

Perspective

Innovations in Amputee Care in the United States: Access, Ethics, and Equity

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Abstract

Limb amputation is a growing health concern worldwide, driven largely by the rising incidence of vascular and metabolic diseases and military conflicts. In the past two decades, remarkable advancements in surgical techniques, prosthetic technologies, and rehabilitation strategies have made a profound impact on outcomes for individuals with limb loss. In this article, we explore the evolving landscape of limb care in the United States, highlighting innovations in prosthetic technology and amputation surgery including osseointegration, neuromuscular surgeries and interfaces, artificial intelligence, sensory feedback, and the importance of prosthetic embodiment. We discuss limb care systems and the continuum of limb loss rehabilitation, focusing on the need for coordinated models of patient-centered care. We present the demographic biases and healthcare disparities related to insurance coverage and reimbursement in the United States and the explore ethics and equitability considerations pertaining to prosthetic standard of care and advanced treatments for limb loss. Finally, we lay out the systemic reform, policy advocacy, and future research needed to ensure that everyone with limb loss has equitable access to the benefits of modern amputee care.

Keywords: amputation medicine; amputation surgery; limb loss; osseointegration; bone anchored limbs; prosthetics; TMR; RPNI; coordinated care; healthcare equity; healthcare policy



Academic Editors: Winnie Jensen and Marco Cicciu

Received: 13 August 2025

Revised: 7 November 2025

Accepted: 16 November 2025

Published: 21 November 2025

Citation: Cain, J.; Earley, E.J.; Potter, B.K.; Grover, P.; Thomas, P.; Stark, G.; White, A. Innovations in Amputee Care in the United States: Access, Ethics, and Equity. *Prosthesis* **2025**, *7*, 153. <https://doi.org/10.3390/prosthesis7060153>

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1. Introduction

Limb amputation is a common surgical intervention worldwide and is projected to continue to increase due to the rising incidence of vascular and metabolic diseases and ongoing military conflicts. After decades of stagnancy, the last twenty years have seen profound advances in surgical, [1] prosthetic, [2,3] and rehabilitative care [4] promising dramatic improvement in function and quality of life for people with limb loss. All medical innovations introduce questions about how people will be able to appropriately access new technologies, their risks and benefits, their integration into healthcare systems, and how to address the ethical considerations that arise from their introduction.

In this article, a multidisciplinary group of consumers, experts, and leaders from academic institutions; the Amputee Coalition, the largest patient advocacy organization in the United States; and the National Association for the Advancement of Orthotics and Prosthetics (NAAOP), a policy thinktank; will provide their insight on these issues. We will address the current incidence and rising rates of amputation (Section 2), provide a brief history of innovation in prosthetic care (Section 3) and surgical procedures (Section 4), discuss issues of coordination of care for new technologies (Section 5), and identify the challenges with insurance coverage and reimbursement (Section 6), and public policy as they relate to emerging innovations (Section 7). We will also discuss the ethical and health equity considerations that emerge (Section 8) and offer potential solutions to address these issues.

2. Background and Patient Forecast

Despite advancements in medicine and new techniques for limb preservation, the rates of amputation throughout the world continue to rise. Discrepancies in amputation trends exist throughout much of the world when factors such as level of limb loss, etiology, age, gender, and race are compared. Understanding these differences is important for optimizing coordinated healthcare and the development of patient and provider education. Despite the limited availability of reliable data on global prevalence of limb loss, the lessons learned from any given region can provide valuable insight into the nuances of limb loss and limb difference everywhere.

An estimated 1.6 million individuals were living with limb loss in the United States in 2005. Without effective interventions, it was projected that this population would increase to 3.6 million by the year 2050 [5]. Recent analyses estimate that, as of 2021, the number of people living with limb loss in the United States is nearly 2.3 million (of whom 69% are men and 31% are women), quickly approaching the 2050 projection. By including the 3.4 million people living with congenital limb difference (52% men and 48% women), this population now consists of over 5.6 million people in the United States alone [6].

Most amputations in the U.S. result from the cumulative illness burden of multiple comorbidities, a trend that has been observed in many parts of the world (Figure 1). Diabetes remains the most diagnosed condition prior to amputation, occurring in 57% of the estimated 465,000 annual amputation procedures. Diabetes is far more likely to precede an amputation procedure than trauma (13%), cancer (1%), or congenital anomaly (0.5%). Other commonly diagnosed conditions prior to amputation included the presence of an infection (43%), including osteomyelitis (27%), vascular conditions (39%), and ulcers (38%), which are common along the complex pathogenesis and clinical manifestations of diabetes [2]. In parts of the world with lower incidence of diabetes, it is expected that a larger percentage of amputations result from other causes, particularly trauma. In 2017 it was estimated that 57.7 million people were living with limb amputation due to traumatic causes worldwide [7]. Amputations due to malignancy (cancer) or congenital anomalies have not demonstrated rapid growth or decline in recent years.

Amputations occur most frequently in adults 65 years or older (45%), followed by adults ages 45–64 (42%) [6]. Furthermore, the demographic affected by upper extremity amputations, and particularly those related to trauma, is younger than those affected by lower extremity amputations [8–10]. The needs of each patient subgroup differ significantly. While the priority for older patients may be safety, younger patients often demonstrate an increasing need for high-functioning prostheses that allow them to pursue active lifestyles and return to work or military service [11].

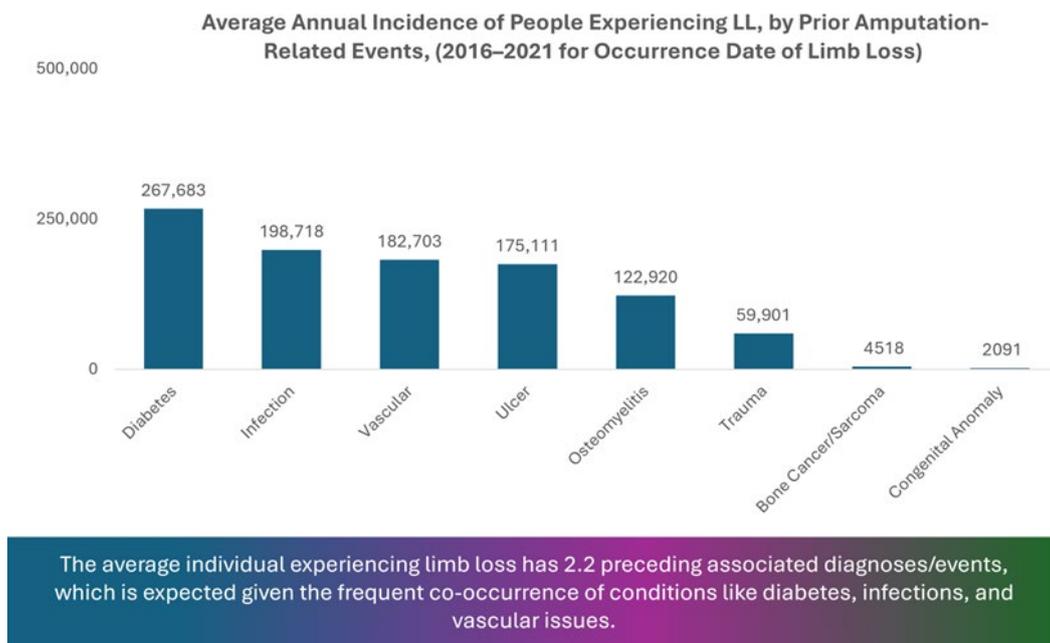


Figure 1. Annual incidence of prior amputation-related events in the United States (2016–2021). Infographic courtesy of Amputee Coalition.

3. Innovations in Prosthetic Technology

The rising demand for prosthetic care has led to significant innovations in prosthetic technology in recent decades. Today, lower limb prosthetics are often comprising engineered materials that increase user comfort, performance, and device utilization. Carbon fiber blade prostheses allow athletes to run, and microprocessor knees can prevent falls and improve safety [12–14]. Together, technological and surgical advances have been combined to significantly alter the landscape of the prosthetic industry over the past decades. Advances in areas such as myoelectric sensors [15], osseointegration [16,17], and neural integration [18] may hold the key to fitting prostheses that are intuitively controlled and restore function and sensation similar to a biological extremity.

Current state-of-the-art approaches to prosthetic control seem to blur the line between reality and science fiction. Advances in computation power and efficiency over the past few decades have facilitated the use of sophisticated artificial intelligence (AI) algorithms for decoding electromyographic (EMG) signals to predict user intent for both upper limb [15] and lower limb prosthetics [19]. These pattern recognition approaches to prosthetic control synergize strongly with the increased availability of multifunction prosthetic hands, allowing patients to seamlessly switch between grasping modes [20,21]. Furthermore, innovations in implantable electrodes can mitigate some of the challenges associated with surface EMG (such as changing EMG signals across multiple days of donning and doffing the prosthesis [22]) by instead measuring these neural signals directly from the muscles in the limb [23,24]. The benefits of these approaches are further enhanced by emerging surgical techniques that can extract more neural information from the nerves and muscles in the limb (discussed further in Section 4). However, learning to control a prosthesis using these control methods is a unique skill, which may require dedicated training [25] or practice [26] to obtain, else patients may experience frustration or dissatisfaction with their prosthesis [27]. Other techniques for prosthetic control which are still in development include tracking the locations of magnets implanted in residual muscles to detect muscle contraction [28,29], and using wearable ultrasound sensors to measure muscle movement [30,31].

Innovations in prosthetic technology have also expanded in scope to consider not only the control of prosthetic limbs, but also the feedback that these prostheses provide to patients. Artificial sensory feedback is an area of rapid growth and interest over the past decade [32,33], in large part inspired by fundamental research in human motor control—after all, the bi-directional communication that occurs between our brains and our extremities is crucial for dexterous control of our bodies and is the key to learning new skills [34]. The same has been found for prosthetic skill learning—artificial sensory feedback via vibrotactile motors has been shown to improve postural stability [35] and gait symmetry [36] in individuals with lower limb amputation. However, sensory feedback is not guaranteed to improve the use of prosthetic limbs—while such feedback may help users control hand grasping at low levels of force [37], the incidental feedback from vision and the vibration of the prosthetic motors is sufficient for routine daily grasping [38]. Indeed, an argument exists for allowing patients to customize the feedback that is most useful or desirable for them—for example, feedback about prosthesis position [39] or speed [40], or object contact [41] or slip [42], instead of just grasping force. Furthermore, the same advances in implantable electrodes that can facilitate prosthetic control can enable new pathways for sensory feedback via direct neural stimulation [43]. An advantage of this neural stimulation is the possibility of eliciting naturalistic sensations by varying the stimulation patterns to create different sensations [44–47]. This approach has been applied to improve walking speed and confidence and reduce phantom pain and fatigue in patients with transfemoral amputation [48]. However, some questions remain regarding the long-term viability and safety of direct nerve stimulation. For example, spiral cuff electrodes which wrap around the nerve have demonstrated long-term stability of several years [49], however their design limits the ability to selectively stimulate individual axons to generate targeted sensations [50]. On the other hand, the Utah Slanted Electrode Array (USEA) has been used to both control a virtual prosthetic arm and restore cutaneous sensations on the phantom limb [51], but because its leads penetrate into the nerve, it typically only has a usable lifespan of a few years [52]. Regardless of the electrodes used, care must be taken to prevent damage to the nerve and maximize long-term safety [53].

Beyond potential improvements in prosthetic use and performance, technological innovations in bionics are driving new research into the core experiences of patients who feel that their artificial limb is a part of them—the sense of *embodiment*. According to modern frameworks, a person can embody a prosthetic arm or leg if three conditions are met: (1) they believe that have *ownership* over the prosthesis, that it belongs to them; (2) they envision the prosthesis when they picture themselves, that it is part of their *body image*; and (3) they have *agency* over the prosthesis and how it moves, and it reacts in a way that is predictable [54]. Prosthetic embodiment is a crucial psychological factor associated with a patient's satisfaction with their prosthesis [55]. This is not to say that prosthetic limbs are perceived as indistinguishable from biological limbs; on the contrary, for patients who use their prostheses regularly, their brains represent their prostheses differently than both biological limbs and artificial tools [56]. As a result, even body-powered prostheses can be embodied by their users [57]. This highlights the importance of the bespoke and personalized nature of amputee care—that prosthetic prescription should be guided not just by function, but by form, and that a patient-centered approach is needed to ensure that patients have the best possible experience with their prosthesis such that it becomes a part of them. We further note that, despite these significant advances, even those with the most sophisticated prosthetic limbs may still encounter daily challenges and barriers requiring further technological development [58,59].

4. Advances in Amputation Surgery

After decades of stagnancy and lack of substantive innovation with regard to the general principles of amputation surgery, the last 10–20 years have seen profound advances in what is possible and should be considered at the time of, or shortly after, major limb loss. First, modern osseointegration (OI) for amputations—the direct, transcutaneous skeletal attachment of a prosthesis to bone—has existed for over thirty years [60]. However, OI has become more commonplace and an accepted treatment modality in the United States only in the last few years with the Food and Drug Administration’s approval of the OPRA device for patients with transfemoral amputations (Figure 2). A variety of custom use and investigational implants are being utilized in some patients for other amputation levels as well. In addition to the obviation of socket- and suspension-related complications [61] and the ease of donning and doffing a terminal device [62], compelling evidence of improved function, gait or dexterity, and improved quality of life now exists [63]. While OI is not a panacea and superficial infection remains a common but manageable part of the natural history of a transcutaneous OI device, major complications such as fracture, deep infection and implant removal have generally occurred at reasonably low, if not yet optimal, rates [64]. Substantial ongoing research efforts are being directed towards skin-implant interface modification (e.g., to make the transcutaneous abutment into the biologic equivalent of an antler versus the current state of a chronic controlled minor wound) as well as several novel means of infection monitoring, prevention and treatment. The rapid growth of OI in amputation care may also represent a paradigm shift in prosthetic education, where the guidelines for prosthetic prescription for socket prostheses may not align with the recommendations for OI prostheses [65], requiring dedicated or specialized training.

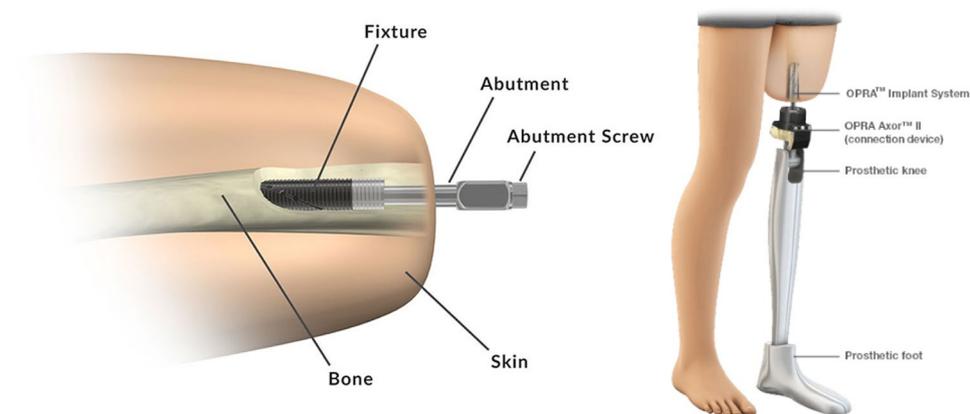


Figure 2. Osseointegration. Courtesy of Integrum AB.

Major extremity amputation surgery requires the obligatory transection of major motor and sensory nerves. The management of these nerves has made giant strides in the last 20 years. Targeted muscle reinnervation (TMR) utilizes the functionally expendable muscle groups that follow limb loss as reinnervation targets for these transected nerves. After TMR, the muscles reinnervated by the transected nerve produce EMG signals and become myosites for a myoelectric prosthesis with improved intuitive control [66,67]. This may be achieved via direct control (one muscle, one function) or further harnessing the AI algorithms discussed in Section 3 for additional degrees of freedom (e.g., grip patterns, wrist rotation) utilizing commercially available pattern recognition systems [68]. While TMR remains predominantly a consideration for patients with upper extremity loss [69], the technique lends itself to easy, immediate adoption once lower extremity prostheses with integrated myoelectric sensors become more commonplace [70]. As TMR has become more broadly utilized, pain relief in the form of both decreased residual limb (e.g., neuroma) and

phantom limb pain has been noted as a fortuitous side effect [71,72]. We believe that this is due to TMR most closely approximating primary nerve repair of any described nerve intervention following limb loss; by giving the nerve an environment for this process, we can provide not just an efferent (muscle) target, but also afferent (sensory) feedback to the brain.

Another side effect of TMR is the restoration of cutaneous sensation mapped to the phantom limb. This finding has led to the development of a related surgical procedure, Targeted Sensory Reinnervation (TSR), wherein nerves are redirected to innervate the skin rather than the muscles [73]. This sensory reinnervation allows for tactile sensations to be felt on the phantom limb but is unable to provide a sense of proprioception. Instead, the creation of an agonist-antagonist myoneural interface (AMI) has been shown to bridge this gap. The AMI is a surgical construct comprising a pair of surgically connected muscle tendons, arranged such that the contraction of one agonist muscle stretches the other antagonist muscle, activating the mechanoreceptors within the muscle and providing a sense of proprioception [74].

A related and, in some views, “competing” technique to TMR is called the regenerative peripheral nerve interface (RPNI). Like TMR, this surgical technique matches amputated peripheral nerves with denervated muscle grafts. Unlike TMR, the targets used in RPNIs are much smaller; devascularized muscle grafts are taken from either the amputated limb or from elsewhere in the body, then transposed to the residual limb. Axonal regeneration, reinnervation, and revascularization then occurs over time [75]. While an RPNI does not include a motor nerve conduit, it is a technically simpler procedure and can be performed virtually anywhere in the body independent of the availability of full recipient nerve/muscle dyads.

These surgical innovations synergize strongly with the technological innovations described in Section 3 and have been combined in numerous configurations. TMR and RPNIs with implantable electrodes have been used to decode individual finger movements in patients with transradial [76] and transhumeral amputation [77]. TSR has been used with sensory feedback systems to reduce phantom limb pain and improve proprioception for patients with lower limb amputation [78]. Osseointegrated implants have been combined with implantable electrodes to create prosthetic limbs that “plug in” directly to the nervous system of patients with transhumeral [77] and transradial amputations [59], as well as patients with AMIs [79]. These emerging technologies move surgeons, rehabilitation physicians, therapists, and prosthetists closer to the goal of creating highly functional prostheses with higher satisfaction and increased utilization among users. Collaboration between medical teams will be required to keep pace with patients who require these highly functional prostheses.

The above current and developing advances hold great promise for decreasing chronic pain and improving function and quality of life for patients with limb loss, although some limitations and barriers still persist [80–82]. When combined, these techniques and technologies may serve as a bridge towards not just a continuation of the paradigm shift from the unfortunately pervasive view of amputation as a simple ablative procedure to one of functional limb reconstruction but also moving towards truly “bionic” reconstructions. It remains true and worth noting, however, that the best bridge to a good, advanced amputation surgery is a good basic amputation; while plans for OI may obviate some residual limb soft tissue concerns or requirements, most of the above advances will not rescue a poorly executed primary procedure.

5. Limb Care Systems and Limb Loss Rehabilitation Continuum

Events leading up to and following limb loss across a person's lifespan can be conceptualized as that individual's journey with limb loss (Figure 3). While this journey can differ based upon a variety of factors such as the level and cause of limb loss (Figure 1), the individual's pre-amputation health status and sociodemographics, the common thread leading to best outcome is access to limb care continuum programs. Such programs optimize this journey by facilitating timely access to medical, surgical, and rehabilitation care, prosthetic devices, durable medical equipment, and integrated community resources. Healthcare institutions, organizations, and health systems can create such programs through partnerships between limb loss rehabilitation programs, limb preservation programs, mental health and primary care [83]. However, there is a lack of uniform care provision for limb loss and limb preservation care across the United States and worldwide, be it in regard to prosthetic prescription [84], inpatient rehabilitation [85], or utilization of a team-based approach [86].

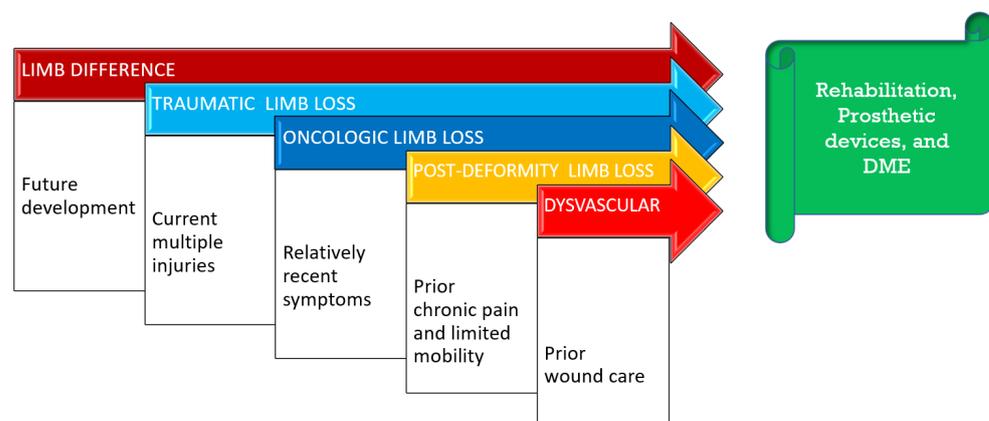


Figure 3. Patient Journeys with Limb Loss. DME: durable medical equipment. Reproduced with permission from [87].

While inequity leading up to limb loss related to factors such as race [88], rurality [89], income, and insurance [90] is well recognized, little was known about inequity following limb loss until recently. The recent Government Accountability Report provides clarity on the inherent inequity, which is quite stark (see Section 8) [91]. From the Medicare population in the 2016–2019 period, over 50,000 people lost limbs, with 61% people dying within 4 years, a 3× mortality rate compared with other Medicare beneficiaries. Only 30% of people received a prosthetic device, with inequitable receipt. Time to prosthetic device delivery exceeded 10 months, potentially exacerbating the impact of physical inactivity. This statistics is even more concerning in light of the fact that there exist Limb loss rehabilitation continuum programs that can help to complete the entire journey from limb loss to rehabilitation with a prosthetic device in about 5 months, [87] if the prosthetic device were received in a timely fashion in about 2–3 months post-surgery. Out of pocket expenditures for a prosthetic device exceeded \$3500 USD, which can be unaffordable by many people. A 2024 study found that upwards of 12% of Veterans and 42% of non-Veterans have paid such out of pocket costs for upper-limb prostheses, and nearly 30% used two or more funding sources to pay for their prosthesis. Up to 25% of individuals who never used a prosthesis or abandoned their prosthesis cited an inability to afford the prosthesis or its repairs as the reason [92].

From an implementation perspective, just as the field of limb preservation is focused on developing and implementing limb preservation programs [93], there needs to be a stronger focus on developing limb loss rehabilitation programs for post-limb loss care. Even

if institutions and organizations have the will to develop such programs, what makes this implementation challenge so difficult, first and foremost, is the limited explicit recognition of the complex multiphasic, multistep, multidisciplinary, and multifactorial nature of the patient journey through the healthcare system [87].

Comprehensively characterizing this patient journey through the healthcare system can be used to guide design and implementation of effective, efficient, and equitable programs and systems of limb care that span multiple care settings, effectively creating a limb loss rehabilitation continuum (LRC) program [87]. This section delves into an overview of a living model that can be used for LRC program development, stakeholders in limb care, and examples of responsive implementation strategies to address existing challenges.

5.1. The Patient Experience: Care Delivery Model of the Patient Journey with Limb Loss

Understanding patient experience and how it changes with major events in the journey is vital for designing patient-centric systems that facilitate patient enablement and shared decision making. Building upon previous work on lower limb loss rehabilitation continuum (LLRC) implementation frameworks [87], and Multilevel Limb-loss and Prevention Rehabilitation Continuum (MLPRC) models, Figure 4 presents an overview of how an individual’s journey with limb loss through the health system can be modeled to ensure inclusion of patient, caregiver, provider, and organization perspectives for program design. The first constructs presented are phases of patient experience (limb preservation, pre-prosthetic, prosthetic, and post-prosthetic), using limb status and prosthetic devices as two cornerstones, phases of patient experience, separated by major events (milestones). This represents the person with limb loss and their caregiver’s experience. The phases of patient experience likely differ based upon the patient journey. As an example, the milestone of shared decision for amputation surgery separates the limb preservation and pre-prosthetic phases. The shared decision making would look different for a person who has chronic wounds versus somebody who lost their limb in a motor vehicle accident.

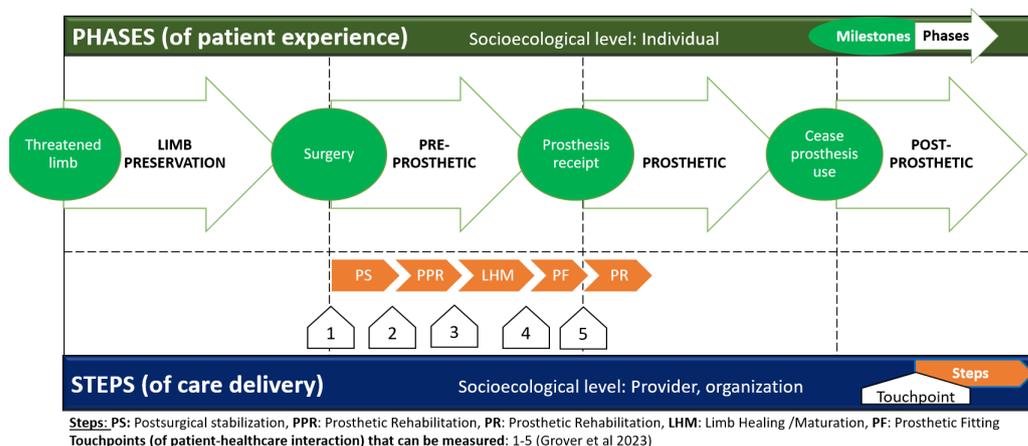


Figure 4. Limb Care Continuum Structure. PS: Postsurgical stabilization, PPR: Pre-Prosthetic Rehabilitation, PR: Prosthetic Rehabilitation, LHM: Limb healing /Maturation, PF: Prosthetic Fitting. Touchpoints (of patient-healthcare interaction) 1–5 can be measured. Reproduced with permission from [87].

The second construct presented is steps of care delivery occurring within a phase defined using measurable dates of patient-health system interaction (touchpoints). As an example, the initial episode of care within the health system following limb loss includes the steps such as Postsurgical Stabilization (PS), Pre-prosthetic Rehabilitation (PR), Limb Healing and Maturation (LHM), and prosthetic fitting (PF) within the Pre-prosthetic phase, and prosthetic rehabilitation (PR) within the Prosthetic phase [87]. The LHM and PF steps

are separated by the touchpoint of Functioning Evaluation and Prescription in the Physical Medicine & Rehabilitation (PM&R) clinic, and the PF step within the preprosthetic phase and PR step with the Prosthetic phase are separated by the prosthetic device delivery touchpoint [87]. These steps and touchpoints may differ based upon the healthcare organization characteristics.

5.2. Stakeholders in Limb Care

Recognition of the multidisciplinary nature of this journey is vital for minimizing discipline-limited and step-limited siloed action and maximizing interdisciplinary care coordination across the steps of the limb care continuum. Major stakeholders include but are not limited to: patients and their caregivers; medical care providers such as primary care physicians, surgeons, and physiatrists; clinical care providers such as rehabilitation nurses, occupational therapists, physical therapists, orthotists, and prosthetists; non-clinical care providers such as case managers and admissions liaisons; and community team members such as peer mentors and patient advocates (Figure 5).

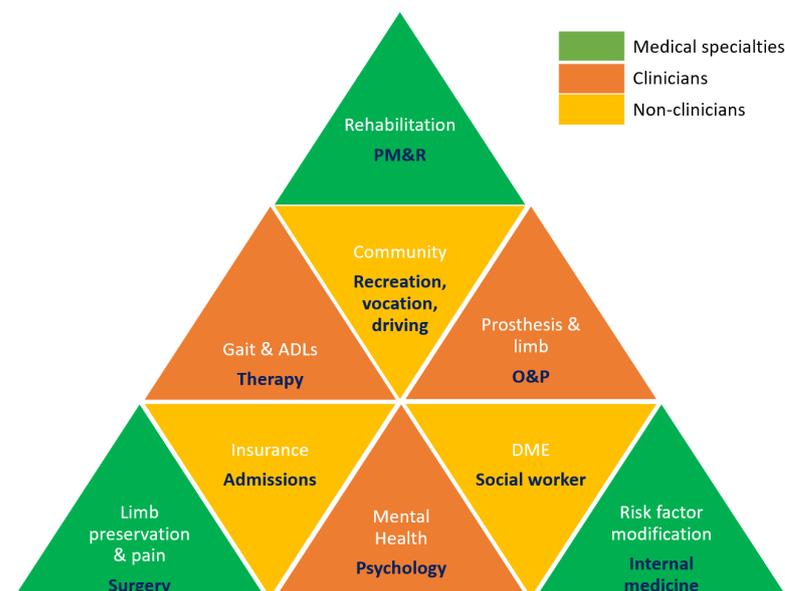


Figure 5. Stakeholders in Limb Care. The pyramidal structure represents multidisciplinary interaction within a team-based care model, where all disciplines are equally important for providing optimal care for the limb loss and difference community. Reproduced with permission from [87].

Many of these team members are involved in multiple steps. Coordinating personnel such as patient navigators and navigation apps, and communication platforms such as unified electronic medical record systems, can help to optimize the patient journey timeliness, maximize resource utilization, and minimize cost.

5.3. Understanding Contextual Factors for Limb Care Continuum Program Development

Using the socio-ecological levels framework (Figure 6), hierarchical factors pertinent to limb care can be systematically analyzed to define targeted multimodal interventions and responsive implementation strategies. For limb loss and preservation, these hierarchical levels include persons with limb loss and their caregivers at the center, surrounded sequentially by care team, healthcare delivery organizations (e.g., hospitals, inpatient rehabilitation, skilled nursing facilities, clinics), community advocacy patient (e.g., Amputee Coalition) and professional organizations (e.g., American Congress of Rehabilitation Medicine Limb Care Networking Group, International Society of Prosthetics and Orthotics, National Association for the Advancement of Orthotics and Prosthetics), national specialty

networks (e.g., Veterans Health Affairs Amputation Systems of Care) and national health systems (e.g., US mixed model vs. Canadian socialized medicine).

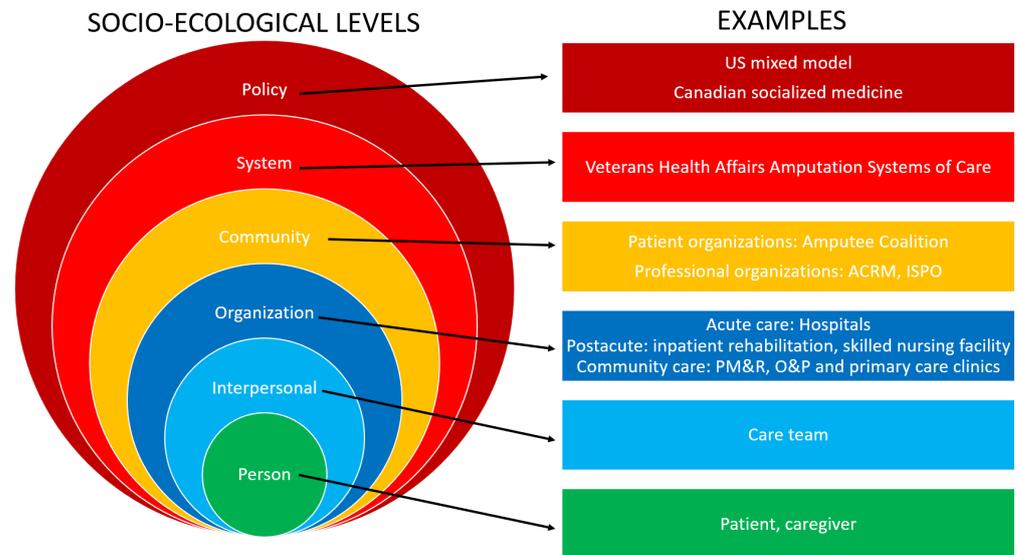


Figure 6. Socioecological Level-based Implementation Strategies. ACRM: American Congress of Rehabilitation Medicine; ISPO: International Society for Prosthetics and Orthotics; PM&R: physical medicine & rehabilitation; O&P: orthotics & prosthetics. Reproduced with permission from [87].

Healthcare organizations typically monitor and intervene directly at the first three levels that lie within their sphere of influence (patient, provider, and organization levels) for compliance, reimbursement, and market differentiation purposes. These data can be harnessed to understand baseline factors, develop new, and refine existing limb care programs. Going one step beyond, healthcare organizations can, and should, partner with community organizations and with the government on educational, research, and policy items to positively influence limb care provision and outcomes not only for patients they serve, but the community at large.

5.4. Summarizing Steps to Effective, Efficient, and Equitable System Design for Limb Care Continuum Programs

In summary, the concepts of phases of patient experience and steps of care delivery have been combined to design and develop an effective limb loss and preservation continuum structure. Collaboration and interprofessional education across all disciplines and stakeholders should be used to establish efficient care processes for patient navigation and shared decision making. Organizations should utilize the socioecological level-based frameworks such as LRC to analyze their context-specific factors by an organization specific to their context can be used to comprehensively optimize their limb care continuum for care equity and continuous quality improvement. They should then foster partnerships with their community-based and national patient advocacy and professional organizations to impact care through synergistic education, research, and policy mechanisms.

6. Insurance Coverage and Reimbursement Challenges

As innovations in orthotic and prosthetic (O&P) design have accelerated over the past several decades, so have the challenges for provisions of these services in healthcare systems across the globe. Countries with national healthcare insurance systems must assess the overall cost and benefits to their system in addition to benefits to the individual consumer. Consumers in countries without adequate insurance coverage face significant financial barriers to these innovations. Increased health-economic research and analysis would

help inform health systems internationally through the development of more value-based decision matrices and coverage guidance [94].

Internationally, payment systems and coverage guidelines vary significantly but frequently use a single-payer model or a heavily regulated mixed-payer model with set provider prices and limited competition across insurers [95]. Even in countries with national coverage systems, regional discrepancies and options available to patients can differ significantly. In Canada, provincial independence creates discrepancies in prosthetic coverage across the country [94].

Advanced prosthetic technologies, in principle, are covered in Germany through statutory provisions that expand healthcare access for persons living with disabilities; however, some European nations with similar healthcare statutes do not extend coverage to advanced technology, e.g., Poland does not currently cover microprocessor-controlled prosthetic technology under its public healthcare system [94].

Asia-Pacific countries approach prosthetic coverage assessments as separate sectors from other healthcare provision. While Japan's national healthcare system covers prosthetic care, coverage of advanced technology is determined at the local prefecture and municipal levels, which can lead to significant regional discrepancies [94].

The US healthcare system, by contrast, includes upwards of 1100 health insurance companies [96] and payers with differing incentives, including employer provided insurance, private insurance, Medicare (ages 65 and older and those who cannot work due to disability), Medicaid (low income), active service military, Veterans care, and the uninsured, with different rates of prosthetic coverage across each [92]. Although the U.S. healthcare system publicly accepts modern orthoses and prostheses as the standard of care and nearly all public and private payers claim to cover comprehensive O&P care, consumers commonly face overly restrictive definitions of medical necessity or denials of care in a complex insurance process that effectively re-strict access to appropriate prosthetic care. Coverage of more advanced technologies, including microprocessor components, powered O&P components, and emerging techniques (Sections 3 and 4) such as osseointegration (OI) are often restricted due to insurance company claims that these technologies are investigational, experimental, or that the evidence base does not support coverage. Many suspect these restrictions are motivated more by a desire for insurance companies' profit than a lack of a sufficient evidence base.

There are three key elements of O&P reimbursement in the US: coverage, coding, and payment. A deficiency in any one of these components can seriously limit patient access to O&P care. Deeming an O&P technology investigational or experimental is but one way payers can restrict coverage. Additionally, patient access can be curtailed if the new technology is inappropriately assigned to an existing code with insufficient reimbursement or if the new technology is improperly coded as durable medical equipment (which is referred to as a benefit category determination). Finally, if a payment level is inadequate for O&P practitioners to purchase the technology from a manufacturer and cover the clinical costs of care while making some margin on that service, patient access may suffer. All three—coverage, coding, and payment—must be aligned and appropriate for providers to make ends meet and for individuals with limb loss and limb difference to have their O&P care needs met.

Medicare and the Veterans Health Administration cover O&P care, including many of the advanced technologies. There are exceptions and coverage exclusions, but patients in these programs generally have sufficient access to quality O&P clinical care. For Medicaid, prosthetic devices are considered "optional" under federal law and coverage varies state by state with typically lower payment rates for O&P providers. The Patient Protection and Affordable Care Act similarly covers O&P care under the broad category of "rehabilitation

and habilitation services and devices” as part of the Essential Health Benefits (EHB) package, but the level of coverage is defined to be equivalent to the most common commercial health plans as provided in individual states and varies widely across states. From 2000 to 2010, 21 states adopted so-called “insurance fairness” laws which established mandatory insurance coverage of O&P care. Recently, these laws have begun to be extended to mandate coverage of activity-specific and recreational prostheses and, in some states, orthoses. However, over 60% of employed Americans have insurance provided by self-funded large employer (ERISA) plans, which are exempt from state insurance regulation [97].

7. Ethical Considerations of Advanced Treatment Modalities

Technological and surgical innovations promise a number of impressive functional and biomechanical advantages for the prosthetic user. Just as with many innovations, though, these give rise to an equal number of ethical and legal concerns. Many countries have stringent regulations regarding the usage of implanted devices that evaluate safety, validate procedures with long term studies, and seem to reduce the risks of their use, but a number of ethical considerations remain [98], including the underrepresentation of minoritized individuals in rehabilitation clinical trials investigating this technology [99]. Especially for these novel technologies, the “Amputee Bill of Rights” (Table 1) serves as a common resource for both patients and healthcare providers, and can still provide the foundation for the ethical use and treatment of all patients with limb loss and limb difference [100].

Table 1. Amputee Bill of Rights, as proposed by Amputee Coalition of America [100].

You Have the Right to:
Receive clear, complete information about your surgery, medical care and therapy.
Take part in decisions affecting your health and well-being.
Be involved in developing your plan of care.
Set goals for what you want to achieve.
Set goals for your physical and emotional well-being.
Set goals for preventing other health conditions that may result from your amputation.
Receive support from a certified peer visitor.
Be informed about funding for healthcare.
Be informed about returning to work and opportunities for recreation.
Be informed about prosthetic services, healthcare products and new technology.
Select qualified healthcare providers.
Ask for help when you are unhappy with healthcare products or the care you receive.
You Have the Responsibility to:
Stay informed about healthcare products and services.
Learn about products and services that are appropriate, safe and effective for you.
Express concerns about quality of care, billing practices, and products or services.

7.1. Informed Decision Making and Plan of Care

Patients should be clearly informed of not only the promises and advantages of these novel treatments, but also the inherent risks, challenges, and side effects. The patient and their family must be consulted regarding candidacy as well as the outcomes evidence that may show rejection rates and various negative factors that may arise. Just as with the numerous disclaimers from pharmaceutical ads, patients should be aware of the possibility of unintended side-effects that may be present well after implementation. The providers

of these emerging technologies must remain transparent and should have stated levels of consent that allow the prospective candidate to psychologically evaluate each step to make an informed decision, in accordance with the Declaration of Helsinki [101] and all relevant local ethical regulations.

7.2. Setting Personal, Physical, and Emotional Goals

Every provider should maintain a well-established evaluation process for setting personal, physical, and emotional goals, similar to those that follow knee or hip replacement implants. In this way, the patient can take an active role in monitoring their rehabilitation from an advanced procedure. Usually these are established during the FDA vetting process, but there is a responsibility of the provider and manufacturer to outline this process for the patient as well as documenting patient acknowledgement.

7.3. Receiving Support, Funding, and Follow-Up Care

The value of rehabilitation varies across countries and cultures, however access to state-of-the-art medical care for acceptable candidates should be universal. Surgical and technological advancements should not be restricted based on the relative costs to the patient. The patient should be able to pursue the support and funding if they are considered a suitable match in terms of qualifying factors. To withhold these procedures from a patient who is willing to undergo the process should be considered unethical in the same manner as denying a transplanted organ or cochlear implant. Human mobility is a critical component of social and cognitive integration. Knee and hip implants were initially considered to be unsustainable financial burdens in the healthcare market, so the relative costs had to be reduced in the form of cost containment measures and procedural changes [102]. Eventually, providers will need to work with manufacturers to allow access for qualifying patients. Third-party payers and medical insurance providers need to consider how the increasing demand for advanced prosthetic care can be met.

7.4. Sharing of Information Between Healthcare Providers

Another concern in need of addressing is the sharing and standardization of componentry dimensions with prosthetists and other healthcare providers. If the various dimensions are withheld under proprietary information of a device or implant, the prosthetist will not be able to make adaptations for componentry with proper adapters. This would greatly limit what the prosthetist can provide to the patient. All adaptations will need to be carefully vetted because liability is shared for the performance of the device. If patients transfer care between physicians or prosthetists, they will need access to fitting geometries so they may have full access to appropriate prosthetic componentry. Withholding this information unduly would bind a patient to a particular set of components. Future innovations also depend on this sharing of information for the prosthetic componentry that will be used. Providers must also consider the risks that may require removal or recalls. Even though these would be avoided at all costs, there should be contingencies in place if this is mandated [98].

Observing the “Amputee Bill of Rights” can help ensure that all parties are acting ethically and transparently [100]. As technology continues to evolve, we can anticipate future ethical needs arising that can be approached using these same guidelines.

8. Health Equity Considerations

Emerging technology in healthcare is rarely accessible by everyone in need of it without significant institutional intervention [103]. The lack of access to emerging technology is just one factor contributing to disparities within the limb loss and limb difference population.

Health inequities are systematic differences in the distribution of health resources and opportunities that groups can access to achieve optimal health. These differences lead to disparities in health outcomes for disadvantaged groups [104]. Structural inequities are the systemic drivers that contribute to barriers to the fair distribution of health opportunities and outcomes [105].

Health disparities among Americans who identify as Black or Latino and have experienced amputations are well documented. Studies show Black Americans are four times more likely to undergo amputation than White Americans and are twice as likely than White Americans to receive an amputation resulting from complications due to diabetes [106,107]. Americans who identify as Latino are 30% more likely to experience an amputation preceded by a diabetic foot ulcer [108].

Systemic barriers such as ableism, racism, sexism, and classism, contribute to the structural inequities acknowledged by the authors of this article, including but not limited to lack of equitable access to healthcare coverage, inadequate healthcare coverage policies, lack of institutional support systems, and lack of patient-centered research design. These and other such challenges, including geographic isolation from prosthetic care centers [109], may also factor, to different extents, into access and barriers to prosthetic care in other countries [110].

The care continuum for individuals who have experienced limb loss and those born with limb differences involves a complex and often disparate network of providers with a common goal of restoring lost or diminished function for increased quality of life. Innovative and/or novel approaches to amputation care create additional complexities in this care continuum due to the lack of coordination between systems at the community, provider, and payor levels.

In response to a request from Congress, the Government Accountability Office (GAO) published a report in 2024 looking at existing barriers to access of assistive technologies and prostheses for patients living with limb loss and limb difference [91]. Notable findings from this report include a 61% four-year mortality rate for Medicare beneficiaries who acquired an amputation in 2016, compared to 20% across all beneficiaries, and that 71% of beneficiaries with limb loss had diabetes compared to 24% of all beneficiaries. Furthermore, 31% of beneficiaries with lower limb loss received a prosthetic limb, but only 4% of beneficiaries with upper limb loss received the same. The report also identified that Black Americans are disproportionately impacted by amputation (21% of beneficiaries with limb loss, compared to 8% across all beneficiaries), and rates of limb loss were disproportionately high in the American South and in rural areas, indicating gaps in care.

Much of the currently published prevalence data result from studies using methodologies that incorporate retrospective claims analysis. One of the primary limitations of these data sources is the absence of data representing those who are uninsured, further contributing to the lack of understanding of the impacts that limb loss or limb difference have on the most vulnerable populations. Data sources like the Limb Loss and Prevention Registry (LLPR) collect longitudinal data on all patients within a healthcare system, regardless of coverage status, and could contribute to a more holistic understanding of patients' experiences from pre-amputation through post-prosthetic delivery follow up care. Furthermore, combining these data with data from national registries in other countries (such as the Swedish *SwedeAmp* [111] and the German *Amputationsregister Deutschland* [112]) may further enhance this holistic understanding of patient outcomes.

There also exists an opportunity to impact the downstream effects of structural inequities as early as the ideation phase in healthcare innovation. Utilizing multidimensional models to identify health inequities, such as the National Institute on Minority Health and

Health Disparities Research Framework, can contribute to more equitable access to health-care innovations when implemented early in the research and development process [113].

9. Summary

Due to increasing numbers of vascular and metabolic disease, continuous military conflicts, and failing former limb-salvaging reconstructions, amputation is an increasingly common surgical intervention in hospital operating rooms worldwide. Post-operative limb loss care is undergoing a transformative shift to meet these demands, centered on the diverse needs of patients with respect to their mobility, independence, and quality of life. Modern innovations in prosthetic technology and surgical techniques are providing new tools which with to offer more opportunities to people living with limb loss. However, the question of who has access to these technologies, how prosthetic care can be equitable and affordable, and how patients can be supported throughout their journey must be considered. Providing successful amputation medicine is therefore only possible in both a highly specialized and multidisciplinary setting with an awareness of relationships between the patient, surgeons, orthopedic technicians, ergo-physio- and pain therapists as well as psychologists. Rehabilitation starts with a multiprofessional team in the planning of the surgery and the prosthetic fitting: informed patient consent, involving peers, appropriate postoperative care with early shaping of the residual limb, evaluation using computer-assisted gait analysis for the selection of the appropriate prosthesis, and adaption of the rehabilitation training to the needs of the individual. Inclusive and equitable patient-centered programs are required to ensure that everyone with amputation can benefit from the future of limb care.

Author Contributions: This work is a result of the individual contributions provided by several authors. Conceptualization, J.C.; writing—original draft preparation, J.C., E.J.E., B.K.P., P.G., P.T., G.S. and A.W.; writing—review and editing, J.C., E.J.E., B.K.P., P.G. and A.W. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: Not applicable.

Acknowledgments: We wish to thank Natalie Harold for her contributions towards early drafts of this manuscript.

Conflicts of Interest: Author Gerald Stark was employed by the company BionIT Labs Inc., Brooklyn, NY 11201, USA. No products from BionIT Labs Inc. are discussed in the manuscript, no other representatives from the company reviewed the manuscript, and the author declares no other conflict of interest. The remaining authors declare that the manuscript was written in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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