Repairing the prosthetic science-policy rift: Challenges to improved access to and translation of prosthetic technologies

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Edited by M.S. Suryateja Jammalamadaka and Jennifer A. Cascino

HIGHLIGHTS

- We outline a brief history of the technology and state of medical care for individuals with limb loss throughout several eras of innovation in the United States
- We review current challenges to preventative and post-amputation prosthetic health access, as well as the racial and socioeconomic health disparities among individuals who experience limb loss
- We explore scientifically-inspired solutions to bridge the gap between current and emerging advanced technology and health coverage that can expand patient access to prosthetic devices and services.

Penicillin, artificial heart valves, blood banks, and cardiopulmonary bypass technology are all medical developments less than 100 years old. In the last century, the design of prosthetic limbs has emerged as a discipline that spans biomechanics, neural engineering, human physiology, and materials science, resulting in a transformation of technologies and services that rehabilitate mobility and restore lost function after limb loss. In the future, prosthetics will enhance and augment human abilities, making it possible for people to seamlessly move, create, play, and simply go about the daily business of living. In theory, that future is nearly upon us—yet a huge gap exists between the capabilities of these advanced technologies and what is actually accessible to patients who can most benefit from them.

Both healthcare to prevent amputations and the impact of prosthetic care to replace lost limbs are seriously limited by the inequities in health access and outcomes between communities. In the United States, a political and social bottleneck restricts the promise of technological healing for those who need it most: Disabled people are largely unable to access advanced technologies to restore lost limbs. Americans who are poorer, more marginalized, and less insured are more likely to experience dysvascular or preventable amputations and thus join the largest and least visible group of Americans with limb loss.

For millions affected by limb loss, policies that regulate the provision of prosthetic technologies dictate access and therefore mobility and function. Public perception of the prosthetic field and social pressure can encourage both technological development as well as movements to improve accessibility of prosthetic technologies as they have throughout American history. As the future of prosthetic sciences beckons, both medical advances and troubling health disparities warrant a review of current and emerging challenges to adoption and distribution of prosthetic technologies.

Section I: Eras of innovation in prosthetic sciences

Revisiting the history of the prosthetic field in the United States lays a foundation for understanding the current state of related technology, policy, and societal attitudes. This history can be divided into three periods.

Early American prostheses and care | 1700s - 1930s:

Before the American Civil War, prosthetics mainly consisted of simplistic peg legs or arm hook designs made of copper, iron, steel, and wood. The Civil War spurred a marked interest in advancing the field of prosthetics because about 70% of war-time injuries affected soldiers’ limbs [1]. Congress passed the first disability pension law in 1887, which stated that all Civil War wounded Union soldiers would receive pensions, a debt-free token of gratitude from the general public; the disabled soldier had performed their civic duty and deserved recompense. However, prosthetic technology of the time was rudimentary and exaggerated its benefits in terms of both comfort and functionality. One of the earliest American technological contributions to prosthetic technology, “Artificial Limb” [2, 3], was developed by Confederate soldier J.
E. Hanger, who was granted U.S. Patent No. 95198 in 1910. As a prosthetist and inventor, he later founded Hanger Clinic, a leading organization in the provision of prosthetic services and products to this day.

After World War I, Progressive Era reformers began a movement opposing this pension system on the basis that it was economically inefficient and politically corrupt [4]. Their growing “ethic of rehabilitation” held that an injured war veteran failed unless they worked hard to overcome disabilities and become as financially independent as possible. Thus, the government decided there was a financial incentive to build rehabilitation programs and institutions to “rebuild war cripples” for the benefit of society. This shift into a rehabilitation movement marked the merging of the Protestant work ethic with medical therapeutics. Post-war artificial limb production reached a level of standardization in the form of the E-Z leg, designed and created by the orthopedic surgeon who founded an artificial limb lab at Walter Reed Army Hospital [4]. The E-Z leg anatomically resembled a biological limb yet was highly simplistic technically, designed mainly with the intention to delegitimize extra government-sponsored aid and curb general sympathy and pity [4]. Realistically, the E-Z leg was inaccessible to the vast majority of lower limb amputees, who did not have residual limbs healthy enough for prosthetic limb wear [4]. The propagandized ideal of rehabilitation did not deliver actual amelioration of life conditions for amputees.

Post-War professionalization of prosthetic field | 1930s - 1980s: Two consecutive World Wars ignited a surge in the field of rehabilitation, prosthetics, and artificial limb design; as technological advances in weaponry and medicine raced against one another, a growing number of soldiers returned home disabled after losing limbs to trench foot, exploding artillery, and other wartime realities.

Public support for the Wars extended to a sociopolitical movement to honor veterans for their service. That created a demand for improved prosthetic and rehabilitative services. The Veterans Affairs (VA) was officially established as a department of the federal government to provide life-long healthcare services to war veterans. Amputee clinics staffed with surgeons, physical therapists, and prosthetists were established at military hospitals across the country [5]. The increased number of injured veterans also created an impetus to advance materials from which prosthetic devices were fabricated: for example, strong, light-weight materials were developed to replace the heavy wood and leather that were used to construct earlier artificial limbs [6]. The defense company Northrop Aviation was an early developer of thermoplastics in prosthetic fabrication, which prompted the trend towards lighter materials such as plastics and carbon fiber [6] that are still used today.

The social momentum also had an impact on the larger population of individuals with limb loss as the field of prosthetic sciences emerged and prosthetic services transitioned from artisan to scientific. Surgeons, scientists, and prosthetists concluded that little effort had been invested into the development of prosthetic technologies [6]. An influx of funding improved research programs at universities, industrial laboratories, and government programs. For example, the Artificial Limb Program, launched by the National Academy of Sciences and funded by the VA, enabled physicians and surgeons to offer design criteria for prosthetic limb components. Engineers then developed improved prototypes based on clinical input. Biomechanical research laboratories were established at universities and hospitals around the country to further progress surgical and prosthetic device research through the study of gait, biomechanics, and other relevant medical and engineering pursuits.

The technology boom | Late 1990’s - modern day: Following the professionalization and institutionalization of prosthetic sciences, the field experienced an explosion of technological progress that spanned from design to materials, control methods, and approaches to fabrication. Technological improvements gave rise to more natural movements, expanded abilities, and customizable designs; while the developments of this time period are numerous, here we note only a handful of examples.

Prosthetic design for lower limbs continued to advance and become increasingly specialized, from high-performance running blades to responsive legs and feet for varying terrain. The advent of this era was marked by the introduction of the Ottobock C-Leg in 1997 [7], which was the first computerized (microprocessor-controlled) prosthesis system to intelligently control and adapt to a user’s gait. Similar technologies were developed by academic and private entities with a focus on improving prosthetic control, mimicking natural human gait, and reducing strain on users. For instance, the BiOM foot-ankle, launched in 2014, presented a commercially-available device that emulates natural muscle function and gait using power assist and programmable stiffness modulation, resulting in lower metabolic energies, higher speed, better balance, and lower joint stresses throughout the musculoskeletal system [8]. Now, there are numerous bionic foot-ankle and bionic knee joints available for a variety of users and ability levels like Ossur’s Proprio bionic foot-ankle, Ottobock’s Genium X3 bionic knee, and the Raize bionic foot-ankle from Fillauer, to name a few [9].

In parallel, upper-limb prostheses were undergoing transformative development. Myoelectric upper limb prostheses, devices that utilized electrical activity of the muscles to control the arm prosthesis, were first invented in the 1940s by German scientist Reinhold Reiter, developed into clinical devices by Russian scientist Alexander Koblinski in 1960, and used widely by patients beginning in the 1980s [10,11]. However, myoelectric technologies were plagued with challenges to widespread adoption: the out-of-pocket cost to patients was steep, learning to use the devices was frustrating, and the devices required constant visual supervision, leading to high rates of prosthetic abandonment [12]. Responsively, notable advancements were made to improve the performance of upper-limb prostheses in terms of dexterity, control, and feedback during this era. One notable
example is the Defense Advanced Research Projects Agency (DARPA)-led Revolutionizing Prosthetics Program, launched in 2006 to develop a neurally-controlled artificial limb that mimics natural arm and hand motion [13]. This technology was drastically updated in 2016 through the Program’s LUKE arm, an advanced upper limb prosthesis that promised unprecedented, near-natural arm and hand motion.

Further, landmark neural interfacing technologies that enable patients to both control and feel a prosthetic limb have been invasive, requiring surgical implantation, which poses challenges to long-term clinical translation. Subsequently, researchers at the Johns Hopkins Applied Physics Laboratory are working on noninvasive brain-computer interfaces (BCI) to improve aspects such as resolution, portability, and cost. They are exploring optical techniques to record neural activity and methods for decoding motor intentions, the basis for a new era of computing [14].

Finally, 3D-design and printing technology has begun to shift prosthetic design and fabrication to algorithm-led methods optimized for comfort, functionality, and fit. Notable examples include LIM Innovations, a company that uses measurements from digital images of the amputee’s limb to create more comfortable, custom-molded sockets [15], and Limbitless Solutions, a team that distributes personalized and expressive myoelectric upper limb prosthesis through clinical trials [16,17].

Section II: Current challenges in access and translation

Despite many decades of development and progress, it is estimated that only 15% of persons with amputation in the U.S. have access to advanced prosthetic technology and its mobility-permitting and quality of life-enhancing effects [18]. Generally, people living with disabilities are more likely than non-disabled people to receive lower-quality care, experience chronic conditions and serious illness, live below the federal poverty line, and generally experience a lower quality of life [19]. For persons with amputation, prosthesis use is the biggest influence on quality of life and affects not just ambulation, but also physical and mental health, socialization, work, and self-image [5]. Utilization of prostheses requires the provision and maintenance of parts and appropriate therapeutic services following the amputation surgery and recurrently over a lifetime. Obtaining and maintaining prostheses is a lifelong obligation that is expensive in both time and money. Infrastructure and resources dedicated to offering prosthetic services are vastly insufficient even for today’s amputee population and will worsen with the increase in amputations anticipated throughout the coming decades. Finally, despite belonging to the largest etiological group of persons with limb loss, patients who lose their limbs due to dysvascular causes like diabetes are the least likely to utilize prosthetic limbs and the most likely to experience deteriorating overall health, increased financial burden, and lack of medical coverage.

Two major challenges exist in the field of prosthetic science today: caring for those who have experienced amputation, regardless of the cause of their limb loss, and preventing amputations from occurring whenever and wherever possible. While the majority of research and development is centered around the design of artificial limbs to benefit individuals already missing limbs, reducing the incidence of preventable amputations is a serious, fast-growing, and deadly problem in the U.S. In the prevention space, there is significant inequity that leaves certain individuals and communities more vulnerable to experiencing limb loss and complications. In the realm of post-amputation prosthetic services, the same social inequity gradient translates to disparities in quality of life, mobility, and health outcomes. This section will analyze the state of amputation prevention and treatment in the U.S. and illustrate various disparities in this field.

Race and disparities in limb loss and outcomes: On average, Black Americans develop chronic diseases a decade earlier than their White counterparts and are twice as likely to die from diabetes [20]. According to the National Inpatient Sample hospital database, while fewer than one in five patients admitted for limb ischemia treatment is Black, every one in four patients undergoing amputation is Black [21]. Thus, Black Americans are under-represented in treatments that would prevent or delay preventable limb loss and over-represented in amputation surgeries. Medicare data [21] demonstrates that Black patients not only had lower rates of revascularization, but had a longer time between the onset of symptoms and their first revascularization treatment and overall a shorter time to amputation [21]. These disparities remained statistically significant even when controlling for factors like age, gender, and comorbidities [21,22]. Moreover, non-diabetic amputations (such as those caused by trauma, congenital conditions, and cancer) have an even higher level of disparity between racial groups [23,24]. Marginalized groups undergo debilitating, higher-level amputations more often than White patients [21]. Black patients are four times more likely to undergo an amputation than non-Black people in the U.S. [21]. Notably, Black women are 7.6 times more likely to receive an amputation than other women [23].

In some areas, the disparities between communities are even more pronounced and are shown to persist for decades: a study analyzing hospital discharge data spanning 18 years in Northern Illinois showed that areas with large Black populations (>50% African-American population per ZIP code) had amputation rates over five times higher than areas with primarily White populations, and that while amputation rates in White ZIP codes were increasing over time (50% increase, from 2 to 3 per 100,000 from 1987 to 2004), the rate of amputations in majority Black ZIP codes rose sharply (a 157% increase, from 7 to 18 per 100,000 from 1987 to 2004) [25]. While the disparity is most pronounced in Black communities, there is evidence that other marginalized communities are also affected to varying extents; for example, Latinx patients are one and a half times more likely and Native Americans are twice as likely to experience amputations than their non-Hispanic White counterparts [26,27].
Another clear example is observed in a study by Fanaroff et al. that analyzed Medicare data across metropolitan ZIP codes between 2010 and 2018. Higher amputation rates were observed in ZIP codes with a majority of Black residents than in ZIP codes with a minority of Black residents, and 76% of majority-Black ZIP codes had top quartile amputation rates [28]. Figure 1 provides a selected example of their conclusion: ZIP code-level maps of amputations per 100,000 Medicare beneficiaries in Philadelphia, Dade (Miami), Wayne (Detroit), and Fulton (Atlanta) counties with parallel maps indicating ZIP codes with greater than or equal to 50% Black inhabitants. As shown in Figure 1, majority-Black ZIP codes colocalize with high amputation rate ZIP codes.

**Socioeconomic status and disparities in limb loss and outcomes:** Poverty is a significant risk factor in amputation rates [26,29]. Those living below the poverty line tend to have less formal education, limited health literacy, inadequate housing, and lack of transportation, as well as inadequate access to high quality and well-coordinated primary and specialty care [29]. Amputees with a household income close to the poverty line are two to three and a half times more likely to observe barriers to joining the workforce and engaging in community life compared to wealthier individuals [29]. One study mapped diabetic amputations across California and found that the lowest-income neighborhoods had amputation rates 10x higher than the richest [24]. Another study found a statistically significant decrease in the odds ratios for amputation as household income increased from one quartile to the next (Figure 2) across all insurance types (and for those who are uninsured); lower socioeconomic status was strongly associated with reduced attempts at revascularization and increased likelihood of amputation [29]. Finally, these disparities do not end in the operating room; a major multi-center study determined that following the amputation procedure, factors like poverty, insufficient insurance, and racial identity were the strongest predictors of worse health status [26].

**Dysvascular conditions and disparities in limb loss and outcomes:** In the United States, as the prevalence of diabetes grows, so does the rate of untreated and undertreated diabetes. This leads patients to a heightened risk of developing one or more of the three pathologies that lead to diabetic amputations: peripheral arterial disease (PAD), peripheral neuropathy (PN), and infection. This triad is the harbinger of the final pathological events: gangrene and amputation. The rate of amputations grew by over 50% between 2009 and 2015 alone, and the majority of cases in the U.S. are now due to dysvascular diseases like diabetes [30]. In 2005, a study using a multistate probabilistic model projected that the population of people with amputation in America would more than double from 2005 to 2050, largely due to dysvascular diseases like diabetes [27]. Further, more than 85% of diabetic amputations were preceded by a foot ulcer—indicating that there are identifiable clinical opportunities to intervene preventatively.

Diabetic amputations are the most preventable surgery in the United States, according to the Agency for Health Research and Quality. These surgical procedures are used...
Increasing odds ratio for undergoing an amputation


Figure 2: Odds ratio for undergoing an amputation. Likelihood of undergoing amputation based on insurance status and median household income (MHI) quartile. Reproduced from "The effect of income and insurance on the likelihood of major leg amputation" by Hughes et al. (2019) [29].

as a performance indicator for primary and preventative healthcare [31]—higher incident amputation rates signify that communities are struggling to obtain proper diabetic medical care that would prevent their occurrence. However, diabetic mismanagement leading to amputations is not equally spread throughout the United States. Studies show that certain low-income neighborhoods have 10x higher amputation rates compared to their high-income counterparts [24].

The health disparity between diabetic patients who can successfully manage their condition and those who experience serious complications is only exacerbated after the amputation event; newly amputated patients exit the hospital with an additional chronic condition in the form of a physical disability—requiring frequent care to sustain mobility and extend life. The manifestation of this patient burden can be observed across health outcomes and prosthesis usage [32]; while the survival rate for traumatic amputees is comparable to non-amputee patients, the 5-year survival rate of diabetic amputees is comparable to that of patients with brain cancer.

Medical care to treat diabetes and to respond to the loss of limbs is similar in many ways: both are chronic lifetime conditions that, with the proper resources and support, can be managed on a regular and predictable basis to avoid acute complications that threaten mobility and life. There is no evidence to suggest that patients are better equipped after amputations to manage diabetes, or to respond to their acquired physical disability. The Diabetes-Amputation Clinical Spiral (Figure 3) presents a visual to explain a clinical progression that is experienced by many patients whose social determinants, environment, biological, and genetic predisposition begins with 1) increased likelihood of diabetes diagnosis and leads to 2) difficulty managing diabetes over a longitudinal timeline, 3) heightened rates of preventable dysvascular amputation, and, subsequently, 4) lower rates of rehabilitation of mobility via prosthetic use—at higher than average rates than others. As patients progress through each status, their likelihood of reaching the next state is driven by the constant influence of the social determinants, biological, and environmental factors. However, that influence is intensified as the States themselves begin to act as mediating factors that transform the influences from risk-introducing to life-threatening. For instance, the rate that a person newly diagnosed with diabetes [State 1] will ultimately experience major limb amputation [State 3] is just 2%, but a person who struggles to manage their diabetes [State 2] is 15-30x more likely to experience amputation [State 3].

Insurance and coverage: Insurance status, coverage, and comprehensiveness plays a large role in both preventing amputations and providing rehabilitative and prosthetic medical services for many persons with limb loss, regardless of the cause of their amputation.

Preventing amputations: Limb amputations can be divided into preventable and non-preventable cases: conditions like uncontrolled diabetes and PAD give rise to preventable amputations, whereas trauma (violence, motor vehicle accidents), congenital conditions, and tumor/cancers
The Diabetes-Amputation Clinical Spiral

State 1: Increased likelihood of Type II Diabetes diagnosis
State 2: Difficulty managing diabetes over a longitudinal timeline
State 3: Heightened rates of dysvascular amputation
State 4: Lower rates of mobility rehabilitation via prosthesis use post-amputation
State 5: Risk of early death from associated medical complications and/or subsequent amputation

social determinants of health (such as race, income, or community marginalization), biological and genetic predisposition, environmental factors

Figure 3: The constant influence of factors like social determinants of health, environmental, biological, and genetic predisposition propels patients from State 1 (Increased likelihood of Type II Diabetes diagnosis) to State 5 (Risk of early death) in The Diabetes-Amputation Clinical Spiral. As patients progress from earlier to later States, the States themselves act as mediating factors that accelerate progression through the Diabetes-Amputation Spiral.

cause most of the non-preventable amputations. Health insurance coverage can greatly influence the rate of preventable amputations by slowing the cascade of medical complications that necessitate limb amputation. Further, when complications arise, health insurance provides additional protection: being uninsured is strongly associated with significantly higher odds of receiving a leg amputation as opposed to a potentially limb-salvaging revascularization procedure [20].

The landmark 2020 article, The Black American Amputation Epidemic, published by ProPublica [33] and told through the lens of an expert vascular surgeon who treats patients in one of the most heavily affected counties in the U.S., shed light on how limited health insurance coverage leads to higher rates of incident amputations. In these pockets of the country, general surgeons have a financial incentive to amputate because they do not get paid to operate if they recommend saving a limb. Additionally, many of these hospitals do not direct doctors to order angiograms, nor do insurers require it. Angiograms are essential as it is the most reliable imaging to show if and precisely where blood flow is blocked, giving the clearest picture of whether an amputation is necessary, and, if so, how much needs to be amputated. Subsequently, more than half of patients do not get an angiogram before amputation—and unfortunately, the statistics are divided largely along racial and socioeconomic lines.

Prosthetic service coverage with insurance: Ideally, prosthetic medical services, prosthetic devices, and rehabilitative care can restore lost or missing function to support maximized mobility and quality of life for persons with disabilities. However, discrepancies between gold-standard comprehensive treatment guidelines and the type and amount of treatment covered by most health insurances cause a rift between what is imaginable for persons with amputations and what is realistically attainable.

Comprehensiveness of health insurance coverage for prosthetic services and the out-of-pocket costs that patients pay is shown to affect patients’ utilization and selection of prosthetic devices [34]. Some insurance providers have implemented yearly or lifetime financial caps that limit the number of prosthetic devices that patients can acquire and the frequency with which they can visit a specialist clinic to adjust their prosthetic devices for comfort, repairs, and maintaining mobility. Analyses have concluded that yearly limits for prosthetic services can be as low as hundreds of dollars, while the cost of a single lower or upper limb device can range from $3,000 to $100,000 or $4,000 to $75,000, respectively [34,35]. Further, even the most advanced prosthetic limb devices and component parts often have a lifetime of 5 years or less of use before repairs or total replacements are warranted [35], making out-of-pocket investment in prosthetic devices even more difficult for patients to bear. It is pertinent to point out that for patients with higher level amputations
falls, reduce the incidence of osteoarthritis, and consequently reduce the number of major and minor injurious back, and joint pain. MPKs have been shown to result in improved clinical benefits compared to non-MPK [39]. Results from modeling and clinical studies indicate that MPKs drastically improving quality of life for patients, it is not a standard of care for those who would benefit.

Some medical insurers claim prostheses with microprocessors are unnecessary unless the patient needs to ambulate quickly (e.g. while participating in sports) or over difficult terrain. As such, MPKs would be considered outside the scope of “medical necessity” based on an outdated medical policy that posits that this standard and well-established prosthetic technology is still “experimental and investigational” and thus not covered [40], despite the recommendations of the patient’s physicians and prosthetist. Ultimately, quoting insufficient clinical outcome data, it is a common practice for insurers to deny coverage of more advanced prostheses for the reason of it not being a medical necessity. Other types of prosthetic technology that are currently not considered medically necessary under most plans include powered ankle, ankle-foot, or knee systems, osseointegrated prostheses, targeted muscle innervation, and implanted myoelectric sensors [41,42].

Section III: Next steps

Millions of people in the U.S. are affected by limb loss, and despite improvements in medicine and technologies, the number of people living with an amputation is projected to increase sharply in the next three decades [27]. The regulation of prosthetic services and thereby access to prosthetic technologies largely determines patient access to the fruits that tremendous research and development efforts have grown in the most recent era in prosthetic sciences, what we call “the Technological Boom.” However, as detailed in Section II, investments in technology translation, technology adoption, and improving health access are insufficient to keep pace with the billions of dollars invested in the research and design of prostheses and neural interfacing strategies. In this section, we will discuss select emerging technologies and explore several actionable strategies that could bridge the gap between prosthetic technology and policy that dictates its translation and adoption by patients.

Emerging technologies: The technological advancement of prosthetic devices involves intersecting disciplines, from mechatronics to materials science to neurosurgery. However, when comparing a state-of-the-art prosthetic limb to its biological counterpart, one quickly realizes there is still a significant gap. Fortunately, thanks to the timely intersection of advances in virtually every scientific and technological discipline, the prosthetic field has never been closer to designing an artificial limb that is functionally indistinguishable from a biological one. To illustrate how to achieve such a feat, in this subsection we outline recent advancements in surgical, electrical, and mechanical interfaces and their integration to prosthetic devices.

Surgical interfaces: Advances in the technological and medical landscapes have facilitated the understanding of biological processes, such as how regeneration takes place in the peripheral nervous system, and thus have given rise to amputees who have amputations of multiple limbs, not only is their disability intensifies, but so are the costs of rehabilitating their mobility. Finally, a lengthy and difficult process is typically required to warrant the provision of any secondary devices or prosthetic devices for exercise or sport [34], making post-amputation engagement in healthy activity highly inaccessible and largely dependent on charitable organizations like Move United [36] or Challenged Athletes Foundation [37].

An influential organization in the provision of prosthetic services is The Center for Medicare and Medicaid Services (CMS), one of the largest health insurance agencies for persons with amputation in America. CMS uses the Medicare Functional Classification Level, also known as K-levels, to permit or prohibit specific prosthetic technologies to patients at each level so that the type of prosthetic limb provided is appropriate for the patient’s rehabilitative potential. The majority of their beneficiaries are enrolled in Medicare, which serves Americans over the age of 65, rather than Medicaid, which serves Americans that meet income requirements. Since decision-making revolves around the needs of its beneficiaries, CMS understandably uses evidence and makes recommendations based on its majority 65+ base. However, the coverage determinations made by CMS are often adopted by private insurers [38], and thus their permission or prohibition of prosthetic services and technology is extrapolated to patients of all ages and backgrounds. While this is not the responsibility of CMS to rectify, it presents a barrier for patients nationally in accessing appropriate services and technologies. Finally, unlike prosthetic hips, knees, or heart valves, prosthetic limbs are categorized alongside Durable Medical Supplies (to which blood glucose monitors, commodes, and elastic stockings belong) in the CMS system. This categorization limits the coverage amount for medical devices and, therefore, for prosthetic devices and services.

Technology and insurance policy discrepancies:
Finally, one of the biggest limitations to translating prosthetic technologies is a dearth of data on health outcomes and clinical metrics to warrant coverage expansion. There is a considerable disconnect between what is understood by patients, clinicians, and decision-makers. This results in policies that, based on limited data and older clinical trials, are insufficient in providing patients state of the art, comprehensive care.

Coverage of microprocessor knees (MPKs) for use by patients with transfemoral amputations offers a common example of this type of challenge. Amputees are largely at a biomechanical disadvantage that makes them more likely to develop musculoskeletal complications such as osteoarthritis, back, and joint pain. MPKs have been shown to result in improved clinical benefits compared to non-MPK [39]. Results from modeling and clinical studies indicate that MPKs reduce the number of major and minor injurious falls, reduce the incidence of osteoarthritis, and consequently significantly reduce direct healthcare costs [39]. Despite the MPK drastically improving quality of life for patients, it is not a standard of care for those who would benefit.
to the development of biologically-inspired neural interfaces. These interfaces use existing neural pathways, enabled by advanced surgical techniques, to connect the nervous system with prosthetic limbs in a bidirectional manner such that users can control and feel the prosthesis.

Amputation disrupts neural pathways in a number of ways. It restricts muscle movement, so that amputees are unable to connect their thoughts with appropriate movements. Similarly, these movements and their interaction with the environment are not perceived by the person with amputation. Scientists and physicians are beginning to harness their understanding of neural communication to improve both their surgical methods and the way people with amputation interact with prosthetic limbs. Targeted muscle reinnervation (TMR), one of the first examples of a surgical neural interface, was implemented in humans in 2004 [43]. TMR is a surgical architecture wherein neural signals traveling through the peripheral nerves that were used to control muscles from the part of the limb that was amputated are redirected to the muscles that remain after amputation, to then read those signals for prosthetic limb control. This surgical interface has been implemented in more than 100 patients at all levels of amputation in the upper extremity, with over 90% reported reinnervation success [44]. By placing electromyographic electrodes on top of these reinnervated muscles, electrical signals from the patient can be used to interpret desired actions. Patients with this interface have been able to simultaneously control the hand, wrist, and elbow of a prosthetic limb, demonstrating more efficient task completion and more intuitive prosthetic control compared to traditional amputation [45]. However, since TMR requires denervation of healthy muscles, this limits the number of muscles that can be used and hence the degrees of freedom that can be achieved. The regenerative peripheral nerve interface (RPNI) is another surgical innovation, which provides more degrees of freedom compared to TMR. The RPNI uses denervated and devascularized muscle grafts, which can be harvested from donor muscles from the user, and thus provides a scalable architecture where multiple degrees of freedom are required [46]. The RPNI also helps enable intuitive and enhanced control of prosthetic devices [46].

While the aforementioned neural interfaces provide improved prosthetic control, they do not provide any sensory feedback to the patient, which is critical for accurate prosthetic control. The agonist-antagonist myoneural interface (AMI) is a surgical construct and neural interfacing strategy that consists of the mechanical linking of agonist and antagonist muscle pairs to enable proprioceptive signaling, as well as bidirectional communication between prosthetic limbs and the nervous system. By preserving natural mechanical coupling at the interface between agonist-antagonist muscle pairs, native mechanoreceptors (such as spindle fibers and Golgi tendon organs) are stretched to provide relevant proprioceptive feedback when forces are generated by contraction of either muscle in the pair. This interface has shown increased muscle fascicle strain, improved neuromuscular controllability, reflexive behaviors, and closed-loop torque control [47].

**Electrical and mechanical interfaces:** The aforementioned surgical architectures require additional components to be able to communicate with biological components. One example is the electromyography electrodes placed on muscle to decode the electrical signals from users and command movements in a prosthetic device. The signals from electromyography electrodes can be disrupted by sweat and the movement of the electrodes. That causes variability in the recorded signals and limits the value of this modality for prosthetic control. Researchers are devising new means to capture signals from neural tissues. Magnetomicroscopy is one of them, comprising the implantation of small magnetic beads in muscles and an external array of magnetic sensors to track the positions of the magnetic beads as the muscle moves [48]. This is important because the movement of muscles provides additional information beyond electrical signals. Another example is microfabricated channel arrays that leverage the regenerative properties of peripheral nerves. These micron-size arrays are positioned over a transected nerve so the nerve can grow between its structures that contain electrodes for recording and stimulation [49]. This approach allows for the recording and stimulation of a selected number of nerve fibers, which can provide enhanced decoding of user intent and precise stimulation so the user can distinguish different sensory modalities, such as touch, temperature, vibration, etc. Another promising technology for stimulation is optogenetics, which makes it possible to introduce photo-sensitive genes that aid light stimulation for the control of neural tissues. This approach has shown impressive demonstrations of physiological stimulation of muscles [50], inhibition of pain [51], and transdermal stimulation of neural tissues [52].

Mechanical interfaces such as osseointegration can provide a reliable and long-term communication between neuromusculature and the prosthetic device. Osseointegration refers to the procedure of implanting a protruding titanium shaft in the bone of the residual limb. In comparison to sockets, osseointegration provides direct loading of the body weight through the skeleton and not through soft tissues as is the case with sockets. Beyond improved mechanical loading, osseointegration procedures allow for a conduit to communicate implanted hardware with external devices. This procedure has shown chronic bidirectional communication, with improved control compared to surface electromyographic electrodes, and sensory feedback via stimulation of nerves and muscles [53].

**Integration:** Patients with these surgical neural interfacing technologies have demonstrated improved and more intuitive control of their prostheses, subsequently increasing odds of device adoption. This patient population has also shown clinical benefits, such as the prevention of symptomatic neuromas and the reduction of post-amputation pain [54, 55]. Astonishingly, patients with surgical architectures such as the AMI demonstrate comparable functional neuromaging to non-ampuetees, suggesting remarkable promise for the
functional integration of prosthetic devices [56, 57]. Although these emerging technologies result in dramatically increased quality of life, they are largely inaccessible to most patients; most healthcare plans do not regard them as medically necessary and fail to cover them. As such, we explore the following reactionary steps to address these challenges in access to already existing technology that has the potential to positively change patients’ lives.

Looking forward: Improving access and translation

Taking action to prevent amputations: The twin challenges of the prosthetic field are preventing amputations and treating limb loss, both of which are exacerbated by health disparities along socioeconomic and racial lines. Preventable amputations serve as an indicator that a community has critically insufficient resources and healthcare from a primary care to a tertiary level; reducing incidence rates for these types of amputations requires both a systemic and a health equity-informed approach to respond with the appropriate nuance and resources to make significant progress.

Studies have demonstrated the feasibility of reducing amputation risk through improved medical insurance and thereby health access to management health services. For instance, expanded insurance coverage in Massachusetts through the MassHealth program, which expanded coverage to 98% of state residents, resulted in a 12% decrease in PAD in non-White patients, and the amputation risk difference between non-Whites and Whites decreased from 8.5% to 3.9% [21]. These preliminary findings suggest that increased insurance coverage for diabetic management has broad benefits across communities and stages of diabetes to amputation prognosis. Further, focused actions from clinicians and specialists to prevent amputations have been put forth as clinical recommendations—for instance, screening for vascular disease in legs, performing regular diabetic foot exams, and exploring limb salvaging options before amputation [20, 58].

Clinicians alone do not bear the responsibility of improving health outcomes as they are limited by the health systems in which they work and treat patients. From a policy standpoint, ensuring that insurance providers cover preventative medical services that are proven to prevent amputations can allow doctors to contribute to reduced incidence rates. Specifically, this issue has been raised by vascular surgeons working in communities that are heavily affected by preventable amputations with patients whose insufficient insurance covers amputation surgeries but not preventative measures [33]. Similarly, policies written by hospitals, insurers, and the government often do not require surgeons to consider limb salvaging options before amputation [20]. As a last example, specialists have noted that government loan forgiveness programs will forgive the debt of some doctors in underserved areas but not certain specialists, leading to shortages of physicians critical to treating diabetic and amputee needs.

Reclassification of prosthetic limb devices: Once a patient has undergone an amputation and enters the pool of those living with limb loss, lifelong care is required to rehabilitate mobility, restore function, and enable independent living. Whilst prosthetic technologies are and have been advancing significantly, strategies to ensure these products reach patients have not kept pace. One approach that can be explored to improve current and future access to prosthetic technologies is the policy reclassification of prosthetic limb devices in order to urge a broad expansion of insurance coverage.

Broadly, the term “prosthetic device” refers to any artificial body part that replaces a biological one, such as a limb, heart, or ear—not just a replacement limb. One of the most widely distributed prosthetic devices is the cochlear implant, which restores hearing to patients with severe to profound hearing loss. According to CMS, cochlear implants are reasonable and necessary for treatment of moderate-to-severe hearing loss in individuals who demonstrate limited benefits from amplification. Mechanical heart valves and cardiac pacemakers are also covered as prosthetic devices under CMS. Patients who have had a heart attack in the past 12 months, bypass surgery, heart transplant, or require valve repair or replacement are eligible. Another common implanted medical device is hip replacement, which involves replacing a damaged hip joint with an artificial joint that is attached to the thigh bone using surgical cement or screws. CMS typically covers hip replacement surgery once a doctor confirms it is medically necessary, as it can help with mobility and maintaining a healthy lifestyle.

The notion that prosthetic limbs are any different than these non-limb prosthetic devices, especially when contextualized with modern technological advances, does not make sense. One historical and visible discrepancy between prosthetic limbs and these other prosthetic devices is their externality, specifically that they are not being surgically implanted or merged with the biological body. However, based on the emerging scientific and clinical evidence previously described, the level of integration of prosthetic limbs with the biological body—both mechanically and neurally—is increasing. Furthermore, limb prostheses also help with functionality, mobility, and maintaining a healthy lifestyle, improving overall patient health and outcomes post-amputation [59, 60]. While such rationale is considered sufficient justification for the coverage of other non-limb prosthetic devices, limb prostheses are classified as durable medical equipment alongside crutches, canes, and walkers. Consequently, and contrary to these other medical devices, most advanced prostheses are not termed medically necessary and thus are uninsured, with every extra functionality adding on costs that exacerbate the financial inaccessibility of prosthetic limbs.

Reclassifying prosthetic limbs from rudimentary, household assistive devices to biomedical devices like cochlear implants, heart valves, or hip replacements has the potential to change the societal understanding of their importance and complexity. Subsequently, health insurance agencies may begin to treat prosthetic limbs as medically necessary and
integrated parts of the human body that warrant a high-level of design and medical standards. Advances to policy and societal understanding of prosthetic technologies can ensure that the benefits of developing technology and expanded possibilities of human rehabilitation and augmentation are enjoyed equitably in society.

Social barriers, rehabilitation, and cyborg sensationalization: Ultimately, access to prosthetic care is critically important, but social attitudes have historically provided barriers to access. There are two models of disability that are helpful in understanding this notion. The medical model posits that people are disabled by their impairments or differences, and that these impairments should be “fixed” or changed by medical treatments. Alternatively, the social model of disability posits that disability is a result of the way society is organized, and that it is possible to remove certain barriers that restrict life choices for disabled people—an idea partially enabled by the Americans with Disabilities Act (1990).

The notion of a rehabilitation ethic that began with Civil War veterans is one social lens through which to view functional impairment that has perpetuated into modern day. It comes with an accompanying social attitude that one should get a prosthetic device and by necessary extension maximize its use to overcome disability and perform at the highest level. War veterans as well as paralympians and disabled champions have, according to this model of social perception, achieved the peak of moral goodness and worth. This concept that “honorability” must be achieved to be accepted as a disabled person marginalizes the majority of functionally impaired people who simply cannot compete with this notion.

Along with advances in prosthetic technology have come sensationalized narratives that often misleadingly portray robotic limbs as granting enhanced physical competence that could even surpass able-bodied limbs. In this supercrip narrative, the disabled body has undergone physical trials and tribulations and not only has overcome them, but prospered. This supercrip ideal is a modern adaptation of the rhetoric of the civil-war era Protestant reformers, repackaged as a science fiction narrative that changes social attitudes towards prostheses and disrupts the disabled stereotype. It aestheticizes and romanticizes transhumanism and cyborg identities, when in fact most people who experience limb loss or other mobility issues experience considerable social barriers.

Historically, this social cherry-picking of deserving patients upon whom to endow care has given rise to and aggravated health inequities. By centering the stories of the few who receive proper healthcare, an inaccurate message that all patients with the same condition experience this level of care is communicated. This misunderstanding can have deleterious effects that undermine the efforts of those who seek improved access to healthcare: the difficulty of their struggle is underestimated and the scope of their challenge is minimized. Clarifying this misunderstanding is in the interest of improved public health and health equity so that demonstrated trends in health disparity can be mitigated. Several efforts to this end can be imagined: accurate and representative portrayals of the limb loss community, increased awareness of major challenges in this field and whom they affect, centering communities that have been marginalized, and emphasizing a sense of responsibility in representatives of the limb loss community to learn, engage with, and invite others to their advocacy. Ultimately, a more equitable future with improved care, technology, and services is possible for all but requires reflection, recognition of challenges, strategic planning, and coalition-building.

Conclusion

The field of prosthetic sciences has progressed profoundly in the past century. Prosthetic technology is in some ways nearly unrecognizable from the technologies of the 1920s, yet many of these high-tech solutions are kept siloed in government and academic research labs where they and other quality prosthetic care remain inaccessible to the people who need them most. Historically, social movements to support amputees have pushed the field forward, but at the cost of inadvertently excluding those who do not fit the criterion of “ideal patient.” Simultaneously, both preventative care and treatment for restoring limb functionality has been limited along a socioeconomic gradient that is pronounced and growing. The most common etiology of amputation in America is dysvascular complications, yet patients who experience amputations of this type have a 5-year survival rate on par with a brain cancer diagnosis. Meanwhile, developments in surgical techniques, electrical and mechanical control, and bodily integration will allow us to restore limbs in ways that blur the line between body and machine. Policy to regulate prosthetic care and the provision of prosthetic technologies largely does not, and likely will not, permit equitable translation and access without serious reforms. As researchers and developers in the prosthetic field, we imagine a future where every person with a disability can receive comprehensive, state-of-the-art care and benefit from our work. Our work is cut out for us: let’s make it a reality together.

Acknowledgments

The authors would like to thank MIT Media Lab’s Biomechatronics group and Professor Hugh Herr for bringing them together and giving them the inspiration to research what we love and to write this article. We thank our editors Jennifer Ann Cascino and Mani Sai Suryateja Jammalamadaka for their time, guidance, and encouragement to pursue the communication of this important message through MIT SPR. We would also like to thank Dr. Sheffler and Dr. Moran-Thomas for the valuable insights and resources gleaned from their Anthropology of Medicine and History of Biology course at MIT. Finally, we would like to thank our friend and fellow writer Ayse Guvenilir for her time, review, and support and Professor Michael Specter for his insightful edits, feedback, and for inspiring us to use writing to safeguard our future. Last, we would like to give a warm
thank you to our friend and colleague, Paris Myers, for her generosity in designing and creating the beautiful artwork accompanying this article.

Citation

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