Utilizing 3D Technology in the Ocularistry Industry to Improve Accessibility, Affordability, and Patient Comfort

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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:

In Fairfax, Virginia, a high school English teacher named Mr. Syder prepares daily lessons and meets with students. He is a well-loved teacher among the students and faculty. Each morning, he cleans his ocular prosthesis and carefully places it underneath the lids of his empty eye socket, similar to a contact lens. Like Mr. Snyder, many people wear ocular prosthetics to restore a normal facial appearance. When I spoke with him last July, it became clear that wearing an ocular prosthesis is an important part of his appearance–like putting on shoes or wearing a coat (S. Snyder, personal communication, July 8, 2021).

Every few years, when Mr. Snyder visits his ocularist–the craftsman who makes prosthetic eyes–he will endure a painful fitting procedure, spend thousands of dollars, and likely travel a long distance. Although Mr. Snyder needs a new prosthesis to prevent medical complications due to natural wear and tear on his current prosthesis, he will not be able to easily obtain one. Worldwide, five million people wear ocular prosthetics (Keith R. Pine et al., 2015). These people may have endured trauma to the socket, suffered from retinoblastoma, or developed a painful blind eye as a result of diabetes, among other conditions, that led to their eye removal and needing a prosthesis (Günalp et al., 1997). In ocularistry today, prosthetic eyes cost between $1800 and $8500, making them difficult for many people to afford (Collins, 2019). Custom prosthetics are made using the injection of hydrocolloid impression material into the empty socket, which is a painful experience for patients. On top of the money and pain being strong deterrents, patients will likely travel far to get to an ocularist's workshop, since they are such rare craftsmen. Many patients without adequate financial means or ability to travel long distances opt out of buying a custom prosthesis, leaving them vulnerable to medical complications as well as social and professional repercussions since they cannot conceal their disability.

In order to make an ocular prosthesis available to anyone seeking one, the ocularistry industry has to change. The barriers to buying a prosthesis need to be reduced and the painful procedure to create a prosthesis needs to be revamped using 3D scanning technology. 3D technology would streamline the process, saving time, resources, and patient distress since ocularists could forgo the use of impression materials. Unfortunately, the technology exists, but has not been implemented. Unlike its sister industry, anaplastology, ocularistry uses no 3D scanning tools. My research seeks to understand and explain the factors that have contributed to the current state of ocularistry and why the necessary changes to the industry would be difficult to instantiate. Ignoring this problem would result in the continued privileging of patients able to afford a prosthesis and marginalization of those who cannot.

Background:

To be able to understand ocularistry, it is important to first understand the preceding surgery, enucleation, which necessitates use of an ocular prosthesis. Many circumstances can lead to enucleation, or surgical removal of the eye, with the most common being trauma (Farokhfar et al., 2017). During enucleation, a surgeon will remove the globe but leave behind the muscles that control eye movement, which will still move in accordance with the contralateral eye post-enucleation. After the eye is removed, the lost volume is replaced with a spherical implant to maintain facial symmetry and prevent drooping over time. Eventually, when the implant and subsequent prosthesis rest on top of the eye muscles, they will move in the appropriate direction, but the movement appears slower and slightly out of sync. I have personally met with patients who wear ocular prosthetics and observed that even the best custom prosthesis has the appearance of a lazy eye. Without a prosthesis, the socket's outward appearance looks as if a layer of pink scar tissue, called the conjunctiva which is sewn across the top of the orbital implant, is exposed (Leclerc & Olin, 2020).

The prosthesis lies on top of the pink scar tissue (Figure 1). There are two types of ocular prosthetics which patients have the option of choosing after enucleation. A patient can either buy a stock ocular prosthesis or be fitted for a custom prosthesis; custom prosthetics are recommended by physicians due to their superior fit and comfort (Barman et al., n.d.). The current process of creating a custom ocular prosthesis is complicated and takes multiple clinical visits. In order to obtain topographical information about the empty socket such as the volume of the cavity and fornices, silicone-based impression material is put in the socket until the eyelids lift to their normal position. The procedure resembles the process of creating dental impressions for a custom retainer or braces. Because of the discomfort caused by this step of the process, children are sometimes sedated. After several more steps, an ocularist will cast the prosthesis in acrylic. The intricate details of the iris and veins of the sclera are hand-painted at the end (Barman et al., n.d.). To properly upkeep the prosthesis, adult patients are advised to replace their prosthesis every 3-5 years, while children may need a replacement multiple times a year (Bonaque-González et al., 2015).

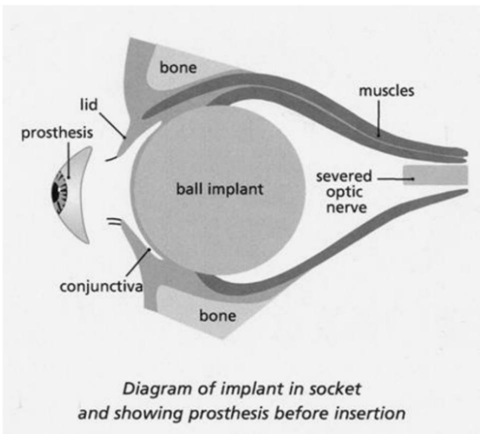

Figure 1: Prosthesis and implant

The fabrication technique has been passed down generations largely through familial apprenticeships (R. Dudash, personal communication, November 18, 2021). There are relatively few official guidelines for how to make an ocular prosthesis, and the ones that are in place are scarcely enforced. Today, ocularistry is essentially a monopoly due to several factors including the impressive accuracy of the final ocular prosthesis, the limited number of ocularists, circumstances of the patients in need of a prosthesis, and the ability to direct patients with more complex needs to anaplastologists.

Analytical Framework:

Methods:

To answer the question of why ocularistry has not incorporated technology into practice, I will evaluate the factors that have contributed to the current state of the industry. In my research, I will consider the personalization and labor that goes into creating an ocular prosthesis, which justifies the price. To do this, I will collect data on patient satisfaction with their ocular prosthesis from studies performed through the Korea University, College of Medicine, specifically focusing on patients' opinion of the final product and price. Second, I will consider how the limited number of ocularists has allowed the industry to thrive with few regulations. In this step, I will research the regulatory board of the ocularistry industry, the American Society of Ocularists (ASO), and use my first hand experience attending the ASO's annual conference. Thirdly, I will consider the circumstances of ocular prosthesis patients, which affects their role in the industry. I will include the most common causes of enucleation and the psychological hardships associated with living with a disability. In this step, I will include ocular prosthesis patients' quality of life using data from a study at the Moorfields Eye Hospital in the United Kingdom on how well patients adjust to their disability post-enucleation and evaluate the patient experience through the lens of Erikson's stages of psychosocial development. I will conclude my research by analyzing the influence of anaplastology on ocularistry. I will do this by evaluating the different technologies used by both industries, how their capabilities differ, and the implications that this has for ocularistry. I will then explore why it may be easier for the anaplastology industry to incorporate technology than it is for ocularistry.

***STS Theory*:**

To construct my analysis of the ocularistry industry, I will use actor network theory (ANT) as a framework. ANT is a methodology that suggests that a socio-technical system is influenced by actors, which each affect the system's activity or functioning. ANT explains the social aspects of a given system by evaluating the roles of these actors, which can be either human or non-human (Crawford, 2020). ANT applies very well to my analysis because the socio-technical system I am researching, the ocularistry industry, is affected by many actors. The ocular prosthesis itself, ocularists, patients, and anaplastology have an influence on ocularistry in meaningful and diverse ways. Ocularistry is complex, but can be better understood by exploring the aforementioned actors and how their interactions are interwoven in the field today.

Actors of the Current System:

Ocular Prosthesis:

The first important actor is the ocular prosthesis, which interacts with both patients and ocularists. Although the fabrication process of custom ocular prosthetics is inefficient, the resulting prosthetics are highly realistic and effective at protecting the socket, which is why they continue to be used. As shown in Figure 2, the ocular prosthesis is an impressively accurate replica of the lost eye. Although patients may endure a distressing fitting process or pay a high financial price, the general consensus is that patients are often satisfied with their prosthesis (R. Dudash, personal communication, November 18, 2021; McBain et al., 2014). Additionally, patients are fond of the personal touch that hand-painting the prosthetics offers. That being said,

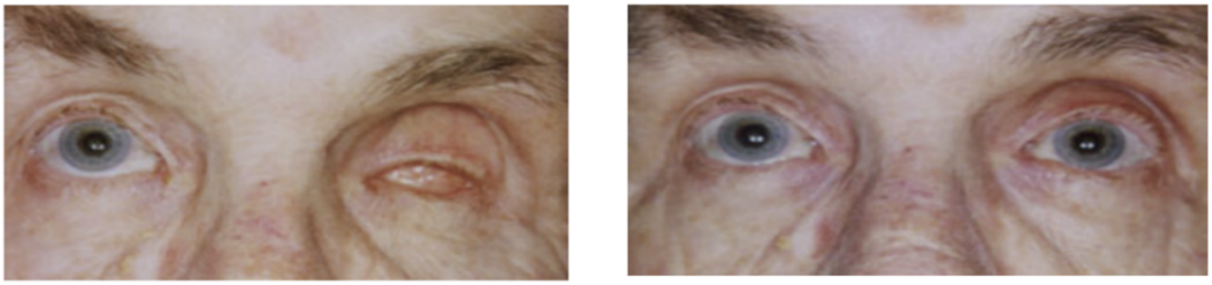

Figure 2: Patient with enucleated socket (left) and wearing a custom ocular prosthesis (right)

ocularists have the advantage of pricing their prosthetics how they see fit because of the personalization and high attention to detail that often goes into the fabrication process.

While this may benefit the ocularist, many people in need of a prosthetic eye will be faced with insurmountable financial barriers that lead them to purchase a stock prosthesis instead. As such, ocular prosthetics selectively advantage patients able to afford high prices and with sufficient time to attend numerous appointments. These problems reinforce the power dynamic between different socioeconomic classes in the United States since patients willing to pay are able to reap the benefits of concealing their disability, while others are not.

Figure 3: Stock ocular prosthesis (right eye)

A cheaper alternative is a stock prosthesis. Stock ocular prosthetics, which can be purchased for $15 on eBay and do not require an extensive fitting process, appear much less accurate than custom prosthetics and subsequently draw more attention to users' disability (Figure 3). There is also a greater risk of medical complications with stock prostheses due to the potential for socket secretion to collect between the backing of the prosthesis and the contours of the socket as a result of the imperfect fit (E. Shildkrot, personal communication, June 18, 2021). A study of ocular prosthesis satisfaction from the Department of Ophthalmology in Korea University, College of Medicine revealed important results. Although 71.8% of patients surveyed reported satisfaction with their prosthesis, the variable most associated with patient dissatisfaction was economic status (Song et al., 2006). A patient's ability, or lack thereof, to pay for a prosthesis is clearly a problem and warrants evaluation.

As an example, the main clinic serving the Charlottesville and Northern Virginia area is the Artificial Eye Clinic. In order to obtain a prosthesis, their prices oscillate around $1500, *after* coverage from insurance, which is on the lower end of prices for ocular prosthetics. The manufacturing time is four clinical visits, spaced out depending on patient and ocularist availability. Once the process is complete, the resulting prosthetic eye accurately mimics the lost eye (*Artificial Eye Clinic | Michael O. Hughes, Ocularist*, n.d.). However, $1500 may be a steep price to pay for a parent of a growing child who requires a new prosthesis once or twice a year or someone already struggling financially. As such, ocular prosthetics have two main roles as actors in the ocularistry industry. First, the ocular prosthesis interacts with patients by giving them back their preoperative facial appearance. Secondly, the prosthesis interacts with ocularists by giving them their livelihood. Because of this balance between patient and ocularist satisfaction, the current system, albeit inefficient, prevails, with patients unable to pay being left on the periphery.

Ocularists:

Ocularists are another key actor in the system. Since ocularists are rare craftsmen, few practice today. For reference, there are only six ocularist clinics in Virginia (*American Society of Ocularists - Search by State/Province*, n.d.). The limited number of ocularists exacerbates the affordability problem by creating a pricing monopoly as well as limits the ability of patients living outside urban areas to obtain a prosthesis. Also, since the field is small and the fabrication process is highly complex, trade secrets and a lack of standardization bar outsiders from learning the technique; ocularists have the advantage of inflating prices knowing patients have few other options and virtually no other desirable options.

The regulatory board, which is a part of the American Society of Ocularistry (ASO), is a prime example of how close-knit and niche the field is. After speaking with ocularists and ophthalmologists at the ASO's annual conference, it became apparent that a select few families hold the majority of board positions. Walking into a room of ocularists as an outsider can be compared to wearing a red sign labeled newcomer on one's forehead. Ocularists from across the United States and even Canada seemed to have known each other for years. They spoke to each other casually and had clearly shared long term friendships. Because of this, regulating ocularistry is also informal. At the conference, one speaker raised the issue of random checks from the Food and Drug Association (FDA) to a panel of ocularists. Immediately, the room became tense and many ocularists exchanged concerned looks. After a brief pause, one ocularist explained that most ocularists are not registered with the FDA so mentioning a possible surprise visit was alarming. Without the FDA's guidelines, most of the ocularistry's rules come from within the ASO, which is made up of other ocularists who have been in the business for decades. This lack of oversight and familial business style have created an industry that is not easily amenable to changes. As a result, the method of creating an ocular prosthesis has remained largely untouched since its inception. Accordingly, neither patients nor ocularists are able to reap the benefits that could result from using technology to save time, effort, and resources in the fabrication process.

The Patient:

Patients are also important actors in ocularistry. Eyes are often the first part of the face to be noticed. Studies on infants' gazing patterns reveal a clear preference for eyes compared to other parts of the face (Dupierrix et al., 2014). Instinctually, humans interpret situations and understand emotion by looking at someone's eyes. This makes the loss of an eye even more devastating than a loss of another part of the body. A patient wears an ocular prosthesis for two reasons: improving aesthetics and protecting their enucleated socket. As previously mentioned, circumstances such as trauma to the eye, cancer, or diabetes can necessitate an ocular prosthesis. Therefore, obtaining an ocular prosthesis is not an isolated medical treatment. Rather, patients are likely in recovery from their enucleation surgery or in the midst of other treatments when a prosthesis becomes necessary. Additionally, in 53% of enucleations, patients are less than 30 years old (Günalp et al., 1997). Since growing pediatric patients have to replace their prosthetics more frequently than adults, this figure means it is likely that many patients will need to have regular visits to their ocularist. Also, the stage of life that most patients are in when undergoing enucleation affects how challenging the transition from their pre to postoperative appearance may be on their psychological wellbeing. For young, ill patients, a simple and affordable procedure for obtaining an ocular prosthesis is imperative to make the process as seamless as possible.

The psychosocial benefits of a custom ocular prosthesis must be considered to understand the pressure patients are under when they first need a prosthesis. According to Erik Erikson's stages of development, people face the challenge of identity versus role confusion when they are between the ages of thirteen and twenty-one. For a young, healthy patient who suddenly must permanently identify as disabled, they may experience difficulty establishing their sense of self and identity. Then, between the ages of twenty-two and forty, people struggle with intimacy versus isolation. At this stage, an ocular prosthesis patient may suffer to grapple with their new physical appearance in the face of establishing long term romantic relationships (Orenstein & Lewis, 2022). Regardless of their stage of life, undergoing the traumatic experience of losing an eye, which is so difficult to conceal, will be a psychological challenge for patients.

Patients may also experience difficulties in the social and professional world. In a recent study at Moorfields Eye Hospital in the United Kingdom, individuals with ocular prosthetics reported having "difficulty with social interactions." A considerable number of study participants experience "significant distress" as a result of their prosthesis (McBain et al., 2014). These challenges inevitably affect patients' willingness to purchase a superior custom ocular prosthesis instead of a stock. For many patients, despite the financial barriers, there is no other choice than to take on the financial burden since the alternative inadequately conceals their disability and may be dangerous for their health. As a result, patients keep the system in equilibrium by investing in the quality of their new prosthetic and choosing to purchase a custom prosthesis. Patients interact with both ocularists and the ocular prosthesis in the system; the patient agrees to pay for services from an ocularist while also making the choice to buy a highly detailed, custom ocular prosthesis.

Similar industry–anaplastology:

In addition to the other actors discussed, anaplastology also influences ocularistry. Anaplastology is a field of maxillofacial prosthodontics; simply put, it is the industry for creating facial prosthetics including the ear, nose, cheek, or a combination of multiple parts of the face. Although anaplastologists and ocularists both have the same goal of restoring patients' facial appearance, the mere existence of anaplastology has contributed to ocularistry's lack of incorporation of technology. For example, if a patient has a severely irregular eye socket due to trauma that the ocularist's current fabrication method could not accommodate, the patient would simply be sent to an anaplastologist. In this way, anaplastologists are essentially taking patients from ocularists because of their advanced technology capabilities. While it may seem that anaplastologists have a small role in ocularistry since they sometimes collaborate at conferences and in special patient cases where both their skills may be necessary, their influence actually causes problems. Furthermore, anaplastology clinics have historically been affiliated with hospitals or academic institutions (see Discussion). Consequently, anaplastologists have better access to patients compared to ocularists. Physicians may also be more inclined to recommend patients to anaplastologists over ocularists because of their quicker and less painful imaging methods. Even if an ocularist may be capable of creating a prosthetic for a complex case, they may never see these patients because of the superior capabilities of anaplastologists' techniques, which makes them the preferred option.

Essentially, this lowers the incentive for ocularists to improve their processes. Because of anaplastology, ocularists are faced with complex eye-related cases less frequently. Ocularists are still able to successfully create impressive prosthetics for their smaller patient population and earn their livelihood. Therefore, it seems that there is little reason to modify their technique. However, anaplastology may also be a threat to ocularistry. If technologies used by anaplastologists continue to improve, they may be able to complete an ocularist's job more accurately and efficiently.

Discussion:

Although anaplastology plays a role in ocularistry today, it can also be used as a point of comparison to better evaluate ocularistry. The fields of ocularistry and anaplastology are so similar, yet their practices are very different. Many factors have caused the differences between these two fields, two of which are historical precedent and affiliation with academic or medical institutions.

Anaplastology was formally created in the United States in 1980 at Stanford University, while ocularistry can be dated back to the fifth century BC. At its onset, anaplastology was focused on rehabilitating patients who had undergone traumatic injuries. Since its founding at a large institution associated with a top hospital, most anaplastology patients had recently taken medical scans as a result of their injury. Whether it be computed tomography (CT) or magnetic resonance imaging (MRI), anaplastologists often had access to these data to aid in their facial reconstruction. The first anaplastology organization's founder, Walter Spohn, was even a consultant on Stanford University's department of surgery, giving the field a strong advantage over ocularistry since the resources it received from both academic and medical institutions was substantial. Soon after its start as an industry, anaplastology became a worldwide recognized field of facial reconstruction (*History*, n.d.). In contrast, the origins of artificial eyes can be traced back to ancient Egypt, where glass was used to create an ocular prosthesis. The more modern approach that is still being used today (see Background) was developed and fine-tuned in the United States during the World War II era. During wartime, the first modern ocularists did not have the 3D scanning technology that their anaplastologist counterparts had access to. Instead, ocularists modeled their fabrication process after dental prosthetics (*The History and Evolution of Prosthetic Eyes | Blog*, 2015). The technique worked well given the technology available at the time. Since the second World War, ocularists have operated in workshops throughout the United States and have grouped into their own organization without official ties to medical institutions.

As the fields evolved, anaplastology, which remained closely affiliated with academic institutions, went on to incorporate 3D structured light scanning technology if patient data from recent medical scans were unavailable. In a review article of ear prosthetics, a subfield of anaplastology, 3D scanning methods are described as "significantly better than the conventional method"(the conventional method refers to that used in ocularistry) (Thotapalli, 2013). The conventional method is criticized as relying significantly on artistic skills and uses much more time and resources than 3D scanning. However, structured light scanning technology is often extremely expensive. A summary of 3D scanning technologies from a recent international conference on 3D body scanning devices revealed that high end scanners oscillate around $27,000 ("Application of 3D Scanning in Prosthetic and Orthotic Clinical Practice," 2016). Therefore, it's much more feasible for an anaplastology clinic with the backing of an academic institution or hospital to purchase these scanners than an ocularist.

However, as technology evolves, 3D scanning is becoming more accessible and affordable. One potential solution for ocularistry that could bridge the gap between the two industries is photogrammetry. Photogrammetry uses contactless 360° imaging to triangulate points based on surrounding light intensity and generate a 3D mesh model from 2D pictures (Lussu & Marini, 2020). There are minimal expenses associated with photogrammetry since the photos can be taken with any digital camera and the mesh model can be generated in free software. Also, photogrammetry does not use radiation to generate meshes, making it a very safe scanning tool. If photogrammetry were to be incorporated into ocularistry, patients could receive their prosthesis with far fewer clinical visits, and the uncomfortable impression step would be completely eliminated. As such, photogrammetry has the potential to provide great benefit to the ocularistry industry.

With photogrammetry, ocularistry could expand its horizons to be able to scan complicated eye-related cases, which the industry is not currently capable of. Although there have been small advances in ocularistry, none have amounted to any significant change in the field, which I argue is a result of the high cost and unsafety of previously used imaging methods. For example, in Leuven, Belgium, researchers successfully fabricated a custom ocular prosthesis using non-contact scanning, but unfortunately incorporated cone-beam computed tomography, which uses radiation and would be unsafe to use for certain groups of people such as pregnant women and young children. In addition, the equipment required for the method is valued around $100,000 (Ruiters et al., 2021). As a result, the method has not been adopted in ocularistry. I suggest the best way to introduce photogrammetry into ocularistry would be to introduce the technology to a small subset of ocularists first. Since ocularists are such a small group, they may trust the judgment and value the experience of another ocularist more than someone from a different industry. Once the technology works well in a few ocularistry clinics, it may be much easier to advertise it to the larger community. This is significant since, without any changes, ocularistry will suffer as anaplastology continues to advance and soon be able to create ocular prosthetics with superior accuracy and efficiency.

Conclusion:

Regaining normal facial appearance is a major challenge for patients post-enucleation. This challenge is exacerbated with limited financial resources. Therefore, allowing equal opportunities to obtain an ocular prosthesis should be the highest priority. According to the utilitarian principle of bioethics, engineering design should strive to produce a net balance of benefit over harm to the public. The design process is meant to create products that serve their users. Without reevaluating and redesigning the process of creating an ocular prosthesis, the industry will continue to marginalize some while privileging others and create devices that do not operate with the users best interest in mind, or worse, inadvertently cause harm.

In ocularistry, the product–ocular prosthesis–has a major impact on patients' lives. Patients are expected to use their prosthesis daily and trust that it will be crafted well enough to be naturally integrated into their facial appearance. Importantly, patients trust that their healthcare providers will guide them to the best decision. They also expect their prosthesis to be durable, withstanding day-to-day wear and tear. Lastly, ocular prosthesis patients trust that they will not be put in harm's way during the fitting process due to extreme discomfort from an intolerable procedure. Today, several actors in the ocularistry industry are at play in creating the current state of the field. The fine detail and astonishing accuracy of the ocular prosthesis, patients willingness to go through extensive lengths to obtain a decent prosthesis, ocularists own ability to earn a livelihood by being able to price their serves very high, and anaplastology existing to handle any cases ocularistry cannot due to its limited technology all interact in complex ways to maintain equilibrium in today’s ocularistry industry.

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