resulting in higher ground reaction forces [107]. The use of vacuum-assisted socket suspensions has also been shown to distribute pressure away from concentration points [108]. Experimental socket designs for reducing tissue stress as well as discomfort due to tissue volume change and temperature are discussed in more detail in [31].

Socket loads may also be reduced by adding compliance and damping to the prosthesis-socket connection or the prosthetic structure, as has been done for both vertical [104], [109] and torsional loads [105] in commercial prostheses. Refining this concept, recent research has led to elastically actuated devices that modulate transverse plane torsional stiffness during gait, which allows for adaptation to the current motion patterns [12], [13]. Besides considering user requirements when designing this feature, the concept from [18] uses a parallel elastic actuator to further align foot orientation while turning during walking. Relief may also be a design goal for the prosthetic joint itself, as demonstrated by [27] (Figure 1K). This example has been designed to actively align ground reaction forces with the residual limb to reduce the flexion moment exerted on the residual limb by the socket, and has resulted in reduced socket moment and pressures in a pilot study with one participant [110]. Load reduction is achieved through translation of the foot segment, which does not replicate any function of the able-bodied biological ankle, but instead introduces a new axis of motion to address limb loading problems associated with the presence of a non-rigid socket-limb interface [27].

IV. Analysis of Current Designs

This section looks at experimental analyses that have been performed on these devices to assess the validity of the various hypotheses informing their designs. These studies attempt to address elements of a broader research question: How do prosthesis design factors affect experimental user outcomes? The previous section detailed some specific hypotheses for answers to this question – for example, increasing propulsion work at the ankle to decrease the metabolic cost of transport and normalize gait mechanics. This section details the biomechanics analysis and experimental methods used to evaluate these hypotheses then summarizes the various results with respect to desired user outcomes. The analysis studies detailed in this section are listed in Table 1 and are grouped by outcome measure investigated. The "gait mechanics" outcome measure refers to joint kinematics, kinetics, and power, as well as ground reaction forces. While the majority of studies consider global biomechanical measures such as gait mechanics, metabolic cost, or muscle activity, more specific information like joint contact forces or task-specific muscle contributions are less often taken into account. Despite being an important aspect of lower limb prosthetics, the user experience is rarely examined. Additionally, a large amount of the literature supporting the projects described in Section III has been published in primarily a technical context and reports mechanical device performance rather than biomechanical analysis. The analyses listed in Table 1 comprise a subset of the projects discussed in the previous section.

A. Experimental and Analytical Tools

Analyzing the real outcomes of a prosthesis design requires testing with human participants. Typical experiments involve the use of marker-based motion capture techniques, which allow for the calculation of joint kinematics and participant-specific model creation [92]. Motion capture testing also often

TABLE I
OUTCOME MEASURES OF PROSTHESIS DESIGNS

Tested outcome measure	Reference
Gait mechanics	[3], [4], [9], [10], [20], [59], [110], [123], [124], [127]–[132], [134], [135]
Metabolic cost of transport	[3], [19], [20], [125], [127], [128], [130]
Muscle activity	[20], [123]–[128]
Muscle contributions to tasks	[125], [126]
Preferred walking speed	[3]
Joint contact forces	[125]
Socket loads	[12], [110], [129], [131]
Knee external adduction moment	[4], [59], [134], [135]
Leading leg collision work	[3], [20], [127]
User experience	[13], [17], [19], [20]

includes the use of force and moment sensors embedded in the walking surface, which allow for the calculation of net forces and torques at the joints through inverse dynamics analysis [92]. Participants can also be outfitted with a respiration device which measures oxygen and carbon dioxide levels, allowing metabolic energy expenditure to be calculated [3], [20], [71]. Electromyography (EMG) electrodes may be placed above (or, in some cases, into) muscles of interest to measure their level of activity [92]. Other types of sensors may be placed inside or around the socket to measure pressure or motion between the socket and residual tissue, including the use of X-ray fluoroscopy [111]–[114].

From these experimental measures, other model- and simulation-based analyses can be performed which offer some insight into the effect of the design on a person. Induced acceleration analysis (IAA) is a method used to isolate the effect of individual muscles or forces on segments in the model, including segments that may not be directly connected to the source of the force [23]–[25]. This method is implemented by setting all forces and torques to zero for a given frame in the reconstructed kinematics and then individually re-activating each in isolation to observe the effect on the model. For example, this technique has previously been used to identify the role of individual lower limb muscles in energy generation, absorption, and transfer during cycling [25], the role of individual ankle plantarflexors to body support, forward propulsion, and swing initiation during walking [24], and the high magnitude of inter-segment energy transfer in the gait of children [115]. However, IAA remains a controversial method to some members of the biomechanics community, who argue that cannot meaningfully describe the role of muscles in a system because it does not attempt to model the adaptation of the system when a muscle force is changed [116].

The use of optimal muscle control problems is another model-based analysis method and can be applied to estimate the individual redundant muscle contributions to measured joint torques. These estimates are based on minimizing measures of total muscle effort, metabolic cost, task performance, or other objectives, subject to kinematic constraints. The objectives related to effort measures are formulated to represent a realistic approximation of the active muscle load distribution patterns in actual locomotion tasks and have been shown to result in muscle controls which generally agree with measured EMG data [117], [118]. Various optimization techniques have been employed in numerous studies to determine individual muscle excitations for activities such as walking, jumping, and cycling [119], and also used predictively to generate theoretically optimal motions [118], [120]–[122]. Extracting individual muscle activations and contributions to the dynamics of remote segments allows for the identification of compensations not directly observable from the recorded kinematics and net forces. As with other simulation methods, however, model accuracy is a key factor in producing meaningful information.

These tools have been used to assess the ability of various prosthesis designs to achieve the desired results in human users. These objectives can again be broadly categorized into short-term gait restoration and long-term secondary impairment and comorbidity mitigation goals. Propulsion oriented designs have been a major focus of prosthesis analysis work. Analysis of designs which provide flexibility or relief through the prosthetic joints and structures is less common.

B. Gait Restoration

Gait restoration outcomes are targeted by designs across the passive-active spectrum. Metrics such as similarity to biological gait mechanics, preferred walking speed relative to able-bodied levels, reduction of muscle contributions, and reduction in the metabolic cost of walking are commonly used to evaluate the effectiveness of a prosthesis in restoring gait (Table 1).

Optimally, passive prostheses focusing on propulsion attempt to maximize energy recycling efficiency, in theory reducing the amount of energy required from the muscles to compensate for lost torque generation. This requires an understanding of the relationship between the design parameters and the musculoskeletal system response, which researchers have begun to address. For example, the effect of prosthesis stiffness on gait patterns and energy storage efficiency has been analyzed using inverse dynamics and EMG data with human motion capture tests with varying prosthesis stiffness values [123]–[125]. It was found that decreasing prosthesis stiffness led to increased energy storage and return and decreased hamstring muscle activity in the residual limb. This decreased muscle activity was offset by increased muscle activity in other areas providing body support.

In a follow-up study to [123], the experimental data was used to find the individual muscle activations in a mathematical model of the musculoskeletal system by solving an optimal muscle control problem to track the measured kinematics [126]. Induced acceleration analysis was used to identify the contribution of each muscle individually, as well as the contribution of the prosthesis and gravity, to the propulsion/braking force as well as the body support force on the ground. Among other results, the prosthetic foot was found to provide an increased contribution to body support forces and

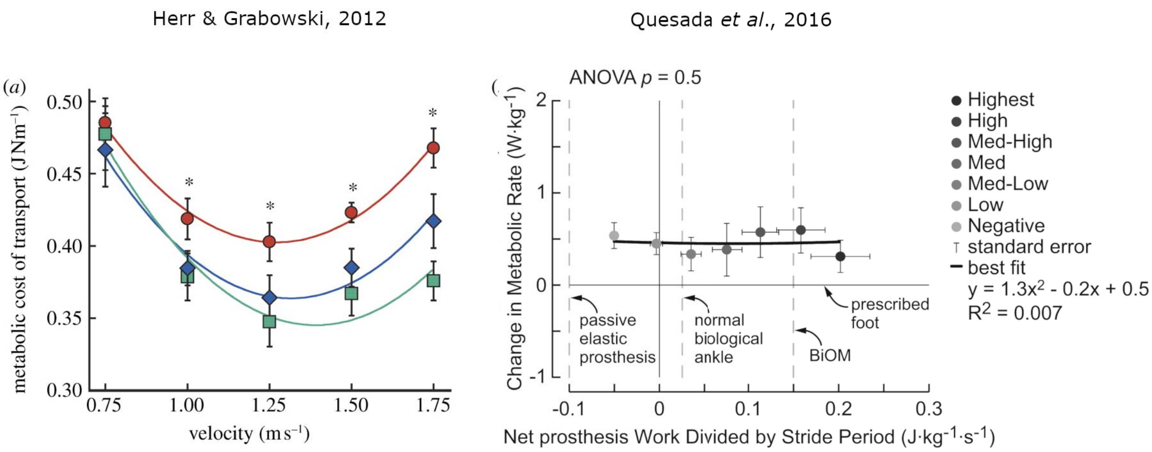

Fig. 2. Comparison of results from [3] and [20]. Note that in [3], the Empower® prosthesis was compared with the daily use passive prosthesis of the subjects, whereas in [20], the work output was varied for the same powered prosthesis for all trials. The results of [3] have been used to conclude that metabolic cost is dependent on the presence of push-off power, but this conclusion has been contested by the results of an experiment that more successfully isolated the presence of push-off power. Other factors such as normalized prototype acclimation time have not been accounted for.

decreased contribution to propulsion as stiffness decreased, despite showing an increase in total energy stored and returned as stiffness decreased [126]. Variations in individual muscle contributions to body support, propulsion/braking, trunk power, and residual leg power were also observed relative to the stiffness of the prosthesis [126]. These results suggest that optimal stiffness may vary depending on the individual compensation needs of the user. Additionally, experiments with powered devices have shown that optimal device impedance changes between different tasks (e.g., standing vs. walking) and even different phases within one task (e.g., phases of gait) [5], [6].

Current powered ankle prosthesis designs show promising results for some gait restoration metrics and mixed results for others. The Ottobock Empower® ankle has been shown to increase the preferred walking speed and decrease the metabolic cost of walking for amputees relative to their daily use ESAR prosthesis [3]. The study theorizes that this relationship is due to the increase in trailing leg push-off work observed, coupled with an observed reduction in leading leg collision work. However, the metabolic cost of walking with the powered ankle is shown to still be higher on average than the cost of able-bodied walking at and above the participants' preferred speeds.

In contradiction to the hypothesis that metabolic cost reduction is caused by increased push-off work, researchers using a tethered prosthesis emulator with off-board power [89] observed no relationship between prosthesis joint power and metabolic cost. Additionally, they did not observe a relationship between prosthesis joint power and intact limb collision work [20]. This experiment tested amputees walking at a set speed with varying prosthesis net-power settings, rather than between powered and unpowered prostheses for slow to fast walking speeds. It was also found that the timing of prosthesis push-off from the emulator device also has a significant effect on the metabolic cost of walking [127]. The combined results from the emulator studies suggest that factors other than the magnitude of network or work rate generated by the ankle actuator contribute to user gait performance metrics. Further complicating the problem, it has been observed that the metabolic cost of walking does not necessarily increase after transtibial amputation in exceptionally young and fit users with passive prostheses [19]. This result can be reproduced through optimal muscle control simulation [128], suggesting that user-specific factors other than the prosthesis design altogether may have a significant effect on metabolic rate as well. Metabolic rate results from [20] are compared with corresponding results from [3] in Figure 2 2.

Some analysis of prosthesis design elements which are not propulsion-focused exists as well. Literature exists which supports the ability of semi-active ankle designs, such as the commercial Össur Proprio-Foot®, to encourage able-bodied kinematics and lower socket pressures [9], [10], [129]. Semi-active knees with viscous damping have also been shown to reduce metabolic cost, as well as biological joint moments and power [130]. Stiffness effects have also been investigated for shock absorption purposes. For example, a study which investigates longitudinal compliance in prosthesis pylons observed no clinically relevant changes to the kinetics of gait for the range of commercially-available, longitudinal compliances [131], [132]. Similarly, work has been done to investigate the role of torsional compliance on the ability to perform turning tasks. Study participants have reported a reduction in perceived load and effort in performing turns while walking with an adaptive shank prosthesis capable of adjusting torsional compliance and foot alignment [13]. Increased torsional compliance in a separate adjustable torsional compliance device has also been demonstrated to reduce measured peak torsion moments when performing large angle turns without adversely affecting normal walking [12], [133]. Additionally, active alignment of ground reaction forces has been shown to reduce in-socket flexion loads and related pressures on the residual limb in a pilot study with a single participant [110]. However, the effects of these flexibility- and relief-focused approaches on broader outcome measures such as metabolic cost, preferred walking speed, walking stability, individual muscle engagement, and osteoarthritis risk factors are not well-characterized.

C. Secondary Impairment Mitigation

As with short-term gait restoration, the focus of many studies analyzing the ability of prosthesis designs to mitigate long-term problems is with restoring propulsion. These studies have produced mixed results in supporting the hypothesis that near-biological levels of push-off work reduce elevated osteoarthritis risk factors like knee EAM. Results that support this hypothesis include significant correlations found between push-off work and knee EAM in a semi-active design [4], the presence of powered ankle plantarflexion and knee EAM [59], and the presence of combined powered ankle and knee toe-off assistance and knee EAM [134]. However, peak EAM values for trials with powered ankle plantarflexion in [134] were comparable to the case where no assistance was provided at all in absence of linearly increasing ankle stiffness through stance. The correlation in [59] was observed only for two of five walking speeds.

A comparison of results is shown in VI from two different studies with one using an energy recycling prosthesis [4] and other using a powered foot-ankle (Ottobock Empower®) [135]. While a peak EAM was observed for the energy recycling foot, no significant decrease in peak EAM or EAM impulse was observed with the use of a powered ankle-foot prosthesis compared to a passive elastic prosthesis in active young individuals within the first few years of walking with a prosthesis. This group also showed EAM values within a normal range for able-bodied persons with both prostheses, suggesting that osteoarthritis risk factors for amputees, and therefore prosthesis design priorities, change with individual health and age.

Because many comorbidities arise due to a decline in overall health and changes in lifestyle [2], another key design goal is to encourage the user to wear the prosthesis often and use it actively. This goal prioritizes outcome measures such as user satisfaction and other human factors. Some analyses of user experience measures have been performed: For example, prosthesis power was found to decrease user satisfaction with the emulator device above and below the network setting nearest to the biological ankle [20]. In another study with young, highly athletic ESAR prosthesis users [19], ratings of perceived exertion, ease of and satisfaction with walking, and pain intensity reflected high levels of satisfaction across all metrics on average. A design method has additionally been proposed which incorporates user survey data involving ratings of perceived security, body schema integration, support, socket satisfaction, mobility, aesthetics, and general satisfaction into the design process [17]. However, a systematic review of studies that provided satisfaction questionnaires to users found that comparisons between studies could not be directly made due to a lack of standardized variables and terminology [136].

The results of these studies suggest that decreasing secondary impairment risk factors depends on more factors than increasing propulsion work. The knowledge gap, as with gait restoration objectives, is the characterization of how design factors affect the risk factors. Work to address this gap is ongoing, and new approaches are emerging to support this effort. The next section details the work supporting these approaches and identifies opportunities for future work building on them, with the goal of developing a framework within which user outcome-based design optimization can be achieved.

V. Emerging Approaches and Research Challenges

A. Experimental Parameterization of Designs

Creating an accurate mapping between design parameters and clinical outcomes is a significant research challenge. Efforts have been made to isolate individual design parameters and experimentally determine their effects on users' biomechanics and experiences. This type of analysis has been performed for passive prosthesis stiffness [123], [126], [137], as well as for parameters of active propulsion designs such as network and push-off timing [20], [127]. However, there are many other parameters and relevant user outcomes for which a considerable research potential remains. Examples include prosthesis size/geometry, nonlinear stiffness response, damping ratio, actuator power density and distal mass distribution, range of motion, deflection or actuation in additional degrees of freedom, and time-variant or actively controlled mechanical properties. User outcome measures include socket loading, user stability, metabolic cost, preferred speed of walking, peak knee adduction moment, and user needs and experience (e.g., satisfaction with a device).

It is possible that some design parameters are more crucial for specific user outcome measures. Identification of population-specific responses to design parameters is also an important research area, as there is a significant amount of variability currently being introduced by comparing young versus old, traumatic versus dysvascular amputation, and months versus years of walking on a prosthesis. Well-modeled relationships between design parameters and outcomes would enable the design process to prioritize specific outcomes differently and arrive at different solutions accordingly.

Experimental approaches also have substantial challenges. Quantifying the parametric effects on the biomechanics of the user requires a significant effort to be made to isolate the parameters being investigated. Variables such as the user's age, weight, time post-amputation, activity level, and preferred walking speed are difficult to control for due to a typically limited number of volunteer participants. Acclimation to a new prototype design is also difficult to control for between studies due to individually varying comfort levels and familiarity with different prostheses. Additionally, it is difficult to determine when a participant has acclimated to a device due to a lack of defined metrics or thresholds. Consistency between subjects is further complicated by the qualitative nature of prosthesis alignment and socket fit assessments and the varying availability of professional prosthesis fitting and installation staff. Aside from the logistical challenges, the existing work illustrates that the biomechanical response to a single

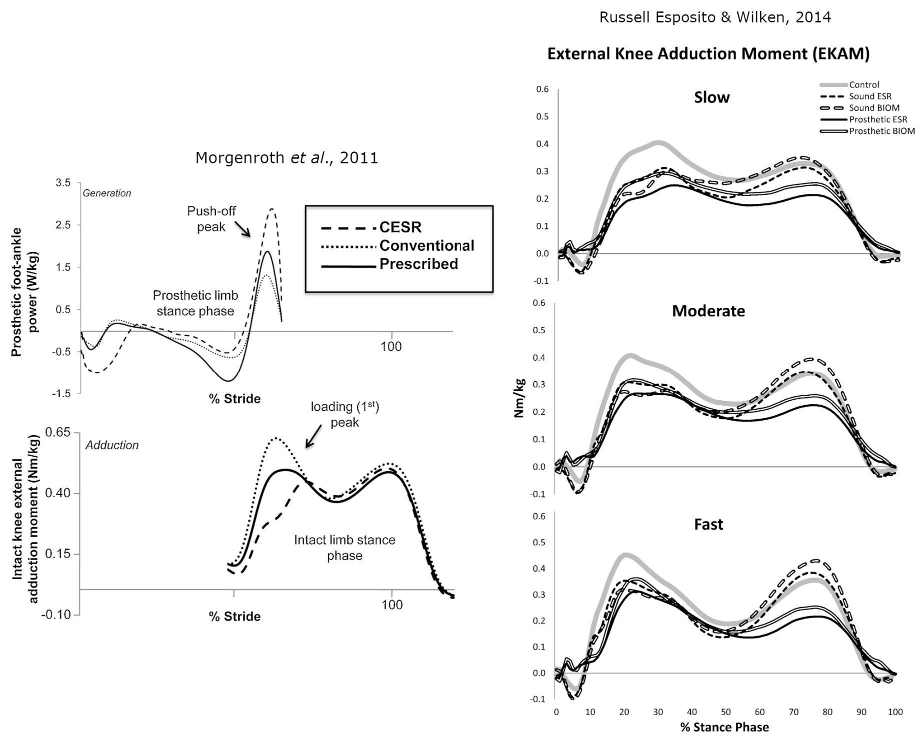

Fig. 3. Comparison of results between two studies with different user populations. The use of additional push-off work from an Empower® ankle with young amputees not showing risk factors for knee OA did not decrease the external knee adduction moment in the sound limb in [135] (right figure), which it did for a more typical amputee population in [4] using a semi-active energy recycling prosthetic foot (left figure).

parameter variation can be highly complex and coupled to other factors that are not measured [20], [126], [127], [137]. For example, increasing push-off work for a powered ankle may increase metabolic rate in one user while decreasing it in another [20].

B. Model-Based Simulation

Model-based biomechanics simulations are increasingly being used to analyze the performance of prosthetic designs on the overall musculoskeletal system. Models of gait based on simple passive dynamic walker models have been used to motivate ankle propulsion work as a critical function of below knee prostheses [83], [138]–[141]. In these models, the stance leg is assumed to act as the rigid rod of an inverted pendulum, with a powered transition period taking place between steps required to accelerate the center of mass forward and upward onto another inverted pendulum trajectory. Other simple gait models include additional degrees of freedom in the leg to more closely resemble human gait mechanics, such as the spring-loaded inverted pendulum (SLIP) [142], [143], telescoping leg [144], [145], and muscle-actuated knee joint models [145], [146].

Recently, more elaborate musculoskeletal models have become prevalent in simulating human locomotion, including physiologically accurate muscle dynamics and insertion points [30], [126]. A dynamic walking model is shown in Figure 4A, and more complex human musculoskeletal models are shown in Figures 4B and 4C. This increased level of detail is due, in part, to the increasing availability of commercial modeling and simulation software such as AnyBody (AnyBody Technology A/S), Visual3D (C-Motion, Inc.), and SIMM (Motion Analysis), as well as open source software such as such as OpenSim [147]–[149]. These platforms facilitate modeling and simulation work by integrating customizable musculoskeletal models and analysis tools. Furthermore, as modeling and simulation become more prevalent as analysis tools, they are increasingly being integrated into the design process.

Researchers have begun to use model-based simulation to optimize designs of assistive devices for simulated user outcomes. For example, gait simulations based on tracking experimental kinematics were used to optimize passive ESAR foot parameters for minimal metabolic cost and knee contact force with a simulated annealing algorithm in [125]. Other projects have used simulation to identify ways in which prosthetic devices may diverge from the biological anatomy to improve performance. The actuation trajectory of the powered ankle in [27] was designed by simulating the gait of a user by tracking able-bodied gait kinematics for the biological joints of the model and measuring the calculated moment through the socket-limb connection. It was found that allowing ankle motion in a non-anatomical translation arc reduced simulated socket-limb interaction moments [27]. Similarly, a parameter search to design an asymmetric transfemoral prosthesis was performed in [150], in which the artificial knee center of rotation and the mass distribution of the prosthesis limb segments were altered to enforce symmetrical passive walking dynamics in forward simulations. It was found that symmetry in the

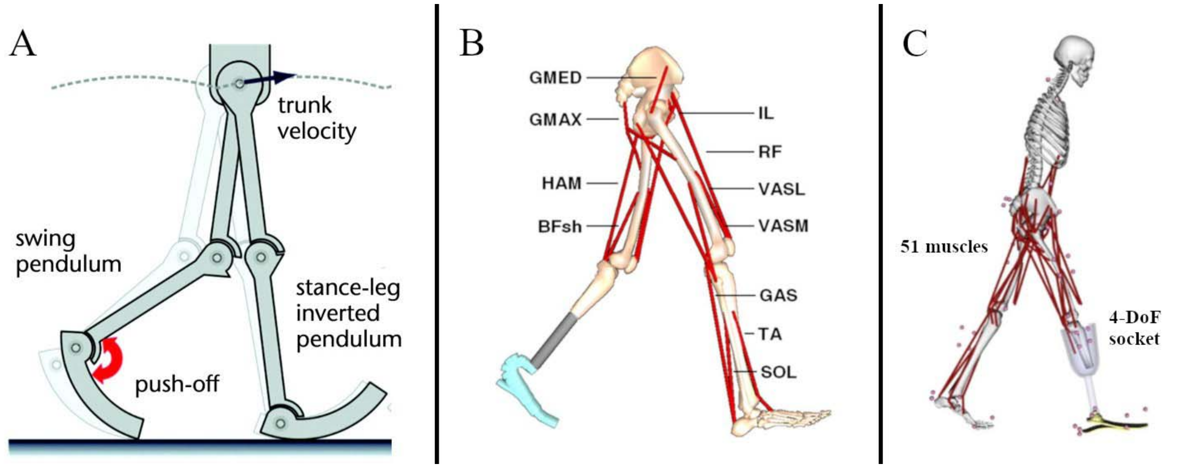

Fig. 4. A) Human walking model based on simple dynamic walking mechanics [83] compared with B) a model incorporating realistic muscle behaviors and a rigid socket connection developed in SIMM (Motion Analysis Corp.), and C) a model incorporating realistic muscle behaviors and socket motion using OpenSim [30]. In the dynamic walking model, the mechanics of walking are modeled as a series of inverted pendulum trajectories with a double-stance step-to-step transition period. In the musculoskeletal models, muscles are modeled with physiological activation dynamics and attachment points, rendered here as red lines.

passive walking dynamics could be restored by designing the prosthesis parameters to be asymmetrical with the sound limb, with different limb segment lengths, mass distributions, and knee axes of rotation [150].

With the exception of the last example, which removes active control from the problem entirely, these examples make use of human data to provide a realistic reference for simulations to track when solving for actuator or muscle controls. However, this limits the scope of the design problems which can be solved and forces the designer to make the assumption that the resulting motion will be the same as some previously recorded motion with a different prosthesis or an able-bodied person. Research in predictive simulations of human gait, alternatively, solves the optimal control problem for objectives in which the resulting motion is not (or is loosely) prescribed in an attempt to simulate the way a person "would" perform a task, considering the new dynamics of the human walking with the device. With accurate and efficient predictive simulations of human gait, virtual experiments could be conducted with hypothetical prosthesis designs. This could eliminate the physical requirement of a working prototype to estimate its effect on gait or be used with simulators to perform human-in-the-loop experiments even before a prototype is built [151]–[153].

Predictive simulations of human walking have been able to capture many of the characteristic features of human gait primarily through optimization of muscle activations for minimum effort [121]. This approach is based on the hypothesis that humans naturally pursue the most energetically efficient means of locomotion [120], based on data which show that preferred walking and running patterns approximately minimize metabolic energy cost [154]–[156]. Minimization objectives for this approach include summed muscle activations raised to a power [121], calculations of metabolic cost based on muscle models [118], [120], [157], summed muscular mechanical energy expenditure [158], and summed muscle stresses [122].

This approach has also been applied to gait with a powered prosthesis, in which prosthesis energy cost and metabolic energy cost are used as competing objectives in the minimization [159]. The results of this study suggest that an ideal powered prosthesis could reduce the metabolic cost of walking below able-bodied levels. The same group later simulated multiple ankle flexion controllers as implemented in specific research prostheses and found that they do not improve the metabolic cost as much as the unrestricted optimal control result, suggesting that control design may factor into the modest metabolic efficiency gains seen in existing prototypes [160]. In [128], predictive gait simulations were used with a passive prosthesis model to determine that metabolic cost may not necessarily increase after limb loss if intact muscle strength is maintained.

However, it is still unknown whether simulation conditions which yield accurate estimates of able-bodied gait may require modification to accurately simulate and address issues specific to walking with a prosthesis. For example, predictive simulations using a passive prosthesis model have included minimization of joint moment asymmetry as an objective [161]. This approach highlights an attribute of gait specific to people with amputations and finds that simulated joint moment asymmetry can be substantially reduced at the expense of muscle effort while maintaining similar kinematics. Additionally, accurately reproducing the features of able-bodied gait is still a major challenge, indicating that perhaps additional objectives or conditions for simulating walking with a prosthesis are necessary as well – for example, physical discomfort or perceived instability. Defining the objective function in the context of prosthesis design could also function as part of the design process by indicating the relative priority of functional design criteria.

However, a major component of this work is being able to identify when results reflect an artifact of the model or simulation method rather than a real physiological trend. Gait patterns due to personal biomechanics and socket fit show strong inter-individual variations, which predictive simulation cannot compute without personalized models. Additionally, simulations with prototype prostheses require assumptions to be made about the mass distribution or other mechanical properties of the design which may not match the final device [162]. It is, however, a significant challenge to establish model and simulation fidelity sufficient to draw generalized conclusions and make design decisions.

One approach toward improving simulation accuracy focuses on increasing the quality and level of detail of the models themselves. For example, a key attribute of the coupled system human-prosthetic system is the mechanics of the socket-residuum interface, due to the potentially large effect it might have on gait mechanics and muscle control decisions. This attribute is often represented as a rigid connection [35], [125], [128], [159], [161].

Efforts to measure and model socket-residual limb behavior are ongoing. One approach has been to indirectly calculate the kinematics of the socket relative to the underlying bone from marker-based motion capture data based on assumptions about joint constraints imposed on the system [30]. This method attempts to calculate socket motion non-invasively and without the harmful side effects of repeated X-ray exposure, but is limited in that possibly non-physiological constraints on the socket joint must be imposed to calculate a unique solution. This work has not yet resulted in the construction of a mechanical model of the socket. Other approaches attempt to model the tissue mechanics directly by fitting parameters to match recorded data. For example, a two-dimensional socket-limb model with elastic and friction parameters was developed and optimized to agree with experimental pressure and kinematic data obtained from previously published experiments in [13]. Other researchers have attempted to model the tissue mechanics of the residual limb using a finite element approach, optimizing the material properties to match force response measurements recorded from indenter devices used on a user's residual limb [115]–[117].

All of these methods face challenges in modeling for a highly variable set of conditions per individual, including tissue mass, limb length, and suspension type, some of which also exhibit strongly nonlinear behavior. They also face challenges in the limited amount of data available for socket forces and kinematics across a wide population.

Another major challenge with simulation-based approaches is resource feasibility. As model realism increases so does model complexity in the form of more degrees of freedom, more muscles, more complex measures of values such as metabolic cost, and more complex or denser contact models – including soft tissue models such as the socket-residuum interface. The trade-off between model complexity and computational cost is a key concern and is especially significant in computationally expensive operations like predictive simulation, of which the cost of each iteration scales with model complexity, number of constraints, and granularity of time resolution. Predictive able-bodied gait simulation studies often use one standard deviation for each coordinate of experimental walking kinematics and ground reaction forces as a simulation accuracy benchmark [122], [157], [161]. However, regardless of complexity, computational models are subject to uncertainty in fundamental parameters such as body segment lengths and inertial properties [163]–[165]. Efforts have been made to identify the sensitivity of simulation results to model parameters [163], [164], which could allow for more efficient models tuned for specific simulation tasks.

Improvements in computing power and algorithm efficiency have made predictive simulation a more practical tool [166], but pushing the boundary of this trade-off to allow more efficient simulations with a high degree of accuracy, as well as identifying the level of accuracy required to obtain practically useful results, remains an important direction for future work. This is especially true for potential future applications in which simulations occur in real-time or in embedded systems (e.g., control and adaptation).

Currently, no method exists for a prosthesis design to be generated or optimized using predictive simulations of its effect on human mobility tasks and outcome measures. To do so and test the resulting prototype on human users would provide valuable insight into the validity of the method as well as potential mechanisms for prosthetic influence on user outcomes. Such experiments could also provide data to assess and modify predictive simulation methods. Development of realistic multi-objective predictive simulations could also help to identify the causes for gait abnormalities by reproducing them with modifications to the optimization objectives.

VI. Conclusions

Research work in lower limb prostheses has focused heavily on restoring propulsive work to the affected limb. The inconsistency of results and broader analysis of biomechanical effects illustrate the degree to which a more detailed understanding of the causal relationships between design factors and outcome measures is needed. Traditional gait restoration metrics such as metabolic cost and kinematic similarity to able-bodied gait are not sufficient to fully capture the efficacy of a prosthesis in enabling optimal gait patterns. Limb loading, socket fit, walking stability, and individual muscle compensations are all likely contributors to discomfort, excessive effort, and user dissatisfaction in general. The characterization of how prosthesis design factors affect the outcome measures remains the primary knowledge gap in targeting design objectives. Efforts are ongoing to experimentally evaluate these relationships by isolating design parameters and observing user outcomes. Many of these efforts have focused on global biomechanical measures such as metabolic cost or gait mechanics, but measures of user experience or more specific biomechanical information such as task-specific muscle contributions are also important aspects to the design problem. It is possible that many of these performance measures may be better improved by de-emphasizing anthropomorphism in prosthesis design because the biomechanical and sensory system of a person with a lower limb prosthesis is distinct from that of an able-bodied person. However, the limits to which deviation from anthropomorphic norms are functionally useful or acceptable to the user are unknown and likely vary by user and application. Modeling and simulation efforts offer the potential to conduct virtual experiments, but establishing accuracy and trustworthiness of the resulting solutions remains a significant challenge, and simulation results cannot replace experimental measures and user feedback.

A range of research opportunities to advance the ability to design for optimal user outcomes exists between two suggested research paths: experimental parameterization of designs and model-based simulations. Progress in both paths could improve the accuracy of a broad scope of predicted user outcomes using prosthesis design models, which may allow these outcomes to be factored early into the design process. Opportunities for work in these paths exist across domains including engineering design, biomechanics simulation and modeling, experimental biomechanics, user experience surveys, and engineering analysis. The advancement and synthesis of these fields may create the framework to optimize lower limb prostheses for desired user outcomes.

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