Prospectus

The Creation of Two Novel Biomaterials and Investigation into their Mechanical and Biodegradability Properties

(Technical Topic)

Bioplastics as a Solution for Plastic Medical Waste

(STS Topic)

By

Wyatt Black

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Technical Project Team Members: Alec Brewer, Ryan Crosser, Cutter Grathwohl, Tilden Winston

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.

Signed: _______Wyatt Black____

Approved: ____ Date _________________________
Rider Foley, Department of Engineering and Society

Approved: James F. Groves Date _____11/24/20____________
James Groves, Department of Engineering and Society

Introduction

In today's hospitals, single-use plastics are seen everywhere from syringes, gloves, medical device packaging, pipets, and bandages. They are an integral part of the healthcare system and provide a vital role in the prevention of the spread of bacteria and infectious diseases (Gibbens, 2019). However, since they are considered a biohazard in the United States (US) they are required to be incinerated or sent to special landfills (WHO, 2000). These unsustainable practices have led to increased amounts of medical plastic waste contributing to damage to the environment.

A catalysis for the adoption of single-use plastics occurred in the 1980s and 90s during the peak of the HIV/AIDS pandemic (North, 2013). Hospitals looked to find an alternative to metal syringes that would be washed between patients. Single-use plastics were able to provide that security. They are cheap, easy to manufacture, germ-resistant, and easy to sanitize (North, 2013). Above all else, they are disposable and can be thrown away after use. Since then they have become commonplace, but after years of throwing plastics away the consequences are just beginning to emerge. This plastic waste build-up is only exacerbated by events like the COVID-19 outbreak and the Chinese “National Sword” policy. In 2020, the outbreak of COVID-19 caused an increase in single-use plastics due to the fear of transmission of the virus. The US generated an entire year’s worth of medical waste in two months because of the impact of COVID-19 (Cutler, 2020) More plastic will continue to accumulate due to the enaction of China’s “National Sword” policy which reduced their import of US plastic waste by 99% (Katz, 2019) All of these things combined lead to medical waste piling up with no way to deal with it and these plastics end up just being burned or buried.

Environmental Harm

Plastics that are discarded in landfills or incinerated cause problems for the environment no matter the source. As time goes on their negative effects only begin to compound and get worse. When plastics are irresponsibly dealt with, they can leach toxins into the air, water, and soil. In the case of incineration, plastics like PVC, a common single-use medical plastic, can lead to lead, dioxin, and mercury being released into the environment (Okafor, 2018). Improper landfill containment can leach compounds like bisphenol A (BPA) and di-(2-Ethylhexyl) phthalate (DEHP) into groundwater (North, 2013). These compounds can lead to complications including cancer, insulin resistance, and damage to reproductive systems (North, 2013). If not in a landfill or burned, plastics can find their way into waterways and lead to partial decomposition and the creation of microplastics. These microplastics can carry harmful compounds via drinking water or cause damage to marine life (Okafor, 2018).

The medical industry is responsible for some 850 million pounds of plastic waste per year (North, 2013). Most of which is incinerated or landfilled due to the fear of downstream contamination when recycled. The problem is that almost 85% of medical plastic waste can be cleaned or recycled but the status quo is to just burn or bury it (WHO, 2000) This occurs because the recycling programs and autoclaving techniques, which sterilize and shred plastics, are too expensive or too labor-intensive for most hospitals (WHO, 2000) This problem isn't across all hospitals worldwide, the US has the highest amount of plastic waste coming in at 8.4 kg/bed/day (Minoglou, 2017) When compared to Europe, the US has about double the amount of waste. Even over the most wasteful country of Spain coming in at 4.4 kg/bed/day (Minoglou, 2017). Operating rooms are among the biggest problems, amounting to about a third of hospital waste and includes items such as IV tubing, syringes, packaging, gowns, and single-use plastic surgical tools (Glauser, 2016). Some procedures can have upwards of 20 pounds of waste (Gibbens, 2019). This massive amount of US plastics waste is a combination of a couple of underlying factors such as high GDP, high life expectancy, high healthcare expenditure, high AIDS prevalence, and high C02 emissions (Minoglou, 2017). Overall, the US creates more medical waste than any other country and if something doesn't change irreversible environmental damage will occur.

The technical innovation of this project is twofold. First, in regards to the two novel biomaterials that will be created for this project and secondly, how they will be joined together into a hybrid biomaterial. This hybrid material will have greater mechanical strengths and degrade faster than either part on their own. This will provide a product that can be used in place of traditional petroleum-based plastics that offer the same level of sterilization and mechanical properties but can be degraded properly as not to harm the environment. Further, this project will investigate the social factors that first created this environment for single-use plastics in the first place and why it's such a hard market to break. Next, the introduction of a novel biodegradable product will have an effect on the way hospitals operate, social-technical frameworks will be used to analyze the disruption to the industry and what other areas of healthcare could be effected.

Hybrid Biomaterial Creation

Polyhydroxy butyrate

The capstone will consist of the creation of polyhydroxy butyrate (PHB) which is a novel bioplastic that can degrade anaerobically in the environment. The innovation comes in the form of the metabolic pathway that is used to convert styrene, a precursor ingredient for plastics, rubber, and resins, into PHB. Strains of *E. coli* will be genetically modified, via plasmid transformation, to enable the complete biochemical conversion of styrene into PHB (Fig. 1). The figure shows the creation of PHB and starts with the uptake of exogenous styrene and conversion to the essential metabolic intermediate acetyl-CoA, then finally to PHB. This process, which occurs through the expression of the *sty* and *paa* gene clusters, will be tested in select *E. coli* strains. Once the confirmation of this pathway is complete the scale-up process of PHB can begin. Then testing the PHB will lead to the identification of certain mechanical properties. The PHB will undergo thermal and mechanical property tests to find out the glass transition point temperature, Young's Modulus, and tensile strength.

Thermal stability tests such as Thermogravimetric Analysis, which measurers changes in mass as temperature is changed, will be performed to find out the optimal operating temperature for the PHB. Mechanical properties such as Young's modulus and tensile strength will be identified via injection modeling and Instron instrument testing. Using this information crosslinkers and copolymerization will be used to increase the strength of the material. The other mechanical properties that will need to be explored are its decomposition and biocompatibility. Bioplastics can't just be thrown anywhere and then be expected to fully decompose. The crystalline network, the addition of plasticizers, environmental conditions such as temperature, humidity, and the presence of microorganisms all affect the degradation of these plastics (Naranic et al., 2020). Each material requires certain parameters to undergo full degradation. If the PHB was to be used as a medical device and not packaging there will also have to be biocompatibility testing to ensure that the plastic doesn't elicit a free body response or other negative consequences.

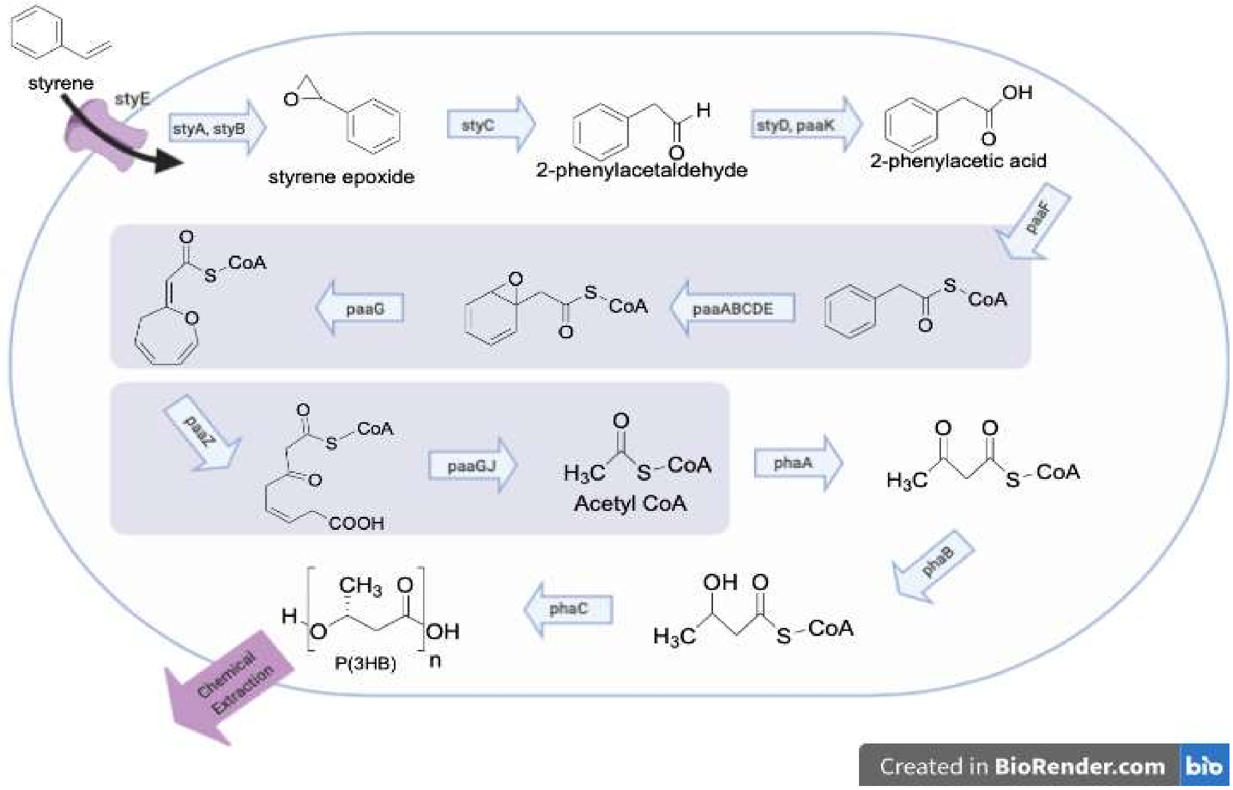

Figure 1. PHB Pathway, Alec Brewer, 2020.

Kombucha and Hybrid Biomaterial Creation

The second biomaterial for this project is a paper that is made from a bacteria cellulose (BC), derived from the live culture that is used to make kombucha. Its innovation comes in the form of using cellulose to form sheets that can act as paper. The process uses transparent BC film made via hierarchical alignment from molecular level crystalline cellulose chain alignment to microscale level fibrils bundle alignment (Wang et al., 2018). The end product is a film that is aligned, tough, and flexible. This paper is also biodegradable and can be used with other products. The last innovation of the project involves overlaying PHB onto BC paper to create a biomaterial with increased mechanical properties. Surface coating techniques or plasticizer methods will be used to form a PHB-BC composite. The main innovation will be aerosolization of the PHB. This will be performed by dissolving the PHB into solution with the help of a nonvolatile solvent, then spray coated onto the BC paper. This will allow multiple coats to be added to create varying levels of thickness for different applications. Finally, CAD designs of medical devices and/or packaging will be created. It's the hope that this material can one day replace some of the plastics in hospitals and help curb waste production. The hybrid biomaterial is designed to be fully biodegradable and can be customized for different applications.

Alternative Solutions and Proof of Concept

PHB isn't the first bioplastic on the market today, the forerunners in the field include Polylactic acid (PLA) and Polyhydroxyalkanoates (PHA) (Naranic et al., 2020). Both of these bioplastics are already viable for use by hospitals and exhibit both biocompatibility and biodegradability. They also have melting temperatures and glass transition temperatures that are similar to traditional plastics, making them mechanically viable for replacements (Bano et al., 2017). These plastics are already being used in the medical industry ranging from tissue scaffolding, drug delivery, and packaging replacements (Naranic et al., 2020). This shows that PHB could be used in the medical industry and the other bioplastics offer alternatives and proof of concept. There are also companies that are creating more sustainable and reusable medical devices. Companies including, EnviroPouch and NewGen Surgical already produce reusable sterilization pouches and medical tools made from plant material, respectively (Okafor, 2018).

Repercussions and Implementation of Bioplastics

This problem is rooted deep in society and will require social-technical analysis to figure out why single-use plastics came into being, the complex network that support the technology, and the challenges ahead for alternative solutions. Looking at other countries may offer insights into how this problem is being mitigated in different ways and the steps that are taken. Defining sustainability will also showcase the societal factors needed to drive the success of this product

Hard Market to Break

The two biggest obstacles for bioplastics to overcome in the medical field are the reliance that hospitals have on single-use plastics and their higher cost. As of now, single-use plastics are considered the gold standard for safe and clean medical care. The American Chemistry Council has even gone to say that plastic is the ideal medical material, “Single-use plastics are the cleanest, most efficient way, to facilitate health and hygiene in hospitals” (Kagonma et al., 2012, p.1) This creates a situation where bioplastics will need to perform as well as, if not better, than petroleum-based counterparts to be considered as a viable replacement. The other problem with bioplastics is their relative cost compared to traditional plastics. The cheapest bioplastic on the market today is PLA and it's almost eight times more expensive than the next petroleum-based product (Choudhary, 2020). The current use of plastics in medicine and the cost of bioplastics will be the biggest challenges in implementing them as common practice. However, the bioplastics industry is projected to be worth 6.8 billion dollars by 2025 (Naranic et al., 2020). This shows that there is a market for it and it's growing too.

Sustainability

Sustainability is a buzzword in almost every industry sector and has a very ambiguous meaning depending on the context. However, it elicits a positive response and has a normative connotation, meaning that people find sustainability to be a desirable facet even if they don't necessarily know why something is sustainable (Bos et al., 2014). For the medical device industry, what society deems sustainable or necessary will be key in creating a product that is holistically sustainable. Sustainability must consider the wider picture including the energy required to manufacture the raw materials, the impact of different logistical demands, and then onto disposal (Mathews et al., 2020). Just because the material can degrade doesn't necessarily make it sustainable. The focus of the project will be to create a product that is balanced in all areas. Sustainability has also come to include this idea of balance between three areas of performance: economic, environmental, and societal which is known as the "triple bottom line" (Carter & Rogers, 2008) If the product is environmentally and socially viable but not appealing from an economic standpoint the product will fail. Only when a solution can be competitive in all three areas will a product become sustainable. Any sustainable product isn't going to be industry breaking overnight, it will need to gather steam from the people who are using the device directly and their values. Another facet of the sustainability question is where the push is coming from and why. Most sustainability initiatives were based upon staff member values, not upon organizational ones (Rodriguez, 2020). These early trends of people wanting to change will hopefully lead to top-down action. This meshes well with the idea that sustainable measures must not only minimize negative effects but also encourage community evolvement (Gibson, 2006). Even with a successful implementation and involvement of the community Gibson highlights the fact that sustainability is an open-ended process and there are always more improvements to be made (2006).

Impact, Social Sustainability, and Global Comparison

Integrating bioplastic into healthcare would require new training and awareness on how to sort medical plastic waste more effectively. This hopefully will lead to a new generation of greener thinking and spill over into other areas. Healthcare is a necessity for today's world, but it doesn't have to pollute the planet at the same time. Bioplastics would be the first step in a new era of sustainable health practices. However, the idea of new training and recycling awareness has already begun in other countries and can serve as a proof of concept and a template for the US to follow. One such program includes an initiative that was started in Australia in 2009 and now contains over 140 hospitals in Australia and New Zealand (Sparrow, 2019). The program provides specialized segregated plastic recycling bins for different types of medical plastics and training to medical staff on how to identify and categorize waste appropriately (Sparrow, 2019). This allows medical plastics, chiefly PVC, to be sorted into correct categories in order to be recycled and not contribute to pollution. This program also works directly with medical device provides to design more recycling friendly products. Australia and New Zealand credit the success of the program to the predisposition that their respective populations have towards recycling and environmentalism (Sparrow, 2019). The hospitals are staffed by people who are already more inclined to recycling due to the position their society takes on the issue. Both Australia and New Zealand already have complex recycling programs in place so it becomes easier to transition to hospitals. This societal outlook will need to be instilled in the US before the success of bioplastics and other hospital recycling programs.

Technological Style

Technology can have style and depending on where it's developed could have different facets while essentially doing the same thing. Bijker states that there is no correct way or more advanced technology to solve a problem, just different styles (1987). The economic, geographical, and societal differences led to slightly different technological solutions that vary slightly and that one isn’t superior to the other (Bijker, 1987). This is important because technological style tells us that there is no best way to treat people with clean equipment. The use of petroleum plastic is nothing more than technological style and became the centerpiece of hospital practice because it came in at the right time and place. This will help to explain why plastics became so widespread when they did and why they are still used today. The hospitals needed a solution to stop cross-contamination and the spread of disease and plastic solved that. After this, it became ingrained into the style of how hospitals work and became a staple. So, I hypothesize that if we can reevaluate the medical device and packaging industry in the new era of sustainability, we can change the style and in turn see a new emergence of bioplastics in hospitals. This concept of style can also show us the differences between hospitals of different nations and how other countries have evolved to incorporate more sustainable practices than the US, without compromising service. This might have happened due to economic, geographical, or societal differences between the regions. Leading to one country using plastics due to the presence of preexisting industry and abundance of natural resources and another relying on washing more equipment and minimal packaging due to the lack of funds or raw materials to make plastic or how their society views recycling as a whole.

I think the connection between the technical and human realms can be explained well by Bijker and his idea of technological style. There are hospitals all over the world but when in the US there is this style of doctors dressed in white, immaculate rooms and sterile single-use plastics. This technological style is what people have become accustomed too and because it deals with health, it will be a challenge to overcome. The one area that I think will help the progression of biodegradable plastics will be the people who want to make a change. People will pay an extra premium to “Go Green” because it makes them feel good. The ability to play on people's emotions when in regards to the planet might just be what the biodegradable plastic industry needs to get the ball rolling.

ISTA

Harrison writes on how Interactive Sociotechnical Analysis (ISTA) can be used to evaluate a new system when it gets put into place and the unintended consequences that could follow (2007). These unintended consequences could lead to implementation failure and undermine what the system was trying to accomplish. ISTA focuses on the emergent and recursive interactions a system has with existing social systems, technologies, and physical environments (Harrison, 2007). It’s impossible to foresee all the outcomes when a new system is introduced however, ISTA can be used to track and identify problems and help solve them before failure occurs. This Interactive Sociotechnical Analysis would be an excellent metric to apply to the new system of introducing bioplastics to hospitals. The ISTA uses categories to stimulate thoughts on how a new system will be received. The introduction of bioplastics will have effects on societal, technical, and physical systems. This analysis will be good to uncover unintended consequences in implementations and address the challenges in my capstone.

Research Question and Methods

Can the introduction of biodegradable bioplastics into the medical industry provide hospitals with materials that meet medical standards while not contributing to the growing plastic crisis?

The research question is important because hospitals play a part in the compounding environmental crisis. The decomposition of medical plastics leads to carcinogens being released into the air, water, and soil. With the use of bioplastics, there exists a solution that can still provide the mechanical and sterile properties that medical devices need in order to be effective but won't contribute to pollution. However, this is easier said than done. The societal factors of why single-use plastics are used pose a big barrier to this project's success. There will need to be an in-depth analysis of who would want this product and for what reasons. Interviews can be conducted to find the right target audience. I would reach out to both Andrea Trimble and Corey DiLuciano, the director of UVA Sustainability and Chair of the Health System Committee on Sustainability, respectively.

As of right now, the economic factors of creating a new product for a well-defined area won't allow overnight success. The topic will be analyzed by looking at the societal factors for change and sustainability and where successful recycling programs have been used before. Data will come from studies based on plastic usage in hospitals, environmental harm from plastics, and ISTA analysis of the interactions between humans and technology. This data will be interpreted to bridge together large areas of study into a cohesive argument about healthcare and sustainability. ISTA then can be used to explore the failures of certain actors and the effect it has on a successful bioplastic launch. For timeline purposes, I need to figure out how to mesh all of these ideas together in a cohesive argument that doesn't seem too convoluted. Over break I will reach out to both Andrea and Corey for interviews to be conducted next semester. From there I will compile the data that I gathered and begin working on the ISTA analysis. Figures will be created to represent the possible pitfalls that an introduction of bioplastics could have on health systems. Further investigation into why the US relies heavily on single use plastics would be used to flesh out the section on technological style. I would also like to do more research on existing recycling programs in US hospitals and abroad to understand how they are implemented and to see if they can be adapted for bioplastic introduction.

Conclusion

Overall, the problem of single-use plastics and their negative effect on the environment is a problem that is deeply rooted in the medical industry and doesn't have an immediate need to change due to the success of petroleum plastics. The negative outcomes of plastic pollution haven't outweighed the need for single-use plastics, however irreversible damage will continue to compound if nothing is done. This project has the potential to not only provide a mechanical and medically viable replacement but also to change the culture around single-use plastics and take a hard look at why US hospitals produce as much waste as they do and the societal factors behind it. The success of this project will hopefully provide a stencil for other sustainable practices to be implemented elsewhere in society.

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