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Publication Date
2023-10-01

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Abstract

In the United States alone, approximately 2.1 million people are living with limb loss, a number expected to double by 2050. Despite the number of amputees expected to increase, current infrastructures, from policies to health personnel, fail to support amputees in need of prosthetics worldwide. This study explores the variables causing the difficulties in accessibility and turn, the factors that affect the quality of life after limb loss. Included in this research paper is the analysis of different barriers to the implementation of prosthetics on a national and public health scale. Current literature suggests a combination of internal and external factors that influence the access to prosthetics and quality of life for amputees including socioeconomic factors such as income, race or ethnicity, insurance, and geographic location. There will be an exploration into the development of 3D printing as a promising solution to improving the quality of life for amputees while addressing multi-faceted concerns including sustainability and biodegradability.

Introduction

About 40 million people globally need prosthetic or orthotic devices. A prosthetic device is defined as an artificial limb or technology designed to improve mobility and self-capacity in place of a missing body part or ability. According to the World Health Organization, only 5 to 15% of amputees have access to these devices. In America, the remaining 85-95% without access are mainly composed of the marginalized, including but not limited to ethnic groups, communities living below the federal poverty line, and medically underserved populations residing in rural areas; all of which showcase similar trends where the need for prosthetics is much greater than the current state of accessibility. Data suggests that overwhelmingly, the burden and consequences of the lack of accessibility fall on these minorities.

More broadly, the entire field of healthcare faces similar challenges as millions of people around the United States lack access to health insurance and therefore don't receive the necessary medical treatment. Consequently, these concerns are exacerbated in minority and underrepresented communities nationwide. This pressing issue of accessibility and affordability is especially prevalent in developing countries where the majority of people need prosthetics but don't have access. The lack of accessibility and affordability of prosthetic devices can be attributed to a variety of factors such as socioeconomic status as well as access to health insurance. However, this paper will specifically focus on the factors that affect the prosthetic industry.

The primary gap in this field can be attributed to the lack of research exploring the connection and relationship between the impact of these socioeconomic factors. The lack of awareness relating to prosthetics is a contributing factor to the lack of policy initiatives to combat the health inequalities in this field. Due to limited national initiatives addressing the prosthetic market challenges, access to these prosthetics has dwindled throughout the years. These vital issues harm marginalized communities the most as they lack the resources to access these prosthetics. This paper will analyze the compilation of multiple socioeconomic factors and examine feasible solutions to tackle the inequalities in the prosthetic market using principles of green chemistry and sustainability. Unless otherwise mentioned, the studies will focus on lower-limb amputations. Furthermore, this paper will answer the question: How do socio-economic factors influence a patient's ability to receive prosthetics, and in turn affect quality of life?

Exploration into Socioeconomic Factors

Prosthetics have the potential to improve the quality of life for amputees. However, access to prosthetics is not equal for all individuals. Socioeconomic factors play a significant role in determining who has access to prosthetics. This section explores how socio-economic factors including income, racial/ethnic minorities, insurance, and geographic location can influence a patient's ability to receive prosthetics and in turn, affect their quality of life. Understanding these factors is essential to address the socioeconomic disparities in access to prosthetics.

Income

Limb prosthetics enable individuals with limb loss or limb difference to regain a level of physical function and mobility to improve their quality of life. However, the cost of amputation, prosthesis, and rehabilitation care is substantial, that is especially financially burdensome for low-income individuals. Accessible prosthetics remain crucial in restoring the physical, emotional, and social well-being of amputee patients and individuals with limb loss which means those who can't afford it also have barriers to holistic health. Direct costs can include the surgical procedure, rehabilitation care, prosthetic fitting, and device adjustment. These lifetime direct costs are estimated to range from $345,000 to nearly $600,000 depending on how often the prosthesis is replaced and the age at the time of amputation [1]. A study conducted by Miller, Paul, Forthofer, and Wurdeman (2020) [2] analyzed the impact of time to receipt of a limb prosthesis on healthcare costs following amputation. The study found that patients who received a prosthesis within 0-3 months had a mean total healthcare cost of $99,409 while those who received a prosthesis between 4-6 months post amputation had a mean total healthcare cost of $123,253. Patients who didn't receive a prosthesis had the highest mean total healthcare cost of $125,492. It is important to note that these costs exclude additional healthcare resources such as prescription drugs, physical therapy, and other out-of-pocket spending. These findings reflect how amputee patients of lower socioeconomic status may not retain the adequate financial means and coverage to afford the limb prosthetic during the 12 months post-surgery. Not only do these high costs prevent patients from getting prosthetics, but the high costs of repairs and replacements also cause patients to neglect or abandon their prosthetics [3]. Frequently patients believe that in avoiding or not acquiring a limb prosthetic after surgery, they are saving money, though instead, delaying a patient's access to a limb prosthetic increases the net healthcare costs and post-care process post-surgery while increasing risks/costs associated with secondary complications related to limb loss such as joint pain and cardiovascular disease.

In addition to these direct costs, there are also significant indirect costs to consider that further exacerbate the financial burden of prosthetics. These individuals who have undergone amputation are also at higher risk of secondary health complications including musculoskeletal pathologies, diabetes, osteoarthritis, and back problems. Without the physical support of a prosthetic device, amputee patients may experience increased difficulties in performing basic activities which can hinder mobility in work environments and increase the need for hired healthcare assistant providers which ultimately increases healthcare costs for the patient. Moreover, amputee patients who chose to not acquire a prosthetic often grapple with prolonged, decreased emotional and psychological well-being leading to mental health conditions and issues that demand further healthcare costs to treat. Therefore a patient's financial disparities reproduce deeper poverty and financial struggle as well as decreased quality of life.

Despite efforts to enact laws that promote equal access to prosthetics, many policies and laws still do not facilitate financial access to the most advanced prosthetic systems [1]. A study found that individuals with annual incomes below $10,000 were 1.5 times more likely to not use prosthetic devices than those with annual incomes above $50,000 [4)] This indicates that the lack of financial income disproportionately affects low-income individuals who are not able to afford prosthetic devices. This financial burden is further exacerbated by a lack of insurance coverage or lack of insurance.

A Case Study on Hearing Aids in America

Hearing loss can impair an individual's ability to perform daily tasks, socialize, and maintain relationships. Hence hearing aids present a remedial solution to address these concerns, yet the high cost of these aided devices along with limited insurance coverage may present substantial impediments for those of lower socioeconomic status. A study conducted by Kochkin and Rogin (2000) [5] analyzes the changes in the cost of hearing aids from the years 2000-2020. The data presented in Table 1 shows that the cost of hearing aid devices has increased steadily over the past two decades.

Table 1: Cost of Hearing Aids over Time

Year	**Average Cost of Hearing Aids**
2000	$1,500

2005	$1,800
2010	$2,100
2015	$2,500
2020	$2,800

This increase in cost can be a substantial barrier for many people who require hearing aids but cannot afford them. This can be especially challenging for those who do not have insurance coverage or have limited financial resources. Additionally, Kochkin and Rogin (2000) highlight how the cost of hearing aids can vary greatly depending on the brand, style, and features which further adds to the financial burden [5]. The relationship between the quality and cost of a device is directly proportional whereby an increase in device quality corresponds with an increase in its price. The higher cost of more advanced devices is justified by utilities such as improved functionality, durability, and reliability. When making purchasing decisions, patients who have less financial means are forced to make a trade-off by prioritizing lower cost over higher, more durable, and long-lasting quality. In the Article Hearing: Aids: Quality of Life and Socio-economic Aspects" by Tsakiropoulou and others (2007), the authors explain how hearing loss can negatively affect employment and income outcomes [6]. Hence, in situations where a patient is unable to afford the expenses of both the initial purchase of a hearing device and subsequent post-care follow-up visits, the lack of access to this remedial solution may exacerbate social difficulties in the workplace thereby leading to decreased earning potentials.

Other medical devices and prosthetic devices offer opportunities for individuals to better grapple with a pre-existing disability. A study conducted by Linda J Spencer, Bruce J. Gantz, and John F. Knutson aimed to evaluate the outcomes and achievements of deaf students who grew up with access to cochlear implants– a type of prosthetic device that can improve hearing abilities in individuals with hearing loss [7]. The study involved evaluating the successful outcomes of twenty-seven prelingually deaf young adults between the ages of 2 and 12 years who received a cochlear implant. The study found that children who came from financially stable, highly educated, upper-middle-class families were more likely to receive cochlear implants compared to those children who came from lower-income, less educated households. There is a positive association between the age at which a child receives these devices and their outcomes in performance, speech intelligibility, and speech perception with younger age at implantation being associated with superior outcomes in these areas. The cost of cochlear implants is still relatively high, which can be a barrier for some patients. Additionally, the cost of cochlear implants can vary greatly depending on factors such as the brand, the number of electrodes, and the level of customization required.

The trends and discrepancies observed in this section reflect a strong need and demand for more affordable prosthetics, particularly for individuals coming from lower-income socioeconomic backgrounds. Policymakers, healthcare providers, and prosthetic manufacturers must utilize this data to invoke efforts to make prosthetics universally accessible for all individuals, regardless of socioeconomic status. This could include initiatives to increase insurance coverage for prosthetic devices, develop more affordable prosthetic technologies, and promote education and awareness about prosthetic options. By addressing the impact of socio-economic factors on access to prosthetics, we can help improve the quality of life for millions of individuals worldwide.

Racial/ethnic minorities

Racial and ethnic minorities also face significant disparities in access to prosthetics. According to a 2005 study, 42% of individuals who had an amputation come from a racial or ethnic minority group [4]. This suggests that not only are individuals from racial and ethnic minorities disproportionately affected by lack of access to prosthetics, but they are also disproportionately affected by amputations. For example, African Americans are four times more likely to undergo an amputation compared to non-Hispanic whites [8]. Furthermore, Hispanic Americans are 1.5 times more likely to undergo an amputation compared to white Americans [9]. This lack of access to prosthetics results in a reduced quality of life for these marginalized individuals from racial and ethnic backgrounds. The rate of amputations is also in part due to diabetes disproportionately impacting minority communities with Hispanics having a 50% higher death rate from diabetes than non-white Hispanics and non-Hispanic Black people being 60% more likely than non-Hispanic White people to be diagnosed [10, 11]. This is extremely alarming because 54% of all amputations result from diabetes and vascular diseases and half of all amputees will die in 5 years, especially for lower limb amputations [11].

Insurance

Health insurance is another barrier to prosthetic access patients have to face. Prosthetic limbs are an incredibly large expense, ranging from $5,000 to around $70,000. Many patients are unable to pay this without the assistance of insurance. However, even with insurance, the full cost of the prosthetics is not covered. For instance, the insurance program Medicare requires the patient to pay 20% of the cost of the device, which can range from $2,000 to upwards of $14,000 [12]. Prosthetic devices, in this case, pose a significant financial burden which is why there is a higher rate of amputation for individuals with lower income and with insurance from companies like Medicare and Medicaid [13].

Location

Location is another key socioeconomic factor affecting prosthetic access. The area that a person resides in greatly affects their health outcomes. A 2021 study found that lower extremity amputation rates were higher in ZIP codes housing mostly black residents, such as Philadelphia, Detroit, Atlanta, and Miami [14]. Because of “racial residential segregation,” black people are forced into these urban and often poverty-stricken areas. These areas have a negative effect on their health outcomes for a plethora of reasons, including a greater risk of exposure to chemicals. Also, despite the increased threat to residents’ health, there is less access to healthcare. In these areas, there are fewer opportunities for career or educational advancement and less government funding which, together, inhibit easy access to healthcare, including primary care, subspecialty care, and pharmacies. Not having access to proper care causes the conditions these patients suffer from to be dealt with in non-ideal ways, such as hasty amputations.

Additionally, people living in underserved rural areas also have disproportionately high levels of lower extremity amputation. This is due to the physical distance from specialists to adequately care for their health issues. If they did receive a prosthetic, it would be difficult to travel back to the doctor for fitting and maintenance [15].

Results

Accessibility in the prosthetic industry is a multifaceted issue as there are a plethora of factors that come into play. The income bracket, race, health insurance, and location of the patient all affect both the quality of care as well as the ability to access adequate prosthetics. These factors are all interrelated with each other. For example, a person who is part of a minority group and has a low income has a higher probability of not having adequate health insurance. Therefore, this lack of insurance would directly impact their ability to access prosthetics and in turn cost them more money in the long run from doctor visits and medications. This cycle of the socioeconomic factors interacting with each other, exacerbates the lack of accessibility in the healthcare system. When policy makers and the government create initiatives or policies affecting the healthcare industry, it is vital that they take into consideration these socioeconomic factors as they are not mutually exclusive from one another.

Discussion

Socioeconomic factors have significant implications in determining who has access to prosthetics. The costs of amputation, prosthetics, and rehabilitation significantly outweigh the financial capabilities of low-income and uninsured individuals. Racial and ethnic minorities also face significant disparities in amputation and access to prosthetics that are further exacerbated by income and lack of insurance, as well as the area they reside in. Minorities that live in urban areas with high poverty rates or rural underserved areas are more likely to undergo amputations simply because the option of other medical treatment is not readily available.

For example, non-white individuals with low income and no insurance are more likely to undergo lower-limb amputation for peripheral vascular disease rather than other procedures that do not require amputation such as revascularization [16]. A combination of these socioeconomic factors can compound the lack of access to prosthetics as individuals who are low-income, uninsured, and marginalized face even greater disparities in access to prosthetics. Without access to prosthetic devices, these individuals may experience poorer quality of life as their reduced mobility can result in restrictions on social activities. Hence, addressing these socioeconomic factors such as income, race/ethnicity, gender, and geographic location is vital in ensuring that all patients can receive prosthetics and improve their quality of life.

Digital Technology

Advances in digital technology in recent years have garnered a new medium in which prosthetics can be manufactured and accessed: 3D printing. With 3D printing's growing availability and refined mechanics, extensive research has been conducted on the reliability and performance of 3D-printed prosthetics on amputated patients from around the world. The question that arises is whether this new and improved technology would resolve a lot of the issues that arise in traditional prosthetic production, such as affordability, accessibility, wear, and mobility concerns. We reviewed several case studies and identified several key trends in the development of digital prosthetics, and the results show an overwhelmingly net positive effect on accessibility, mobility, and quality of life.

Accessibility

In traditional methods of manufacturing prosthetics, prosthetists handcraft sockets using plaster casts and require amputees to get multiple fittings before production is complete. 3D printing's ability to produce prosthetics in an automated, precise, and efficient manner, greatly propels prosthetics' accessibility; 3D printing can complete production in less than half the time it takes for traditional methods [17]. Fit challenges make up approximately 50% of prosthetic abandonment which can be attributed to discomfort and pain caused by the prosthetic. In traditional methods, there is a long manufacturing period that takes place before patients can receive their prosthetics. During this time, weight and limb changes are very common; by the time patients receive their prosthetic, it may fit very uncomfortably and can even be painful. Reducing manufacturing time will reduce the abandonment rate and discomfort rate while increasing accessibility due to the quick turnaround rate [17]. Additionally, open-source applications for 3D printing allow for biomedical engineers, prosthetists, and other professionals to upload their designs for free which greatly improves accessibility because printing can be done remotely [18]. E-nable is a digital humanitarian movement where volunteers use these designs to 3D print prosthetics to send to underserved communities for free [18].

A study conducted in rural Sierra Leone focused on the development of low-cost 3D-printed prosthetic sockets and supplied them to those who lacked access to prosthetic limbs [19]. After six weeks, the majority of participants had reached their personal mobility goals, and all of the participants were still wearing their prosthetics. Although some participants did not reach their personal mobility goals in the first six weeks, all participants no longer needed assistance from crutches after rehabilitation. This study illustrates how mobility and quality of life were both simultaneously improved with the use of a 3D-printed prosthetic [19].

The increase in accessibility by using a 3D printing methodology also comes from the technique itself. In techniques, such as ICRC, patients are required to be on-site for analysis of their fitting, however, this is not the case for 3D. The only technology required to perform the 3D printing fit analysis is a handheld 3D imaging device, which is a task that can easily be done from a patient's home. The analysis' simple methodology reduces the gap in medically underserved areas with a lack of clinics and manufacturing personnel/resources [20].

Another simple correlation this methodology creates concerning accessibility is: faster production creates more time for more patients. One challenge to the accessibility of prosthetics is the lack of public health policies enacted at the national level. This leads to limited funding and consequently, a limited market for prosthetics. With an underdeveloped market, the opportunities to expand data collection on the impacts of prosthetic devices dwindle and the communities left in need are underrepresented and underserved. Because 3D technology is efficient and much faster in its fitting process, this reduction in production time frees up space in prosthetists' schedules, and therefore, can serve more patients through this technique. This allotment of freed-up space provides patients with increased accessibility to prosthetics that would otherwise not have been possible with traditional techniques [17]. Given that production through 3D technology is faster, production costs are cut down, and lead to a more affordable market for prosthetics and increased accessibility for patients.

As technology advances, resources for creating prosthetics and assistive technology become more available; innovative technology education is being implemented in several universities, such as a course taught at the MIT D-Lab. Courses like these encourage students to learn to engineer assistive technologies for real-world applications in several developing countries [19]. With digital technology regarding prosthetics taking place in the classroom, more students can further the development and innovative technology to improve the supply and production of prosthetic devices. This can already be seen through MIT's D-Lab, where students work on a project proposal, prototype prosthetic technology, and design for limited-resourced settings [19]. Though many of these projects do not continue past the course, some do and have been going on for years now. As education in the field of prosthetic and assistive technology continues to expand, more and more students work towards the innovation of such technology while supplying prosthetic devices to more and more people who need them. This addresses the challenges of expense, especially in developing countries where there is often a lack of resources and the federal poverty line is much lower.

Methods and Materials

Current research is focused on which methods of 3D printing are optimal for prosthetics in terms of durability, cost-effectiveness, production time, and accessibility. The most common applications used for 3D printing are as follows: Stereolithography (SLA), Fused Deposition Modeling/ Fused Filament Fabrication, PolyJet, and Selective Laser Sintering (SLS) [21]. Currently, the majority of prosthetics utilize FDM /FFF applications due to the relatively fast production time of 2-5 hours and the variety of materials that can be processed in the application [21]. Performed by the Technical University of Liberec, the durability tests measure the amount of force (in Newtons) a prosthetic finger can take with the independent variable being the different applications used to make the prosthetic. Because some applications can only take certain forms of polymers, i.e. SLS can only use thermoplastic powders, there are confounding variables in the chemical properties of the materials used. The study found that SLS 3D printing could withstand the most force at 60N while FDM only can withstand 30N [21]. SLS uses a CO_2 laser to pack the powder into a solid mass in a process called sintering and the material that had the most durability was PA 3200 GF or Nylon 12. While SLS 3D printing is shown to be the most durable experimentally, the study did not include the most durable materials available for FDM/FFF. PA 3200 and other Nylons can also be used to create prosthetics through FDM/FFF and further research still needs to be conducted to conclusively determine which method would produce the most durable prosthetic while keeping the materials constant.

Sustainability and Green Chemistry

An important aspect of 3D printing, especially in the context of improving accessibility, is sustainability and environmental impact. Thermoplastics like Nylons are most commonly used in 3D printing but they are conventionally non-biodegradable and sourced from petroleum [22]. With the rise in research and development of bioplastics, there are now multiple bio-based and biodegradable options that reduce carbon footprints [23]. Such options are PA 11 or Nylon 11; Polybutylene succinate (PBS), and Polylactide (PLA). The main issue is developing a polymer that has all of the components. The former is only bio-based while both the latter are biobased and biodegradable. Due to the chemical properties of PBS and PLA, though they are biodegradable, they are too brittle and when PLA is exposed to high temperatures, it becomes extremely soft which is not ideal for prosthetics[24]. Attempts to mitigate these weaknesses include blending different ratios of PA 11 and PBS or PLA and PBS to improve ductility [24,25]. Successfully doing so would ensure a ductile polymer that's completely renewably sourced (from castor oil and biomass), biodegradable, and less expensive than using pure PA 11. However, due to different densities, blends containing certain ratios of PBS, PLA, or both are not miscible and can yield high viscosities which can distort the printing process. In two different studies researching blends between PA 11-PBS (study 1) and PBS-PLA (study 2), study 1 found that there is limited miscibility with up to 40%wt PBS blends and fractures are present on the surface of the polymer blend[8]; study 2 reported that blends with over 40%wt PLA proved successful with "excellent processing abilities" and no observable distortions [25]. There is also a new bioplastic in development called Bio-Acrylonitrile Butadiene Styrene (Bio-ABS) which would replace conventional non-renewable ABS that is already widely used due to durability and wear resistance. Currently, there are limited studies with Bio-ABS alone. With promising results in PBS-PLA blends, further advances can be made in sustainability and durability by conducting more research using Bio-ABS blends; especially with biodegradable thermoplastics. [26].

Results

3D printing provides promising solutions to many barriers to access to prosthetics. It reduces the production time, and amount of personnel required, increases the quality of life, and decreases cost. It promotes an era where remote manufacturing of prosthetics is preferable due to the plethora of free 3D designs available and the ease of customization. This paper adds the factor of sustainability into the process, ensuring that the polymers used for the prosthetics limit carbon emissions and damage to the environment. However, current materials used have tradeoffs between the extent of biodegradability and durability, with durability being compromised when prosthetics are made of bioplastics like PLA or PBS. Novel research has found that blends of over 40% PLA and PBS prove the most promising in durability without compromising biodegradability. Another bioplastic with limited research but promising chemical properties for use in prosthetics is Bio-Abs. With further research in cross-linking reagents, the miscibility of other polymers with bioplastics can improve and fully bio-based and biodegradable materials have the potential to be the main polymers used in prosthetics.

Discussion

With a growing population expected to double by 2050, so will the demand for prosthetic devices [1]. By looking into digital technology and its gradual improvements, we can assess that 3D printing prosthetics would be a viable option to supply this inevitable growing demand. The common trends apparent between the research case studies are the speed at which prosthetics are manufactured, and how this directly affects the mobility and quality of life of patients.

As mentioned before, the faster a prosthetic can be produced and patients can be scanned, the more patients this method has the potential to serve and help; 3D printing technology is the method that can complete prosthetic production in less than half the time it takes through traditional methods. This decrease in manufacturing time also provides patients with better-fitting prosthetics, as their bodies would have had less time to change during the production process. A more form-fitting prosthetic also provides comfort and removes pain caused by a prosthetic fitting poorly. This decrease in pain also leads to improved mobility and increased quality of life; all while decreasing the number of patients that would discard or not utilize their prosthetics. The only aspect in question when it comes to 3D printing is how long these prosthetics could last, therefore, durability is still unknown [4]. With concurrent strides and innovations in technology, along with growing student interest, this durability question should be answered in no time. The overwhelming results on the effect of implementing 3D technology as the main prosthetic methodology, showcase a dramatic increase in accessibility along with improvements in mobility and quality of life.

Conclusion

Overall, the barriers to prosthetic access disproportionately affect historically marginalized groups in America with confounding factors such as race, ethnicity, socio-economic status, and location. Ultimately, this leads to an even more decreased quality of life on top of the factors affecting the marginalized. In the United States, the main barrier is expense with the cost of fittings, adjustment, clinic visits, and manufacturing often overwhelming the populations that need it the most. The most alarming risk factor for America is diabetes and other vascular diseases. With the death rate being 50% within 5 years of amputation due to diabetes, minorities are increasingly at higher risk of lower life expectancy. Globally, the main barrier is often a combination of location and cost. Countries with the greatest need are usually third-world countries with a lot of rural areas. This makes the likelihood of medically underserved populations increase and consequentially, access to prosthetic clinics very difficult; not to mention the lack of facilities for the production of prosthetics. However, access could be improved both within America and globally with the following considerations: (1) improving health education and prosthetic awareness on a national scale in order to catalyze policies and laws to improve access (2) developing 3D printing applications to reduce costs and increase production speeds (3) researching sustainable and affordable bio-based polymer and polymer blends (4) further establishment of open-source platforms for ease of sharing functional prosthetic designs for free. Establishing access to prosthetics is evidently necessary in raising the life expectancy and quality in marginalized communities.

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