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Do single-use medical devices containing biopolymers reduce the environmental impacts of surgical procedures compared with their plastic equivalents?

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INVESTIGATING INNOVATIVE MATERIAL SHIFTS IN MEDICAL PRODUCTS TO REDUCE ENVIRONMENTAL IMPACTS: FOCUS ON BIOPOLYMERS

Abstract

While petroleum-based plastics are extensively used in healthcare settings, recent developments in biopolymer manufacturing processes have created new avenues and opportunities for increased integration of biopolymers into medical products, devices, and services. This paper assessed opportunities for using three different biopolymers in healthcare and the resultant comparative environmental impacts of single use disposable devices with increased biopolymer content vs. typically manufactured devices in hysterectomy procedures. This study performed a comparative life cycle assessment of single-use-disposable medical products containing plastic(s) versus the same single-use medical devices with biopolymers substituted for plastic(s). The context of this life cycle assessment (LCA) was that of Magee-Womens Hospital (Magee) in Pittsburgh, PA, and the products used in four types of hysterectomies performed at Magee that contained plastics potentially suitable for biopolymer substitution. Magee is a 360-bed teaching hospital, which performs approximately 1400 hysterectomies annually. Individual participants were not applicable to this study. Rather, medical products used in the hysterectomies were the focus of this study. There are life-cycle environmental impact tradeoffs when substituting bioplastics for petroplastics in operating room procedures such as hysterectomies. The substitution of biopolymers for petroleum-based plastics increased smog-related impacts by approximately 900% for laparoscopic and robotic hysterectomies, and increased ozone depletion-related impacts by approximately 125% for laparoscopic and robotic hysterectomies. Conversely, biopolymers reduced life-cycle human health impacts, acidification and cumulative energy demand for the four hysterectomy procedures. The integration of biopolymers into

medical products is correlated with reductions in carcinogenic impacts, non-carcinogenic impacts, and respiratory effects. However, the significant agricultural inputs associated with manufacturing biopolymers exacerbates environmental impacts of products and devices made out of biopolymers.

Method

a. Background

It was not until the 1960s that plastics became so pervasively used in healthcare (Greene, 1986). At this time, the healthcare industry learned how to substitute polyvinyls, polycarbonates, and polystyrenes for materials originally made out of glass, rubber, metal, and woven textiles (Greene, 1986). The substitution occurred primarily because medical device manufacturing companies learned to make devices with plastics efficiently and cheaply. These factors led to increases in healthcare plastic use, which consequentially led to fundamental changes in the processes that governed medical device manufacturing, use, and disposal. For example, before the substitution of petroleum-based plastics, medical products made of woven-cotton would undergo cleaning on-site at the hospital once they were used (Greene, 1986). Following the substitution of petroleum-based plastics, devices made of plastic that fulfilled the same function would be disposed after being used only one instance; which consequently led to increased quantities of waste created by hospitals.

Over the past half-century, plastics have become a ubiquitous material in the medical device industry. In a study analyzing environmental impact of seven single-use medical devices undergoing reprocessing, all had some form of polyethylene in each of their respective bill of materials (Unger & Landis, 2015). Total polyethylene weight ranged anywhere from 7% to 88% of total weight for individual devices, and made up 52% of total weight for the combined average of the seven devices (Unger & Landis, 2015). In another study of four types of hysterectomy (abdominal, vaginal, laparoscopic, robotic), plastics were again found to be a significant portion of the operating room (OR) waste stream. The study concluded that the plastics used (e.g., thin film packaging wrappers, hard plastic trays) accounted for a minimum of 36% of material solid waste (MSW) by weight for vaginal hysterectomies and a maximum of 46% of MSW by weight for robotic procedures (Thiel et al., 2014).

While petroleum-based plastics are extensively used in healthcare settings, bio-plastics for the past several decades have also formed their own niche market in the healthcare industry. As opposed to petroleum-based plastics that obtain their carbon from non-renewable resources (e.g., petroleum), bio-plastics (a.k.a. biopolymers) are plastics in which some or all of the polymer is derived from renewable feedstocks. With regards to healthcare applications, recent developments in biopolymer manufacturing processes have created new avenues and opportunities for increased integration of biopolymers into medical products, devices, and services (Auras, Lim, Selke, & Tsuji, 2011). On. One factor that has contributed to these opportunities is that newly developed biopolymers are able to retain similar physical characteristics of synthetic plastics. For example, emerging studies show that guayule-derived latex rubber is a suitable substitute for flexible plastics and traditional rubber products (Cornish, Williams, Hall, & III, 2008; Rasutis, Soratana, McMahan, & Landis, 2015). Another study shows that the biopolymer polylactide (PLA) is a suitable substitute for different forms of plastic (Madhavan Nampoothiri, Nair, & John, 2010). Based on the material and chemical properties of PLA, the study concluded that PLA has many potential applications, including upholstery, disposable garments, awnings, feminine hygiene products, and diapers (Madhavan Nampoothiri et al., 2010). One of the benefits of PLA is that it is compostable, and might allow hospitals to decrease the amount of plastics in their respective waste streams (Ghorpade, Gennadios, & Hanna, 2001).

Given recent development in the field of biopolymers and their potential to replace commonly used plastics, there is the possibility to use biopolymers in a variety of medical products. Replacing petroleum-based plastics with biopolymers would not only reduce depletion of non-renewable resources, but could also reduce hospital-generated material solid waste (MSW) and regulated medical waste (RMW) if the biopolymers are composted; however, a systems approach is needed to discern any potential net gain (or losses) from a life cycle perspective. Such a replacement would contribute to the trend of hospitals placing a higher emphasis on sustainability initiatives. The foci of these sustainability initiatives include (but are not limited to) a hospital's efficient use of materials, energy efficiency, water efficiency, green purchasing, and waste diversion strategies (Janet, 2013; Kaplan et al., 2012; Kwakye, Brat, & Makary, 2011). Moreover, an assessment of the environmental impacts of increased biopolymer use in favor of petroleum-based plastics in medical devices and products has not yet been performed. *This study addresses this knowledge gap by comparing the environmental impacts of medical devices composed of plastics versus the same medical devices made with biopolymers.*

The methods section parallels the four major steps of a life cycle assessment (LCA) (i.e., goal and scope definition, inventory analysis, impact assessment, interpretation) as described by the ISO 14040 series. LCAs are used to assess environmental impacts throughout a product's life and seek to address a number of environmentally related concerns, including: compilation of energy and material input and outputs; evaluation of potential impacts attributed to the inputs and outputs; and, interpretation of the results to help make a more informed decision (EPA, 2010). In addition to the LCA, a 2^3 factorial experiment was used to demonstrate the environmental and human health impacts resulting from different biopolymer substitutions.

b. Scope and System Boundary

This study presents a comparative life cycle assessment of single-use-disposable medical products containing plastic(s) versus the same single-use medical devices with biopolymers substituted for plastic(s). The context of this LCA was that of Magee-Womens Hospital (Magee) in Pittsburgh, PA, and the products used in four types of hysterectomies performed at Magee that contained plastics potentially suitable for biopolymer substitution. Magee is a 360-bed teaching hospital, which performs approximately 1400 hysterectomies annually. The products and devices evaluated are those used in four types of hysterectomy (i.e., vaginal, abdominal, laparoscopic, robotic) at Magee. Vaginal hysterectomy is a procedure where the uterus and/or cervix are removed through the vagina, and abdominal hysterectomy results in uterus and/or cervix being removed from lower abdomen (Dicker et al., 1982). Laparoscopic and robotic hysterectomies are both minimally invasive and utilize cameras and 3-D views to remove the uterus and/or cervix (Sarlos, Kots, Stevanovic, & Schaer, 2010).

Waste audits of 62 hysterectomies were conducted by Thiel et al (2014) (15 each abdominal, vaginal, and robotic, and 17 laparoscopic). The waste audits were done to collect the material inputs and to quantify and characterize the products and materials entering Magee's municipal solid waste, recycling streams, and regulated medical waste (RMW). The number of medical devices and products used in each type of hysterectomy and the quantity of plastic(s) within each product were included in the analysis using the inventory data collected in a previous study (Thiel et al., 2014). Figure 1 shows that plastics are the most significant portions by weight of MSW per procedure for all types of hysterectomies. When averaging the total waste from the four hysterectomies, polypropylene, polyvinylchloride, and various forms of hard plastic represented the greatest sources of produced waste by mass. On a percent basis by mass, polypropylene, polyvinylchloride, and hard plastic represented 32%, 25%, and 14%, respectively, of the total waste produced by the four hysterectomies (Thiel et al., 2014). Figure 1 also shows that robotic hysterectomies typically consume more materials than the other three hysterectomies.

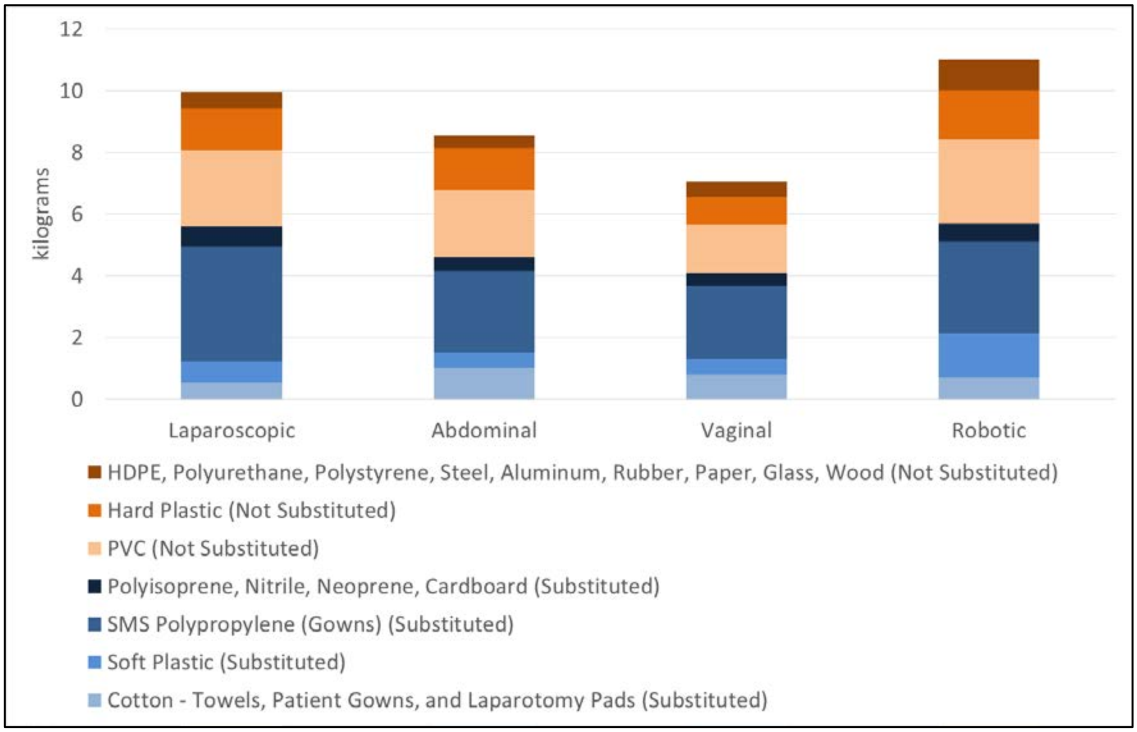


Figure 1. Average Material Composition of Municipal Solid Waste from a Single Hysterectomy by Surgery Type with Assumed Biopolymer Substitution. Adapted from (Thiel et al., 2014).

(Caption Text) This figure shows an average of the waste produced from the four hysterectomy procedures. Materials substituted for biopolymers are colored shades of blue, and non-substituted materials are colored shades of orange. Similarly, all materials with (Substituted) following their name are materials that were substituted for biopolymers. All materials with (Not Substituted) following their names are materials that were not substituted for biopolymers.

Specific types of biopolymers were designated as substitutions to replace the plastics found in each device. The choice of substituted biopolymer was based on which biopolymer has appropriate material and functional properties to that of the original plastic. The functional unit was all medical devices that contained petroleum-based plastics suitable for biopolymer substitution for each of the four types of hysterectomies. The system boundary encompassed activities associated with the raw material extraction, production, use, and end-of-life (EOL) for the products containing plastic in each type of hysterectomy.

Table 1. Potential Biopolymer Substitutions for Petroleum Plastics used in Hysterectomy Procedures. Adapted from (Thiel et al., 2014).

Material found in original waste audit	Substituted Biopolymer (and abbreviation used in figures)	Product	Device
Low-density polyethylene (LDPE)	PLA (P)	Laparotomy drape	8 mm bladeless obturator
Polypropylene	PLA (P)	Gowns; laparotomy drapes; bare warm air drape; blue drape; blue wrap	None
Polyisoprene	Guayule-derived latex (G)	Tan glove; blue glove	None
Nitrile	Guayule-derived latex (G)	Purple glove	None
Neoprene	Guayule-derived latex (G)	Green glove	None
Cardboard	Thermoplastic starch (T)	Bare warm air drape	None

(Caption Text) Materials found in products and/or devices for robotic, abdominal, laparoscopic, and vaginal hysterectomies performed at Magee. Plastic, product, and device information is from (Thiel et al., 2014). The potential biopolymer substitution was determined for the purposes of this study based on biopolymers with similar characteristics.

c. Inventory Analysis

The following plastics were identified in the four types of hysterectomies at Magee: low-density polyethylene (LDPE), polypropylene (PP), polyisoprene, nitrile, and neoprene. Based on their physical properties and delivered function, the weights of plastics found in each device were substituted with an equal weight of suitable biopolymers (see Supplementary Information). Guayule-derived latex was substituted for all products and/or devices containing nitrile, neoprene, polyisoprene. Life cycle inventory data for guayule-derived latex was derived from Rasutis et al., 2015 (Rasutis et al., 2015). PLA was substituted for all products and/or devices containing LDPE and polypropylene. Life cycle inventory data for PLA was derived from Vink et al., 2010 (Vink, Davies, & Kolstad, 2010). Thermoplastic starch was substituted for all products containing cardboard. While cardboard is considerable a renewable material, thermoplastic starch was substituted because of its suitability as a cardboard substitute. Life cycle inventory data for thermoplastic starch were derived from existing ecoinvent v2.2 data, under the classification “Modified starch, at plant/RER U” (Weidema & Hischier, 2012).

PLA is a suitable LDPE substitute, as PLA has properties that make it appropriate for thin film applications including disposable products and packaging. Research is continuing to expand the number of applications for PLA as the potential material characteristics are broadened (Reddy, Vivekanandhan, Misra, Bhatia, & Mohanty, 2013; Shen, Haufe, & Patel, 2009). Similar to LDPE, PP in film applications and packaging can be replaced with disposable PLA products (Shen, Worrell, & Patel, 2010). Regarding this study, PLA’s GHG emissions included direct site emissions, indirect emissions from electricity production, fuel, material, corn production, and reclamation, as well as biogenic CO_2 uptake from the corn feedstock. These emissions are considered within the timeframe of the global warming potential (GWP) impact category. Starch is well established as a low cost material for packaging applications, which can be blended with cardboard and other fibers to achieve a wide range of application specific properties. While cardboard is an effective biobased material, starch may perform favorably and a comparison of environmental impacts will help assess any tradeoffs that exist (Bastioli, 1998; Mohammadi Nafchi, Moradpour, Saeidi, & Alias, 2013; Shen et al., 2009). Clinical and performance trials have also shown that guayule-derived latex have high molecular weights, and products made from guayule-derived latex have desirable performance properties in a clinical setting (Rasutis et al., 2015). Guayule-derived latex has also been shown to be safe for people with Type I latex allergy, where typical latex materials (e.g., nitrile, neoprene) contain allergenic proteins that affect those with Type I latex allergy (Foster & Coffelt, 2005; Siler, Cornish, & Hamilton, 1996).

d. Impact Assessment

Environmental and human health impacts resulting from the calculated inputs and outputs were calculated using the Tool for Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI) 2.1 (Bare, 2002), which was created by the United States Environmental Protection Agency (EPA) to assist in impact assessment. TRACI was chosen because it is the most comprehensive life cycle impact assessment tool applicable to the United States. The following impacts were calculated and reported from TRACI: ozone depletion, global warming, smog, acidification, eutrophication, carcinogenics, non-carcinogenics, respiratory effects, and ecotoxicity. While not included in the TRACI portfolio, cumulative energy demand was also included as an impact category.

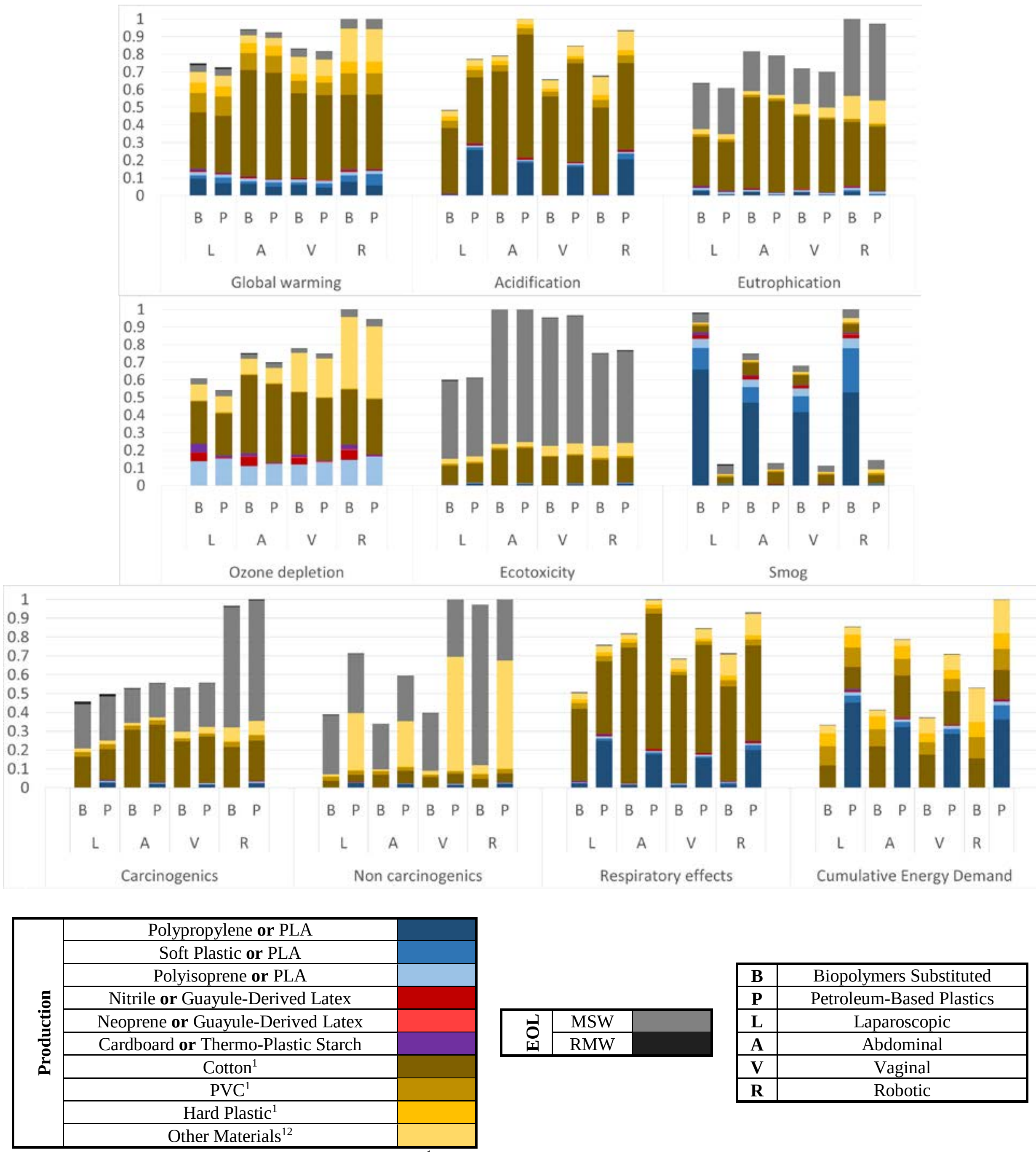
The method to calculate cumulative energy demand (CED) is based on characterization factors that are assigned to energy resources in 5 impact categories: non-renewable (fossil), non-renewable (nuclear), renewable (biomass), renewable (wind, solar, geothermal), and renewable (water) (Frischknecht et al., 2007; PRé, 2016). Normalization is not used to calculate CED, where CED is calculated by assigning a weighting factor of 1 to each impact category (Frischknecht et al., 2007); PRé (2016).

e. 2^3 Factorial Design Experiment

A 2^3 factorial experiment was used to demonstrate the variances of environmental and human health impacts resulting from different substitutions of PLA, guayule-derived latex, and thermoplastic starch. The 2^3 factorial design experiment factors were the three substituted plastics (i.e., PLA, guayule-derived latex, thermoplastic starch) and the two factor levels were whether or not biopolymers were substituted for the three design experiment factors.

Results

Figure 2 shows the comparative environmental and human health impacts resulting from hysterectomies using standard medical products containing petroleum-based plastics and medical products with biopolymers substituted. For each impact category, the results are normalized to the hysterectomy with the greatest overall impact when considering both base-case and biopolymer substitution scenarios. Because the impact categories are normalized for comparative purposes, the generated values may not necessarily reflect the overall magnitude of impact for individual impact categories.



[1]Non Substituted Material

[2]Includes Polystyrene, Steel, Aluminum, Rubber, Paper, Glass, Wood, HDPE, and Polyurethane. All of these materials composed less than 2% (by weight) of Magee's total analyzed waste stream.

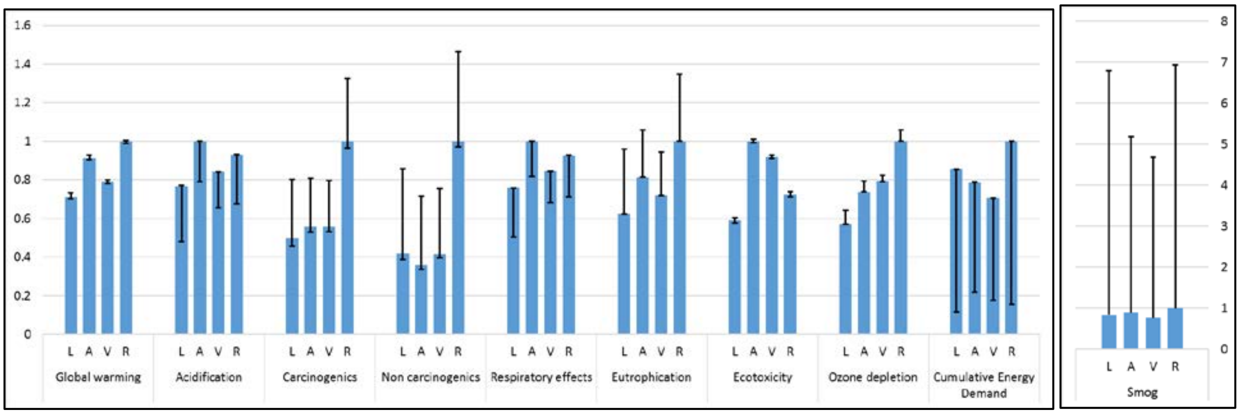
EOL: End-of-Life; MSW: Material Solid Waste; RMW: Regulated Medical Waste

Figure 2. Normalized TRACI Impacts for Medical Products Containing Petroleum-Based Plastics versus Medical Products Potentially Containing Biopolymers Used in Hysterectomies.

The use of biopolymers in surgical devices is preferable for several impact categories compared to petroleum-based plastics which include acidification (19-29%), ecotoxicity (1-2%), carcinogenics (3-4%), non-carcinogenics (25-61%), respiratory effects (16-25%), and CED (53-84%). However, medical devices with petroleum-based plastics that do not include any quantity of biopolymers perform better in several other impact categories such as global warming, eutrophication, ozone depletion, and smog. In particular, the impact category smog for laparoscopic, abdominal, vaginal and robotic hysterectomy procedures performs better by 86%, 62%, 57% and 86% respectively. While the utilization of biopolymers may offer some life-cycle based human health benefits, such as vaginal hysterectomies having 61% lower non-carcinogenic impact, the agricultural activities associated with manufacturing biopolymers exacerbate a number of environmental impacts.

Significant agricultural activities are associated with creating biopolymers, where these agricultural activities exacerbate impacts related to global warming, eutrophication, ozone depletion, and smog. Much of the smog-related impacts resulting from PLA production occur during PLA's fermentation stage, where the fermentation stage is associated with significant levels of emitted NO_X (Auras et al., 2011). Additionally, the transport associated with PLA's production drives the majority of PLA's ozone depletion-related impacts (Auras et al., 2011). On the other hand, guayule-derived latex and thermoplastic starch are correlated with much lower levels of ozone-depleting substances during their associated manufacturing processes. Smog causing emissions result primarily from lactic acid fermentation and agricultural processes on farm in this model, while ODP results mainly from transportation (Hottle, Bilec, & Landis, 2013). It is important to note that the inventories used herein pre-date Montreal protocol ozone depleting substances according to the United States Environmental Protection Agency, Office of Health, and Environmental Assessment Exposure Assessment Group (1989), and as such we normalize the results in order to make comparisons.

Using results from the 2^3 factorial design of experiments (DOE), Figure 3 shows the relative increase or decrease in all impact categories from various combinations of biopolymer substitutions. The error bars in Figure 3 show the most significant increase or decrease for all impact categories using values generated from the 2^3 factorial DOE. The increase of impacts related to global warming, eutrophication, ozone depletion, and smog resulted when PLA, guayule-derived latex, and thermoplastic starch were substituted for typically used materials. The increase of acidification-related impacts resulted when thermoplastic starch was substituted for cardboard. The increase of ecotoxicity related impacts resulted when PLA and guayule-derived latex were substituted for typically used materials. Conversely, the decrease of impacts related to carcinogenics, non-carcinogenics, respiratory effects, and cumulative energy demand resulted when PLA, guayule-derived latex, and thermoplastic starch were substituted for petroleum-based materials. The substitution of biopolymers for petroleum-based plastics decreased cumulative energy demand by approximately 73% and 84% for laparoscopic and robotic hysterectomies, respectively. The substitution of biopolymers for petroleum-based plastics increased smog-related impacts by approximately 700% and 600% for laparoscopic and robotic hysterectomies, respectively. Table S2 through Table S11 in the supplementary information display the DOE results for all nine impact categories.



L	Laparoscopic
A	Abdominal
V	Vaginal
R	Robotic

Figure 3. Change/Percent Increase or Decrease Resulting from Biopolymer Substitutions Using Values Generated from 2^3 Factorial DOE.

(Caption Text) The error bars in Figure 3 show the most significant increase or decrease for all impact categories using values generated from the 2^3 factorial DOE.

Discussion

This study examined the environmental impacts of integrating biopolymers into hysterectomy products. While there are several noteworthy tradeoffs from a life cycle perspective, the use of biopolymers in healthcare would require considerable feedback from the doctors, nurses and patients utilizing the biopolymer products. To evaluate adoption, discourse with hospital personnel would be necessary to determine the utility advantages and disadvantages of products containing biopolymers. For example, doctors and nurses may push back on integrating biopolymers into a certain product because that product requires material and/or technical specifications that may not be fulfilled by a biopolymer. Conversely, doctors and nurses may favor biopolymer utilization in a certain healthcare product because that product's utility may increase as biopolymers are integrated Kumar, Sivakumar, and Dhurai (2013).

Moreover, there are a number of contextual and regulatory factors that would affect the implementation of biopolymers into healthcare products. These factors include policies and regulations, financial and regulatory environment, leadership, workflow, carbon literacy, and support systems. While these factors are typically dependent on individual healthcare providers, one would expect that workflow would not be significantly affected because the biopolymer products proposed herein are functionally equivalent and would still be utilized by a healthcare provider regardless of the level of integrated biopolymers into medical products. Further research on barriers to adoption, market analysis for biopolymer medical products, as well as supply chain and feedstock availability would inform any increased usage of biopolymers in healthcare.

Effective composting of biopolymers used in medical products may decrease environmental and human health impacts resulting from RMW and MSW, but warrant further evaluations since there are studies that discuss industrial composing facilities sending biopolymers to landfills because of the slow degradation rates (Hottle, Bilec, Brown, & Landis, 2015). Primary concerns with composting medical waste include existing regulatory barriers associated with composting medical waste, as well as the necessary life-cycle processes and labor required for composting. For example, implementing a composting waste stream at a hospital would require: healthcare personnel to distinguish compostable from non-compostable products; consistent upkeep and maintenance of composting bins and equipment to ensure their sterility in medical environment; and, disassembly of medical products that are only partially composed of compostable material before those products enter a composting stream. Despite these concerns, there are waste management options such as anaerobic digesters that could decrease global warming and energy use by producing methane and energy from bioplastic waste streams (Hobbs, Devkota, Parameswaran, & Landis, 2016).

The integration of biopolymers into medical products illustrates reductions in carcinogenic impacts (3-4%), non-carcinogenic impacts (25-61%), respiratory effects (16-25%), and cumulative energy demand (53-84%). Cumulative energy demand represents the greatest potential for environmental impact reduction, particularly because devices made with fossil-fuel based plastics require higher quantities of electricity to produce when compared to devices made with biopolymers. However, the significant agricultural inputs associated with biopolymers exacerbate a number of environmental impacts resulting from products and devices made out of biopolymers. The results showed that the PLA and guayule-derived latex substitutions resulted in significant smog-related impacts. Both PLA and guayule-derived latex have smog-related life-cycle impact factors that are at least 40 times greater than that of their respective substituted plastic (e.g., LDPE for polypropylene, guayule-derived latex for polyisoprene). The substitution of polypropylene for PLA resulted in the most significant smog-related impacts, where PLA has a smog life-cycle impact factor that is more than 140 times greater than that of polypropylene. If the biopolymers are cultivated in a locale with high-levels of existing smog (e.g., urban areas), the use of biopolymers is not necessarily favorable. On the other hand, if the biopolymers are cultivated in a locale with low-levels of existing smog (e.g., rural areas), the use of biopolymers is potentially favorable when considering smog-related impacts.

There are life-cycle environmental impact tradeoffs when substituting bioplastics for petroplastics in operating room procedures such as hysterectomies. The substitution of biopolymers for petroleum-based plastics increased smog-related impacts by approximately 900% for laparoscopic and robotic hysterectomies, and increased ozone depletion-related impacts by approximately 125% for laparoscopic and robotic hysterectomies. Conversely, biopolymers reduced life-cycle human health impacts, acidification and cumulative energy demand for the four hysterectomy procedures. The integration of biopolymers into medical products is correlated with reductions in carcinogenic impacts, non-carcinogenic impacts, and respiratory effects. However, the significant agricultural inputs associated with manufacturing biopolymers exacerbate environmental impacts of products and devices made out of biopolymers.

Acknowledgment

The authors declare that there is no conflict of interest.

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