Viability of 3D Printed Prosthetic Devices

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The Current State of Prosthetics and Where 3D Printing Fits

Each year in the United States, 158,000 patients undergo an amputation (Raichle et al., 2008). Additionally, up to 4,500 children in the United States each year are born with congenital limb deficiency, a birth defect causing partial or complete dysfunction of upper or lower limbs (Loder, 2004). Despite the substantial amount of people living without full limb function, 30% to 50% of individuals currently living with limb loss do not wear a prosthetic limb regularly (Duong et al., 2107). Patients decide not to use prostheses due to the lack of comfort in traditional prosthetic devices and the high cost associated with acquiring an artificial limb, which averages between $5,000 and $50,000 per device (Sharington, 2017). This could all change with the introduction of 3D printers to the field of prosthetics.

The proliferation of 3D printing technologies in the early 2010s has led to a dramatic shift in the field of prosthetics. Using this technology, people with limb deficiencies can now acquire their own custom fitted prosthetic limbs within days for less than $50 (“Enabling,” n.d.). Using the paradigm shift theory, the groundbreaking nature of 3D printing technology in the field of prosthetics will be analyzed in contrast to more traditional options for prosthetic limbs. Ultimately, the purpose of this research paper is to study the viability of 3D printed limbs as a practical alternative to traditional prostheses and the necessary steps that will enable 3D printed options to become the norm in the field of prosthetics.

Research Logistics

The research question for this paper is to discern whether or not 3D printed prostheses can be a truly viable alternative of traditional prosthetic devices and the extent to which this shift has already begun. First, documentary research methods will be used to find existing models or examples of this technology and its impact to outline exactly how prevalent this technology already is in the field of prosthetics, utilizing both databases and personal research. Historical case studies will also be used to create a timeline of modern prosthetic devices in order to properly contextualize 3D printed prostheses in a larger scope. Interviews with experts in the field will be conducted at the American Association of Orthotics and Prosthetics (AAOP) 2020 conference to gain first-hand insight into the cutting-edge technologies and practices in the field. Finally, the drawbacks of the technology will be analyzed in the context of their direct comparison to traditional prostheses in order to draw a conclusion on the research question posed.

What is a Prosthesis and How Does 3D Printing Work?

Prostheses are simply defined as an artificial replacement of a part of the body (Shiel, n.d.). “Prosthetic” is the adjective describing such a replacement, while “prosthesis” is the noun referring to said device. Prosthetic devices are not a new invention; in fact, they are a relatively ancient technology. The earliest recorded use of a prosthesis, an artificial toe belonging to a noblewoman found in Egypt, dates back to 710 B.C.E. (Bell, 2015). Since then, prosthetic devices have seen steady progress, from wooden legs to titanium false limbs. Scientific progress in mechatronic systems has introduced the capabilities for prostheses to be outfitted with sensors for closed-loop (sensor driven) control, ultimately approaching perfect mimicry of human movement. However, the vast majority of iterations in the field have been extremely cost-prohibitive. With the cheapest modern prosthetic limbs running for several thousand dollars, the barrier for entry for people experiencing limb loss is often too high to surpass. There is, however, a cheaper new alternative for prosthetic manufacturing that is beginning to revolutionize the industry: 3D printing.

3D printing is a broad term for the process of rapidly manufacturing custom models in almost any shape. This essentially boils down to machines with stepper motors in the x, y, and z directions that move a laser or nozzle to create precise geometries of a model layer by layer. The most common method of 3D printing involves stacking thin layers of thermoplastics extruded through a heated nozzle in accordance to a 3D model. This method is called Fused Deposition Modeling, or FDM printing. Other methods include solidifying liquid resin layers using a laser (SLA) and even melting metal powder to 3D print metal components (SLS) ("Types of 3D Printers", 2017). This paper will focus primarily on FDM and SLA processes, as they are the most common and relevant to the manufacturing of prosthetic devices.

The three key properties of 3D printed components that set them apart from parts made using other manufacturing methods are their cost, customizability, and speed of fabrication. While most plastic parts made for commercial products must be cast into a mold requiring custom machining and the creation of many units to turn a profit, 3D printing is suitable for creating small batch parts at a low price. The only startup costs for creating a part are the cost of the printer itself (modern printers range anywhere from a few hundred to several thousand dollars) and the cost of the filament used, which for most FDM machines is about $0.03 per cubic centimeter. Due to the layer-by-layer process, there are very few restrictions on the geometries that a 3D printer can produce. There is little barrier to entry for creating parts because there are vast amounts of free 3D models on the internet that anyone can download and print. Additionally, anyone with computer-aided design (CAD) skills can easily create novel models themselves. Finally, 3D printers are very fast compared to other manufacturing techniques like manual milling. A part can go from a 3D file to a fully constructed plastic part in a matter of hours. For these reasons, 3D printing has the potential to be an ideal method for the fabrication of upper and lower extremity prostheses, causing a paradigm shift in the field of prosthetics and the ways in which devices are manufactured.

3D printing as a Paradigm Shift in Prosthetics

Applying paradigm shift theory is useful to best understand the impact of 3D printing technology on the prosthetics industry. Paradigm shift theory is a framework proposed by Thomas Kuhn in his 1962 book *The Structure of Scientific Revolutions.* This theory proposes that scientific discovery is primarily made in two ways: incremental developments as what Kuhn describes as "normal science", and revolutionary discoveries that reshape general perception or how science is conducted. Specifically, a paradigm shift can be described as "an important change that happens when the usual way of thinking about or doing something is replaced by a new and different way' (Lombrozo, 2016). As 3D printing techniques become implemented in the field of prosthetics, the new technology fosters a new market for prosthetics, indicating a paradigm shift in the industry. Paradigm shift theory is not without its critics. A well-known review of *The Structure of Scientific Revolutions* by American philosopher of science Dudley Shapere stated that the definition for the idea of a paradigm was too vague to be useful. Yet, philosopher Alan Musgrave criticized the opposite. He claimed that in the second edition of the book where Kuhn reconciles the vagueness of the central idea of a paradigm took back what was revolutionary about the piece and, while making it more adequate as a piece of scientific literature, also made it more "boring" (Gutting, 1980). While these critiques are pertinent, paradigm shift theory has nonetheless become a widely used concept across different scientific disciplines. By nature, the examination of the effect of a breakthrough technology is well developed when viewed through the lens of paradigm shift theory, so it remains valid and relevant to apply the theory to this case study.

The sudden prevalence of 3D printing technologies in the early 2000s started a paradigm shift in the field of prosthetics. Why manufacture standardized devices for each client's unique physiology when custom parts can be created for a lower cost? What will keep people from creating these devices themselves? What does this mean for the future of the industry? These are all questions that are directly caused by the proliferation of 3D printing technology that must be addressed in context of a paradigm shift.

Results and Discussion- Are These Devices Viable?

The inclusion of 3D printing to the field of prosthetics has indeed started a paradigm shift, reshaping the perception of how to approach and solve problems inherent within. However, when analyzing all factors of viability for 3D printed prosthetic devices, it appears that there is still more work to be done before 3D-printed devices become a truly viable alternative to traditional prostheses. 3D-printed devices excel in aesthetics, comfortability, and affordability, but they are currently held back by their ability to function at the level of current traditional prostheses. With more research and continued improvement of 3D printing technologies, 3D printing could likely become the predominant method of production of prosthetic limbs in the future.

To address the viability of 3D printed prosthetic devices, the factors for viability must first be defined. Functionality is paramount for modern prostheses— if a device recipient can function as well or even better without the use of a prosthetic device, there is no incentive to use a prosthesis. However, other factors play a significant role in making the use of a particular prosthetic device desirable. Patients expect their prostheses to be both aesthetically beautiful and comfortable (Plettenburg). Finally, on a larger scale, an effective prosthesis should be as affordable and accessible as possible—developing the perfect prosthetic device means nothing if no one can afford or obtain the device. Therefore, the viability of 3D printed prosthetic devices will be evaluated on these five principles in direct comparison to traditional prosthetics: functionality, aesthetics, comfortability, affordability, and accessibility.

Functionality

Both upper and especially lower extremity prostheses incur significant forces during use, and the chosen material must be able to withstand the forces both cyclically and for extended periods of time. Traditional prosthetic limbs tend to last 3-5 years according to prosthesis manufacturer Ottobock, but they can last for a significantly longer or shorter time depending on the patient's activity level ("What to Consider", n.d.). Even if a 3D printed prosthesis can be manufactured quickly, for one such device to realistically compete in the market it must be comparably durable. 3D printed devices printed with affordable thermoplastics like PLA cannot compete with aluminum or even injection molded (a process in which melted plastics are fit to a mold for mass production) plastic devices. The anisotropic nature of layered 3D printed parts means that a part will always be vulnerable to both shear and tension in at least one direction. This essentially means that, when loaded in specific ways, the molecular adhesion between separate layers will always be weaker than anywhere else in the part. In addition, modern computer aided design (CAD) software packages have yet to include 3D printed thermoplastics into their finite element analysis (FEA) features, meaning the strength and performance of such parts under load are difficult to predict. For lower extremity prosthetics, it is currently unfeasible to create a fully 3D printed device, especially considering the large size restraint due to fixed print bed volume. However, there is promising data to suggest that certain lower extremity components can be effectively 3D printed. A 3D printed prosthetic foot designed in 2015 not only held the user's weight, but showed significant improvements in comfort and energy return over the SACH foot, a model that is commonly donated to developing countries (Yap & Renda). The material cost to make this particular design is less than $8, a far cry from the hundreds-to-thousands range of traditional prosthetic feet.

Figure 1. The SACH foot ("SACH Foot with Titanium Pyramid," n.d.) Retrieved from https://www.willowwoodco.com/products-services/feet/low-activity/sach-foot-with-titanium-pyramid/

Figure 2. Yap & Renda's 3D printed foot prototype V2 (Yap & Renda, 2015)

Similarly, 3D printed sockets are increasing in popularity throughout the field. Sockets are the part of a prosthesis which serves as the interface between the device and the residual limb of the user, and keep the device firmly secured to the user. Unlike the rest of a prosthetic device, the socket must be uniquely designed to best fit each individual patient, an area where 3D printing methods shine over injection molding due to the "one size fits all" parts mass produced to a mold. 3D printed lower-extremity sockets made for cushion liners have been proven to hold up to typical loads, and their static nature makes 3D printing an incredibly effective method for manufacturing them (Poussett, Lizcano, & Raschke, 2019).

Figure 3. Examples of 3D printed lower extremity sockets (Birrell, 2017)

In a presentation at the American Association of Orthotics and Prosthetics (AAOP) 2020 Conference, Minneapolis CPO Nicole Walker presented her research on 3D printed sockets, stating that subjects were satisfied with the products and generally couldn't distinguish between their laminated fitted sockets and the 3D printed sockets. However, after prolonged use, patients found the 3D printed sockets to form small cracks that could become problematic with continued use. Walker is optimistic that this technology could become more commonplace, but acknowledges the need for further research before full clinical application. "Before we know that we can start implementing these ideas and this technology in the clinic, we need to continue to put some evidence behind what we're doing… so that we know that this is a robust technology for use in the clinical environment" (Walker, 2020). In another presentation at the AAOP conference, Jared Howell, director of the Center for O&P Innovation at the Baylor College of Medicine, outlined the pros and cons of 3D printing in the field of prosthetics. In his studies, he found that patients were very excited about the idea of a 3D printed socket, and even claimed they felt lighter despite the devices weighing the same as other tested sockets (Howell, 2020). This is likely attributed to the texture caused by striated layer lines on 3D printed parts giving the socket more friction. Howell also brought up 3D printing as a paradigm shift, stating that the technology was allowing for problems to be solved in new and unique ways. “If our goal is to truly benefit the lives of the people that we serve… if 3D printing can make that better or provide an offering that wasn’t available under traditional techniques, that’s where we should explore and think about. The goal is to use those tools to provide better outcomes and better conditions for which our patients can thrive” (Howell, 2020).

Unlike lower extremity components, upper extremity 3D printed devices have a notable lack of quantitative data on their durability and use (Kate et al., 2017). While organizations like e-NABLE the Future are responsible for the creation of hundreds of 3D printed prosthetics every year, there is only anecdotal evidence to suggest that these devices are effective, with no standard for data collection or device measurement. While the lack of standardization for such devices proves beneficial to the development of new devices by any curious hobbyist with a 3D printer and CAD software, it also becomes exceptionally difficult to judge the effectiveness of the devices for their users. Fingertip force, the amount of pressure or lifting force that can be produced by a finger, is a useful metric for device effectiveness. In a study on one common 3D printed upper extremity prosthesis, the device produced a fingertip force of up to 11.5N, and had a grip strength of 1.5kg (Shima et al., 2009). While this does not match the average human fingertip force of 30N, it is sufficient for most daily activities (Lederman & Jones). One study analyzed the Raptor Reloaded, one of the popular prosthesis models by e-NABLE, and compiled the ability of the device to complete several specific tasks, the results of which appear in the following tables (Dally et al., 2015).

	Smallest Hand Size			Largest Hand Size		
Task	*Total No*	*Total Yes*	*Percent Yes*	*Total No*	*Total Yes*	*Percent Yes*
Pick up Coins	15	5	25%	14	6	30%
Push Buttons	0	20	100%	0	20	100%
Cut Food	11	9	45%	15	5	25%
Turn Page	0	20	100%	0	20	100%
Open Jar Lid	7	13	65%	4	16	80%
Pour Glass Jug	12	8	40%	11	9	45%
Pour Carton	14	6	30%	12	8	40%
Lift a Heavy Object	4	16	80%	0	20	100%
Lift a Light Object	0	20	100%	0	20	100%
Lift a Tray	10	10	50%	13	7	35%
Rotate Key	20	0	0%	20	0	0%
Open/Close Zipper	17	3	15%	18	2	10%
Rotate a Screw	20	0	0%	20	0	0%
Turn Door Handle	7	13	65%	6	14	70%

Table 1: Ability of Raptor Reloaded 3D printed hand to complete simple tasks

	Smallest Hand Size			Largest Hand Size		
Object to Hold	*Total No*	*Total Yes*	*Percent Yes*	*Total No*	*Total Yes*	*Percent Yes*
Tennis Ball	3	17	85%	0	20	100%
Ping Pong Ball	0	20	100%	0	20	100%
Bottle of Water	4	16	80%	0	20	100%
Cup	0	20	100%	0	20	100%
Soup Can	20	0	0%	8	12	60%

Table 2: Ability of Raptor Reloaded 3D printed hand to pick up common objects

Figure 4. e-NABLE the Future's Raptor Reloaded model. Retrieved from

http://enablingthefuture.org/2014/12/18/raptor-reloaded-design-and-intent/

While most 3D printed upper extremity prostheses are incredibly inexpensive, body powered devices, 3D printing has become a facet of high-end myoelectric (externally powered) devices as well. Open Bionics, a UK based tech company, is developing a 3D printed arm fitted with electrodes and motors that can sense muscle patterns in a residual limb and actuate specific fingers accordingly. The parts are printed using a selective laser sintering (SLS) process, fusing plastic powder selectively to make for a more durable product than FDM processes could create. These arms, while not nearly as inexpensive as body powered 3D printed devices, are substantially less expensive than other traditional myoelectric devices on the market. The arm currently costs around $3,000, whereas comparable myoelectric devices sell for around $95,000 (Jefferey, 2019).

Figure 5. Open Bionics' 3D Printed Hero Arm. Retrieved from https://www.accessandmobilityprofessional.com/prosthetics-firm-targets-nhs-affordable-3d-printed-super-hero-arms/

Some industry experts are pessimistic on the usefulness of such devices. "They're complete crap," says Jeff Quelet from Freedom Innovations, a prosthetic device company based in Irvine, CA. Quelet is a certified prosthetist and orthotist (CPO), as well as an amputee. In his eyes, the lack of durability of 3D printed devices prevents them from being worthwhile. "It's like building a car out of LEGO," said Ted Varlyey, chief technology officer of Covvi, an English prosthetics manufacturer, "sure, you could do it, but it's not going to last." These insights, along with evidence on the durability of 3D printed sockets by CPO Nicole Walker provided above, suggest that 3D printed devices may not yet be on par with traditional prostheses.

On a smaller scale, there is evidence for 3D printing as an ideal method for manufacturing prosthetic fingers rather than prosthetic limbs. Naked Prosthetics, a prosthetics company dedicated to developing prosthetic fingers for survivors of severe hand injury, currently uses 3D printers to manufacture artificial fingers using an SLS printing technique (*Naked Prosthetics*, n.d.). By nature, finger prostheses have the advantage of requiring less strength and range of motion than full limb prostheses. For this purpose, the advantages of 3D printing, namely personalized fitting and unique geometries, can be utilized while minimizing the drawbacks of the medium. At the AAOPP conference, users of Naked Prosthetics products were very enthusiastic about their devices and reported satisfaction with their product's utility.

Figure 6. Naked Prosthetics finger prostheses with 3D printed componentry. Retrieved from https://www.pacerehab.com/news/naked/

Aesthetics

In theory, prosthetic devices can take any shape or size. Often, hooks are used in place of full prosthetic hands if full gripping function is not deemed necessary for the patient or if affordability is an issue. However, a high degree of anthropomorphism (a similarity to human form) is desirable for upper extremity prostheses in order to best be suited for human-oriented environments (Gama Melo et al., 2014). While adults generally prefer skin-toned prostheses, children often opt for brightly colored devices (Kate et al., 2017). The artificial and replicable nature of prosthetic devices lends itself to a high degree of personal expression, sometimes even creating prosthetic devices as wearable artwork, as seen in movements like the Alternative Limb Project (*The Alternative Limb Project*, n.d.). 3D printing is perfectly suited for this realm due to the creative freedom and complex geometries that are possible with 3D printing. On a smaller scale, any person with minimal CAD knowledge can create their own custom 3D printed device to look exactly how they want it to. An aesthetically pleasing prosthesis can increase a patient's acceptance of a device and contribute positively to their well-being (Sansoni et al., 2014). This is especially pertinent with children who can take pride in their device to combat the bullying that comes along with almost any visible differences from the norm.

Comfortability

Discomfort is both a primary concern for patients who reject prosthetic devices entirely, and also for occasional nonuse in frequent device wearers. In one study, 95% of nonusers and 66% of frequent users cited discomfort as a major reason for prosthesis nonuse (Biddiss & Chau, 2017). Excessive weight is one of the most common causes of discomfort, which could be somewhat alleviated by 3D printed prostheses which could weigh 56% less than comparable upper extremity aluminum devices (Biddiss, Beaton, & Chau, 2017). The most significant benefit of 3D printing for the comfortability of prostheses, however, is socket personalization. By 3D scanning a patient's specific residual limb, a perfect negative can be made into a socket unique to the patient, increasing comfortability by increasing the contact area of the socket. Personalization of 3D printed sockets increased the tissue-prosthesis contact area by 408%

relative to comparable non-personalized devices (Tong et al. 2019). This increase in contact area is particularly significant considering that 95% of amputees report experiencing socket discomfort, and such an improvement in the prosthetic interface could alleviate some of this discomfort (Bhatia & Sharma, 2014).

Affordability

Affordability is the area where the benefits of 3D printed prostheses are most apparent. In 2009, the associated costs for treating those with amputations totaled over $8.3 billion (Silva et al., 2015). Individually, traditional prostheses are incredibly expensive, averaging between $5,000 and $50,000 per device (Sharington, 2017). Without insurance, patients are left with few options other than to go without a prosthesis. As mentioned previously, 3D printed parts could reduce these costs drastically. The simplest body-powered devices can be produced for less than $50. The cost benefits also extend to more involved devices as well. Externally powered myoelectric devices are more expensive than body-powered prostheses, priced at $25,000 to $75,000. The expected costs for cutting edge 3D printed myoelectric prostheses range between $1,000 and $3,000, still cheaper than most body-powered traditional devices (Kate et al., 2017). As more research is conducted and the functionality of 3D printed devices continue to improve, cost will likely be the primary differentiating factor between 3D printed and traditional protheses.

Accessibility

Even if a device is affordable, it must also be accessible to be a truly viable alternative to other prostheses, meaning the device must be able to be easily obtained. Accessibility to prosthetic devices is entirely different between developed and developing countries. In developed countries, prostheses are generally accessible, provided the patient has the means to pay for a device. 3D printed devices are arguably even more accessible due to the widespread adoption of 3D printers in public libraries and maker spaces. In less than 1 week, someone with a limb difference could order parts and print out an entire upper extremity prosthesis for less than $50. In addition, access to insurance is not needed to obtain a 3D printed device. Where the advantage of 3D printed devices in terms of accessibility is most obvious, however, is in developing countries. Of the 650 million people worldwide with a physical disability, 80 percent live in low-income countries where only 1-2 percent of the disabled population have access to rehabilitative services (Dally et al., 2015). Nonprofit organizations like the Range of Motion Project (ROMP) are dedicated to alleviating this discrepancy by providing prosthetic and orthotic care to people without access to those services (*The Range of Motion Project*, n.d.). 3D printing technology could potentially be utilized to reduce cost and increase device production to expand the impact of such an organization. However, more developments will need to be made before this becomes a reality. As the majority of jobs in developing countries involve manual labor, the lack of dexterity that is associated with a 3D printed prosthesis as seen in tables 1 and 2 would likely prevent the current devices available from being useful.

Regardless of the current degree of implementation of 3D printing, the proliferation of the manufacturing technique has caused a paradigm shift in the field of prosthetics. In his 1962 book *The Structure of Scientific Revolutions,* Thomas Kuhn identifies four stages of scientific discovery leading to a paradigm shift. First, normal science is practiced with generally accepted conditions. During this stage, the means and methods of scientific research remain generally unchallenged. This is the stage that prosthetics research exhibited until the introduction of 3D printing methods shifted the field into the extraordinary research phase. Here, the introduction of a radically-new manufacturing technique in 3D printing challenged the understanding of what was possible for production. Scientists conduct new research and collect potentially controversial data that challenges the status quo. This is current stage of the field of prosthetics as 3D printed prosthetics research continues to develop. In the near future, prosthetics research will likely enter the model revolution stage. Here, 3D printing methods could become an accepted and common method in the development of prostheses, upsetting previous norms. Finally, if deemed a useful and viable method by both patients and prosthetists, 3D printed prostheses would enter a post-paradigm shift period where normal science is again conducted with the new methods. While the latter portion of the cycle is still speculative for this particular field, applying paradigm shift theory poses useful and thought-provoking discussion on the future of the technology.

The most significant limitation in analyzing the viability of 3D printed prostheses is the lack of quantitative data on the durability of the devices. Low durability could ruin even the best prostheses, as constant replacements could prove too costly and cumbersome for a device to be considered worthwhile. While organizations like e-NABLE proliferate their designs and aim to help as many people as possible, they do not collect any usable data on the performance of their devices, a statistic that would seem crucial in improving them. Without this knowledge, it is difficult to make a definitive statement about viability. In addition, studies are limited by the small sample size of potential patients. Only 20% of people with limb loss are upper-extremity patients, with the other 80% being lower-extremity patients. With patients spread out across a large country as in the United States, conducted studies generally have a very low sample size, limiting the statistical significance of a given study’s findings.

For future research, the developments made in 3D printed prostheses should be monitored carefully. As new data is collected and perhaps even new standards are implemented, more quantitative data can be collected to better understand the use of 3D printing in the field.

Interviews with an amputee or other individual with limb loss who have used 3D printed devices should be conducted in order to get a more intimate understanding of their usefulness. More research should also be conducted to evaluate which prosthetics companies are currently looking into 3D printing as a means of manufacturing. Perspectives from these leaders in the field could round out a broad picture for the current and future niche that 3D printers could fill. It would also be useful to collect survey results on a subset of patients to asses their interest and understanding of 3D printed prosthetic devices. The science is ongoing, and as time passes and more professionals continue to adopt the technology into their practice, the future of field will become clearer. Ultimately, only time will tell how radical of a paradigm shift this technology will bring to the industry, and the results of this shift should be analyzed closely as these changes begin to unfold.

Conclusion

The application of 3D printing to the field of prosthetics brings revolutionary manufacturing techniques that have the potential to proliferate the industry. 3D-printed prostheses presently fulfill four out of the five conditions for viability: aesthetics, comfort, affordability, and accessibility. Yet, these devices fall short in the primary condition of function (with smaller devices such as prosthetic fingers as the exception). Without comparable function to traditional prostheses, 3D printed prostheses cannot be considered a viable alternative currently. However, the technology has started a paradigm shift in the field by altering perspectives on how to solve problems in accessibility and affordability. As the technology continues to develop and issues like durability become less of a prohibitive factor, 3D printing has the potential to become a predominant mode of prosthetics manufacturing in the near future.

This technology truly has the potential to change people's lives for the better. In several years when these devices can become more commonplace, it is entirely possible that access to a prosthesis could become a right rather than a privilege.

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