Ocular Prosthetics: The Socioeconomic Properties of Medical Technology

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

Technology is responsible for some of the greatest advancements in modern medicine. It has expanded the reach of care and improved the life expectancy and health status of countless individuals. Medical technologies are a vital part of modern medicine and have become near-ubiquitous in use. There are currently an estimated 2 million different kinds of medical devices available globally, belonging to over 7,000 different device groupings. They are used in a variety of settings by clinicians, opticians, dentists, and laypersons at home, and range from simple devices like bandages to complex ones like hip implants and diagnostic machines (*Medical Devices*, n.d.).

Although these technologies are essential, their advancement has been paralleled by a substantial economic price. Medical technology has been implicated as responsible for up to 50% of the increase in real per capita health care expenditure (Engineering (US) et al., 1988). Medical devices themselves can also be extremely expensive. Life-saving devices like cardiac defibrillators usually cost between \$20,000 - \$40,000, while more common devices like artificial knee and hip replacements cost \$5,000 + (Cost of Caring / AHA, n.d.). Although the economics of increased prices in medical technologies for the healthcare system is concerning, the personal cost of these rising prices lies in the significantly limited accessibility of medical technologies and devices to patients. Factors including cost, ease of use/complexity, and required resources can all limit the accessibility of a technology to patients. This can be a severe issue when the device or technology is necessary for the patient's well-being and physical and/or mental health. Because of this, it is imperative to consider the socioeconomic factors that may arise from the creation and use of medical technology, and whether they may limit accessibility for some intended users. A lack of understanding of the social implications of medical technologies will result in their failure to meet the needs of their users

One case where problems in accessibility for devices has important implications is the ocular prosthesis. Although accessibility issues may be more evident for common devices like orthopedic implants or cardiac stents, there is a lack of information and discussion on the social implications of accessibility issues for ocular prosthetic devices. It is a particularly interesting case because although a prosthetic eye is not medically necessary to sustain life, it is arguably necessary to allow patients who have lost eyes to live normally and comfortably. In this paper, I will explore the social implications and problems in accessibility for the ocular prosthetic, the effects these problems have on patients, and how the field of ocularistry may have to change in order to correct these issues.

Background/Context

Patients wear ocular prosthetics after conditions that result in the removal of an eye, to improve the appearance of the lost eye and protect the socket from potentially foreign bodies (Figure 1). Improved aesthetic appearance of the lost eye is vital to improving patient quality of life. Eyes are one of the first features to be noticed, so the loss of an eye can greatly impact an individual's psychological and



Figure 1: Custom-made ocular prosthetic (Chao, n.d.)

emotional well-being. Many patients with recognizable lost eyes report high levels of anxiety and appearance-related distress, which can lead to psychological trauma and fear of meeting new people. A prosthetic eye can help these patients restore their desired appearance, which improves reintegration into their community (Hatamleh et al., 2017). A well-fitting prosthetic eye can also help relieve stress from other difficulties that accompany losing an eye, such as adjusting to changes in vision like lost depth perception. Eye removal (enucleation) is also often unexpected and distressing; the most frequent cause is traumatic injury (often work-related), followed by

ocular diseases, tumors, and malformations (Modugno et al., 2013). In addition to the aesthetic and psychological benefits, the use of well-fit prosthetic eyes offers functional benefits. Ocular prosthetics protect socket tissue from foreign bodies, and occupy the empty socket space to prevent conditions like ulcers and infection (Hatamleh et al., 2017).

The two main kinds of ocular prosthetics available are stock (mass-produced) and custom-made. While stock ocular prostheses are a more affordable and accessible choice (around

\$15), custom ocular prosthetics offer much greater comfort and aesthetic appeal (Figure 2). They can further reduce the psychological burden accompanying the loss of an eye, and prevent complications that would damage the socket due to improper fit of a stock prosthetic. However, the financial burden of a custom ocular prosthesis for the patient is extreme and ranges from \$2,500 - \$8,300, excluding the cost of surgery for eye removal (*Prosthetic Eye*, 2018). This, in combination



Figure 2: Patient wearing stock (top) prosthetic vs. custom-fit (bottom) (Chao, n.d.)

with how custom prostheses must be replaced every 5 years for older patients and every 6 months for younger patients, results in recurring financial loss over the course of a lifetime. In addition, patients need to attend multiple clinic visits during the creation of the custom prosthesis, as well as check-up visits every 6 months to ensure proper fit of the prosthesis. This excludes patients with busy work or life schedules, and patients in poor health who have trouble attending regular appointments or who may experience distress as a result of the invasive fitting process.

Although ocular prosthetics have an established technical function of restoring patient quality of life and protecting the enucleated socket, they must also be evaluated on how well they

meet the needs of all users. In this case, the ocular prosthetic privileges some users while marginalizing others. Because of this, I propose that the ocular prosthetic possesses political properties that must be considered.

Theory

To support this proposal, I will be utilizing the framework of Technological Politics. This framework, outlined by Langdon Winner, states that certain technologies have political properties, and that they can be judged not only for their technical functions, but for the ways that they embody specific forms of power and authority. Winner describes instances in which the invention, design, or arrangement of a specific technical device or system becomes a way of settling an issue in a particular community. In these cases, the process of technological development is inherently biased, and results in the unintentional marginalization of certain social groups and the benefit of others (Winner, 1980). This interpretation suggests that it is imperative to consider all stakeholders during the process of technological development, as technological development itself can be inherently biased towards particular social groups.

Based on this framework, I propose that the technological development of the custom ocular prosthesis is inherently biased towards particular social groups, mainly those who are in good health, wealthy, and with flexible work schedules, and that this bias has devastating social consequences for excluded users. Throughout the analysis, I plan to show how it is imperative to consider all stakeholders and potential users when designing technology, and how medical device design often has inherent bias towards particular social groups. This will lead to a new interpretation of the social and political properties of ocular prosthetics.

Methods & Literature

There is a lack of information and awareness in literature about barriers to accessibility for ocular prosthetics. This could be because ocular prosthetics in general is somewhat of a niche topic, but their use is not uncommon - an estimated 5 million people wear prosthetic eyes worldwide (Pine et al., 2015). Most of the literature available on ocular prosthetics describes what they are and how they are used, as well as patient reports or case studies where custom fittings were done for a patient. To explore this topic, I had to look at a variety of different sources and compile information. One of the most important sources of information was the American Society of Ocularists (ASO) Conference (Nov. 2021) that I attended, where I spoke to some ocularists and learned from presentations on subjects ranging from how prosthetics are made, to FDA regulation, and more. To better understand differences between clinics, I looked at the websites of different ocularistry clinics and the policies and potential pricing they had, as well as the information on the process of creating a prosthetic. I also read different case studies that detailed specific cases of custom ocular prosthesis creation for patients and reasons why they had not been able to obtain one before. In addition, I looked at some YouTube videos and news stories to find more personal case reports and interview-style information to see how patients felt about ocular prosthetics and the difficulties they may have had while obtaining one.

Discussion

The Ocularistry Industry

While examining the social implications of ocular prosthetics due to problems in accessibility, there is value in looking first at why the price for a prosthetic eye is so high. One of the main impressions I got from the conference was that ocularistry and the creation of custom

ocular prosthetics is almost exclusively a family-owned practice. Methods of practice are passed down generationally, which meant that a lot of the methods discussed at the conference were old. There are some advantages to this, mainly being that the methods they used had been tested thousands of times and were successful; however, they have not changed substantially over the last century. The ASO is also the singular organization that has any sort of regulatory function over the clinics. Ocularists undergo training through the ASO and are expected to adhere to the ASO's standards of practice once they have their own clinics. The standards themselves were originally set by founding members in 1957 when the ASO was formed (*American Society of Ocularists*, n.d.) Within ocularistry, it seems like the families within the ASO have monopoly-like control over the production and cost of ocular prosthetic devices. Many ocularists consider what they do a specialized art, and they are able to set prices as they see fit. As mentioned previously, the price of a custom prosthetic ranges from \$2,500 - \$8,300 (*Prosthetic Eye*, 2018). Although there is certainly an artistry to ocularistry in the sense that the eyes are hand-painted and crafted specifically to fit each patient, they are also a necessity for patient well-being.

The price of a custom prosthetic is also high simply due to the amount of time it takes an ocularist to create a custom-fit eye. There are multiple appointments and consultations required for each fitting, in addition to time and resources the ocularist spends outside of the consultation perfecting the look and fit of the prosthetic. For example, Jardon Eye clinic in Michigan states that their custom prosthetics take 2-3 appointments to create. The second appointment where the ocularist paints the prosthetic typically takes 2-2.5 hours (*Jardon Eye | Custom Ocular Prosthetics*, n.d.). Ocularists at the conference agreed that normally they require 2-4 appointments for a custom fitting (*ASO Conference*, personal communication, November 15, 2021). The creation of the prosthetic itself has many detailed steps that involve taking a mold of

the patient's socket, sculpting the shape, and hand-painting it. Because of the amount of resources and time required to create these prosthetics, clinics are not able to see a high volume of patients. This effect is enhanced by how few ocularists practice in each state. Ocularist clinics are rare; for reference, there are only 4 practicing ocularists in Virginia (*American Society of Ocularists - Search by State/Province*, n.d.).

Additional problems in cost accessibility can arise in relation to insurance. Custom ocular prosthetics are sometimes not covered by insurance, which would increase the price of a prosthetic by thousands of dollars. Some insurance companies cover prosthetic eyes because they consider them to be Durable Medical Equipment (DMA).. However, benefits vary between plans and there are different guidelines regarding prosthetic replacement. For example, Medicare and Medicaid cover prosthetic eyes and related services. They require a request from an ophthalmologist prior to fittings, and cover 80% of the allowed amount (Custom Ocular *Prosthetics*, n.d.). Some insurances do not cover custom prosthetic eyes because they can be considered aesthetic and not medically necessary. In one video from 2017 from a talk show called "The Doctors", a woman appeared to talk about her troubles obtaining a prosthetic eye after losing her eye to cancer. She stated that her main obstacle obtaining one so far had been that "they're really expensive, and most insurances consider it cosmetic or a pre-existing condition so they're not going to cover it" (The Doctors, 2017). Even if insurance does cover the prosthetic, obtaining coverage can be a hurdle for patients. Submitting a claim often requires many personal documents and information, and sometimes a letter of necessity from a medical provider. The site of the ocularist clinic in northern Virginia states that although they will try to assist patients in filing claims, it is ultimately the responsibility of the patient to pay (Artificial Eye Clinic | Michael O. Hughes, Ocularist, n.d.).

Patient Cases

While examining the ocularistry industry itself can in part help to explain why prosthetics are inaccessible for some, it is also important to try to understand the patient experience as a result of these barriers. For a patient who has lost an eye, the use of an ocular prosthetic is monumental in helping them to regain normality in their life and reintegrate into their community (Hatamleh et al., 2017). If a patient is unable to access a prosthetic or unable to obtain one that is a good fit functionally or aesthetically, they could suffer from worsening physical and mental health. A number of cases highlight patterns in patient experiences with accessibility, showing that ocular prosthetics and their fabrication process selectively privileges certain groups of the population.

The most common type of academic papers I found on ocular prosthetics were case reports of patients who were not able to obtain a prosthetic for years and who were eventually given a custom fitting for free. The first such case was of a 60-year old man in India who had lost his left eye at 25 due to traumatic injury. Fortunately, his eye socket was healthy and had maintained its shape well enough so that a prosthetic could be made (Puranik et al., 2013). In another case report, a 62-year old female patient had a new prosthetic made after being unsatisfied with the appearance of her previous one. Unfortunately, she had lost her right eye due to chickenpox at the age of 6-7 and was not able to get her first prosthetic eye until she was 25 (Somkuwar et al., 2009). In the case of a particular geriatric patient, he was unable to obtain any prosthesis for 2 years following the loss of his eye due to the required large number of visits to the clinic, his financial status, and bad general health condition (Kamble et al., 2013). In these cases, the individuals went years without a prosthetic due to either cost or inability to attend appointments, which would've been a great psychological and social burden. In each case report,

clinicians indicated that the patients' quality of life was improved after receiving the new prosthetic.

Another common case were patients who wore stock prostheses because they were unable to obtain custom ones. For a 50 year old female patient from India, ocularist examination revealed she was using a stone as a placeholder in the eye socket, with a damaged and cracked stock prosthesis over it. The patient was in severe discomfort because the stone was heavy and would fall out of the eye while she moved; in addition, her eye socket was too dry and the lids were contracted (Murthy & Umesh, 2018). A different case report of a 42-year old male patient revealed that he had lost his eye to injury about a year prior and had been wearing dark glasses since, suffering from severe emotional trauma. The report states that the patient was not able to afford a fully custom prosthetic, but the clinicians were able to modify a stock prosthesis instead (Choubisa, 2017). While a stock prosthetic is better than nothing, their continued use can cause problems. In addition to the generic appearance of stock eyes, they also have more medical risks due to the collection of socket secretion behind the prosthesis and in front of the enucleated socket, which results from the imperfect fit between the concave backing of the prosthesis and the natural shape of the socket (Chao, n.d.). Unfortunately, because they are much more affordable (~\$15), they are the only feasible option for some patients, such as the male patient mentioned previously.

There are also instances where individuals have been able to get their original custom fit prosthesis, but have been unable to afford the necessary replacements in the years that followed. One news story reported how a teen had lost her prosthetic eye during hurricane Harvey while helping to evacuate her family, and that she had been depressed and worried about having to go back to school without it, as her family could not afford the \$3,000 replacement (KHOU 11,

2017). Fortunately in this case, her community raised funds to replace the prosthesis for her.

Ocularists at the conference also expressed that some of their patients do not like to come back to get adjustments for their prosthetics because they can't afford to (*American Society of Ocularists Conference*, personal communication, November 15, 2021).

These cases show that while custom prosthetics provide great benefit, they marginalize some of their intended users, in some cases to great harm. This marginalization may be unintentional; however, it is clear that its negative effects are noticeable. In general, the patient case reports reveal that ocular prosthetics and their design process privilege those who are wealthy, in good health, and with flexible schedules. Although it may be challenging, it is important to consider all stakeholders during the process of technological development, as technological development itself can be inherently biased towards particular social groups.

Potential Changes

The problems within ocularistry and the barriers to accessibility patients experience together show that the ocular prosthetic currently fails to meet the needs of its users. The whole creation process is inherently biased; but more importantly, many ocularist clinics do not appear to be making significant efforts to improve access for patients who have been previously marginalized. The stagnation within the industry is in part due to ocularistry's niche quality. The ASO is the only significant regulatory body in ocularistry in the US, and it promotes and reinforces the use of current methods that have been passed down through ocularist families. During a presentation at the conference on different methods of prosthetic creation, it was evident that all of the clinics used a somewhat similar technique, involving the mold-cast impression and painting the prosthetic after. Interestingly, when the idea of using alternative technology like 3D modeling and printing instead of current techniques was brought up, there

was definite resistance, with one family commenting that something like that would be perceived as a threat to their practice. Only one clinic agreed with the idea, and said that they had been integrating 3D technology into their manufacturing process to streamline some elements of creation (*American Society of Ocularists Conference*, personal communication, November 15, 2021).

It is certain that many of the socioeconomic issues arising from the custom ocular prosthetic are not intentional or planned by ocularists; however, it is the responsibility of the creators of technology to continuously monitor it once it is in use, and to improve it in the case of its failure. There are many potential ways that ocularistry could expand and change in order to accommodate patients who experience barriers to access. As mentioned previously, integrating 3D modeling technology could be one way to streamline some elements of creation. The one ocularist clinic at the ASO currently using 3D technology is creating scans and printing mold casts for prosthetics, which allows them to keep old casts to use as stock and streamline production. Not only would this be a way of staying familiar with the current advanced technology, it could also potentially reduce the resources and time required for the creation of custom prosthetics. This would allow ocularists to see more patients, and could justify a reduction in price for the prosthetics. Many research groups have explored techniques to digitally print the iris. Using digital imaging eliminates human error that could impact the appearance of the iris (Jain et al., 2010). In addition, while hand-painting the prosthetics has been custom for decades, digital photography has evolved during that time, offering greater color calibration technology and a standardized process for obtaining accurate images (Zoltie et al., 2021).

In addition to exploring 3D technology, there are other ways that ocularist clinics could increase patient access to care. Perhaps they could offer a product somewhat in between that of a

stock and fully custom prosthetic. If they kept a selection of custom prosthetics they have made for previous patients, they could allow customers to view and purchase models of different shapes and appearances online. Or perhaps patients could visit a clinic for a single appointment, where the ocularist could advise them on which of the stock models would best fit their eye shape and appearance. While users may not have access to fully custom-fit prosthetics through this method, they would still be getting a product with significantly higher aesthetic appeal than a generic stock model. This would benefit users who have less flexible schedules and cannot travel for an ocularist appointment, and those who cannot afford a fully custom prosthetic.

There are some limitations on these suggested changes. Primarily, the ocularist clinics may not have the capacity to accommodate additional patients through integrating some of the aforementioned changes. Integrating 3D or other advanced technology would also probably be difficult to adjust to, at least at first. The main issue is that ocularists and the ASO need to place higher priority on improving and expanding patient access to care in any way, as it did not appear to be a main priority. It is also important to note that some of the socioeconomic problems associated with the ocular prosthetic have root in much deeper problems that will not easily be fixed. Mainly, the issues concerning insurance coverage are more systemic. Perhaps this could be addressed with increased ocularist cooperation with the FDA; however, many clinics are reluctant to register with the agency due to the required registration fees (*American Society of Ocularists Conference*, personal communication, November 15, 2021).

Conclusion

In summary, the socioeconomic implications of ocular prosthetics are a niche issue that is lacking attention within the ocularistry industry. Based on technological politics, ocular

prosthetics can be judged not only for their technical functions, but for the ways that they embody specific forms of power and authority. In these ways, ocular prosthetics fail to meet the needs of their users and privilege those who are wealthy, young, in good health, and with flexible work schedules. This is due to a combination of factors stemming from the monopolistic nature of ocularistry. Barriers to access for users has resulted in many patients being unable to access a prosthesis for years, or wearing a generic stock prosthesis that does not fit them in shape or appearance. This is an especially concerning issue considering the importance of a prosthetic to a patients' physical and mental well-being.

The important steps for now are to recognize the significance of the problem, and take reasonable steps to begin correcting it. It is not only important to judge technology while it is being created, but also once it is in use in the general public. It is certain that many unanticipated problems will arise after a product is in use, and even over time as society evolves. Perhaps ocularistry needs to become a more accessible field of work as well. If ocularists expanded the methods they used, there could be more clinics that could specialize in different practices, which would allow more patients to be treated. Or, focusing on more immediate potential solutions, clinics could explore integrating 3D technology or other ways to expand patient access to care. A potential area of future research could be looking into 3D technology to fully 3D print an ocular prosthetic, which would greatly streamline production. It would also be beneficial to investigate how to get prosthetics covered by more insurances, which would likely involve the reclassification of prosthetic devices by the FDA.

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