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Towards Sustainable Design for Single-use Medical Devices

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Abstract—**Despite their sophistication and value, single-use medical devices have become commodity items in the developed world. Cheap raw materials along with large scale manufacturing and distribution processes have combined to make many medical devices more expensive to resterilize, package and restock than to simply discard. This practice is not sustainable or scalable on a global basis. As the petrochemicals that provide raw materials become more expensive and the global reach of these devices continues into rapidly developing economies, there is a need for device designs that take into account the total life-cycle of these products, minimize the amount of non-renewable materials consumed and consider alternative hybrid reusable / disposable approaches. In this paper, we describe a methodology to perform life cycle and functional analyses to create additional design requirements for medical devices. These types of sustainable approaches can move the medical device industry even closer to the "triple bottom line" – people, planet, profit.**

I. INTRODUCTION

SINGLE-USE medical devices have become an accepted design standard in the medical device industry. Fueled by inexpensive materials—particularly plastics—medical devices that were traditionally reused have been redesigned to be disposed after a single use. While these devices prevent the spread of infection within medical settings, and are economical when raw material prices are low, they also present a challenge to the pursuit of sustainable practices in design. Disposable medical devices that come in contact with biological components are classified as potentially infectious waste, and must be incinerated or disinfected prior to disposal. Incineration is inexpensive and used routinely however incinerators are leading producers of dioxins, mercury, and other toxic pollutants. Thus, in addition to the economic and social imperatives, there is also an environmental imperative associated with single-use medical devices.

One medical device that has made a recent transition from reusable to single-use design is the dialysis cartridge, also known as the dialyzer, used during hemodialysis in patients with chronic kidney failure. In the 1970s, it was common practice to reuse a dialyzer multiple times with a single patient. Such reuse occurred largely because a material in the dialysis membrane, cuprophane, made the devices expensive [1]. Furthermore, these dialyzers would occasionally cause a "first use syndrome" in patients, leading to chills, fever, and general malaise within moments of using a new device. However, this effect was mitigated after reprocessing the dialyzer prior to reuse in the same patient. In 1999, new dialyzers with membranes made from polysulfone became prominent. These less expensive devices also mitigated the first use syndrome. The combination of first use syndrome mitigation and no processing costs motivated manufacturers and clinics to transition to single-use designs. The implementation of single-use dialyzers was also motivated by safety concerns, including infection and potential human errors in reprocessing. Another important factor was the simple aesthetic appeal of having a new product every time a patient underwent treatment.

Single-use medical products increase production volumes and in-turn can provide product value through economies of scale. However, most single-use medical devices are not designed with specifications for recapturing material values through a cyclic life-cycle. Rather, they assume a linear, cradle-to-grave life-cycle, ending in incineration or disposal in a landfill. When product developers consider life-cycle analysis (LCA) in the design process, they consider all of the material and energy that go into producing a device, as well as all the by-products of production, transport, use, and disposal or reuse of the device. Thus, LCA becomes a tool for the designer to optimize the device design [2], [3]. More specifically, by using LCA to minimize material and energy inputs and by-products, as well as to specify optimal solutions for materials after their use, the designer is able to create a more sustainable and economical product.

We analyzed the single-use dialyzer for design alternatives that are practical, substantial and move in the direction of sustainability. Realizing that some design goals have more financial headwind than others, and that companies are motivated by profitability, we used a LCA of the dialyzer to identify points of improvement, and prioritized each point with a cost-benefit analysis. Focusing first on design changes that could provide the most benefit with the least cost, we developed a design for the first generation device that used fewer raw materials in production. Because this design would be the first one implemented, we also focused on providing more concrete, quantified details in order to present a clear first step. SolidWorks computer modeling was used to create and analyze several dialyzer designs *in silico*, and by analyzing

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the strength of each design with COSMOSWorks, we developed a first generation design that consumes fewer raw materials by optimizing the *in silico* strength-to-weight ratio. Further design generations beyond this include methods of material recovery and use of renewable resources. While a detailed description of these designs is outside the scope of this project, we will discuss briefly several key points of their implementation.

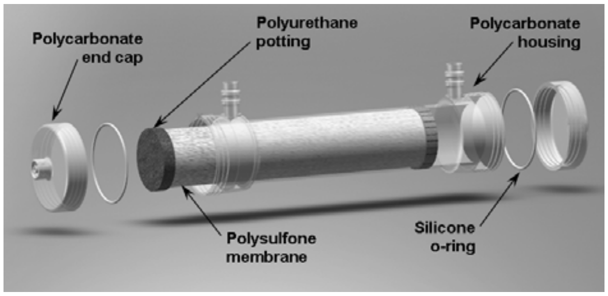

Fig. 1. Dialyzer cartridge components. The assembly is symmetrical from left to right. Five components are labeled.

II. METHODS

A. Life Cycle Analysis

We obtained a standard sized dialyzer (Optiflux F180NR) from Fresenius Medical, disassembled it, and weighed each of the components separately. From this, we identified five major components of the product: the extruded hollow fiber membranes, the housing, the end caps, the potting and the o-rings. For this analysis, we did not consider the packaging or labeling. Identifying the material of each component allowed us to trace their production back to raw biosphere materials such as water or fossil fuels and assemble a list of intermediate products and processes as well as incineration by-products [4]. This was performed for production and disposal. Using the graphing software yED from yWorks (yworks.com), we created a large, dynamic visualization of the LCA information we acquired, showing material and energy flows involved in current dialyzer manufacturing.

B. Functional Analysis

A functional analyses of each dialyzer component was performed for each of the five components. We started the analysis by asking, "On a functional level, what does this component accomplish?" The completed functional analysis provided a basis for new designs. Combined with the LCA, the functional analysis also led to the decision of how to most practically accomplish the first generation design goal of optimizing benefit per cost. In addition, the functional analysis helped us determine how each component could be changed while still maintaining functionality.

C. Geometric Analysis

After choosing the most practical areas of improvement based on data acquired from the life cycle and functional analyses, we began investigating different design forms. Because the dialyzer housing represented the component with the largest mass and most waste by-product, we focused on ways to reinforce the polycarbonate housing and reduce the quantity of material required. Using SolidWorks, we created a 3-dimensional model of the dialyzer. Then, using COSMOSWorks to compute various stresses on the model, we tested different reinforcement strategies, noting both how they altered the strength of the model and how much they affected the mass.

D. Stress Analysis

With the new design determined from the geometric analysis, we then proceeded to determine how much the weight could be reduced with the reinforced model while still maintaining the same strength of the original model. Since the basic shape of the housing was a hollow cylinder, the most practical way to reduce weight was to simply decrease the wall thickness. By systemically computing strength tests for different wall thicknesses, we were able to determine both the weight reduction and its effect on the strength of the device.

III. RESULTS

A. Life Cycle Analysis

While there is vast potential for intricate details and complexity in a LCA, we focused on achieving a qualitative overview in our application in order to understand the overall impact of the dialyzer on resources, energy, and the environment. In addition to this qualitative overview, we chose certain areas to address quantitatively. Figure 1 shows the dialyzer components, figure 2 shows the weight of each dialyzer component, figure 3 shows polycarbonate incineration by-products and figure 4 shows a portion of the LCA flowchart.

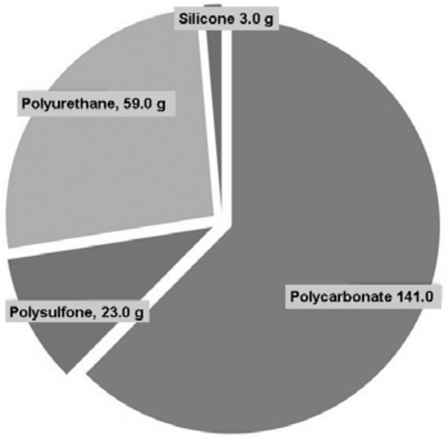

Fig. 2. Dialyzer cartridge component weights. The weights are used as input for life cycle and incineration by-product analysis.

B. Functional Analysis

The polysulfone extruded hollow fiber membranes function to allow solutes and fluids to filter between blood and dialysate fluid. The polyurethane potting is located at both ends of the dialyzer. It serves to organize the fiber membranes into a bundle, create a manifold for fluidic access within the tubular membranes and create a seal between the dialysate and blood pathways. The polycarbonate housing provides the outer form and protective functions for the device. It serves to protect the delicate fiber membranes and to create a closed pathway through which the dialysate fluid can flow. The housing is transparent and allows for clear observation of the device interior. The polycarbonate end caps also provide form, strength, and protection of inner components. They must seal to the housing in order to direct the flow of blood into the fiber membranes. The silicone o-rings seal the end caps to the housing at the point where they thread together.

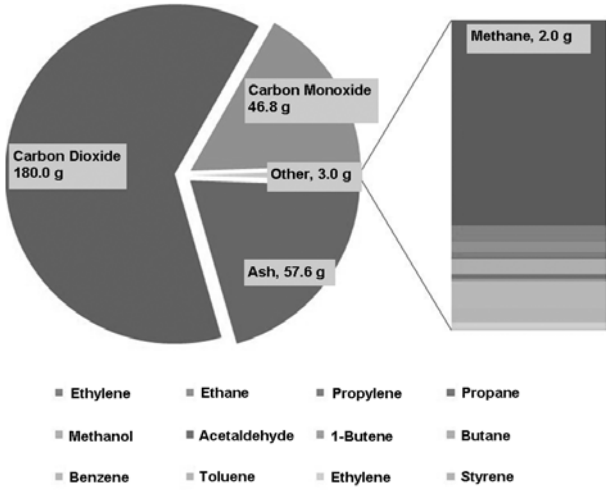

Fig. 3. Polycarbonate combustion products in lbs. 2.04 lbs. of incinerated by products are produced for every lb. combusted.

C. Directing Design Decisions with Life-Cycle and Functional Analyses

Polycarbonate had the greatest mass and occurrence of environmentally harmful and toxic compounds. Specifically of concern were acetaldehyde, a probable carcinogen [5], benzene, a known carcinogen [6], and styrene, a possible carcinogen [7]. We note that polysulfone also releases benzene and styrene upon combustion, but in light of its minimal presence in the dialyzer relative to polycarbonate, it was not considered as a primary focus. Likewise, the substantial cyanide produced by polyurethane combustion was also a concern, but again, was not as substantial when compared to polycarbonate. Considering the functional analysis, we drew several conclusions regarding the feasibility of altering each component. First of all, we realized that the polysulfone hollow fiber membranes served the most complex functions, and would not be simple to alter. Combined with the fact that they weighed so little, this led us to conclude that they were not an optimal area of focus. Likewise, the polyurethane potting had a more complex function and smaller weight relative to the polycarbonate housing. Finally, in our last step to determine a concentrated area of focus, we concluded that the housing functionality would be easier to maintain than the end cap functionality. Therefore, this led us to the design goal of reducing the polycarbonate used in the housing, while maintaining its strength and functionality.

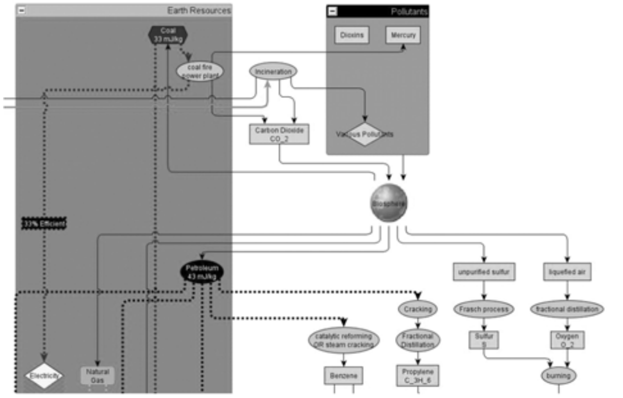

Fig. 4. A portion of the life cycle analysis chart showing earth biosphere inputs and return of pollutants. The entire analysis flowchart is too detailed to include in this paper and is available upon request from the corresponding author.

D. Geometric Analysis

In order to reduce the polycarbonate in the housing while maintaining strength, we used COSMOSWorks to test the effectiveness of novel reinforcement strategies. Through an iterative process of testing new strategies, we progressively improved our reinforcement model. Ultimately, we decided upon a helical reinforcing mesh on the outside surface of the dialyzer. This mesh consisted of 16 clockwise helices and 16 counter-clockwise helices, spaced at even intervals around the cylindrical surface of the dialyzer, with each helix completing 2 full rotations as it stretched from one end of the dialyzer to the other. The helices were in the form of half-circle protrusions with a radius of 1 mm, extending out from the outer wall of the housing.

Fig. 5. An example of a stress analysis model for three cartridge designs. Left is the original design, center is a new design with a cross-helical reinforcing mesh, right is the same new design without the reinforcing mesh. Stresses are calculated as Von Mises stresses and reported a factor of safety (FOS) for reported values of molded polycarbonate.

E. Stress Analysis

With the helical mesh reinforcement in place, we were able to reduce the wall thickness of the housing from 1.8 mm to 1.2 mm, while maintaining strength under the following stress situations: 1. Torsional: 50 Nm torsional load on one end while the other end is held; 2. Columnar: 500 N load perpendicular to one end while other end is held fixed; 3. Radial “Pinch”: 50 N point load on outside center of cylinder, point restraint 180 degrees around cylinder; 4. Impact: 50 N point load on outside center of cylinder, fixed on both ends.

Stresses were reported in the form of a factor-of-safety (FOS) using maximum von Mises stress and a stress limit equal to the ultimate strength of polycarbonate, 4×10^7 N/m^2. By applying the helical reinforcing mesh, we were able to reduce the weight of the dialyzer by 17% while maintaining the strength of the original device design.

IV. DISCUSSION

A. Impact

The goal of this project was to utilize a life-cycle analysis in order to improve material and energy utilization in dialyzer design. In order to make the design practical for near-term implementation, we focused on reducing the amount of material required to make a product with the same functionality. Given that about 80,000 people undergo dialysis every day worldwide, the potential impact possible from the 17% weight reduction we achieved, if implemented in all dialyzers used, is 426,000 kilograms per year. If that amount of polycarbonate were incinerated, it would release into the atmosphere 560 metric tons of carbon dioxide and 6.1 metric tons of methane, as well as 830 kg of the carcinogen benzene. Furthermore, reducing the material used in the housing results in reduced material and energy consumption through the entire branch of the LCA devoted to polycarbonate production, although quantifying this impact is significantly more complicated.

B. Future Design Considerations

The work done in this project focused on the preliminary phase of material reduction through careful and deliberate product design. Beyond this, we also envision a product designed specifically for material recovery. However, given the physiologically intimate nature of dialyzers, disinfection and sanitization must be a requirement when complete material reuse is implemented. Indeed, single-use products within the medical device industry were developed in order to reduce the spread of infection. Therefore, when reprocessing the material from dialyzers, the potential spread of infection must be taken into careful consideration.

We suggest that one possible method of mitigating infection while still thoroughly reusing raw materials could be the LCA-driven design of a hybrid disposable-reusable device. In this implementation, the largest part of the device does not come in contact with biological components, and is reusable without the need for disinfection. We also envision another paradigm shift in the design of medical devices that focuses on material recovery through natural processes rather than through implemented systems. In this case, the materials chosen for the dialyzer will be designed deliberately for biodegradation and natural reentry into the biosphere. As described by McDonough and Braungart[4], a product designed in such a way is composed of natural nutrients, which, upon disposal and degradation, become food for microorganisms such as soil bacteria. In this way, the product life-cycle forms a closed loop.

C. This Project as a Template for Applying LCA to Other Products

By creating and analyzing a detailed life-cycle analysis, an engineer can better understand how to design a product that utilizes a closed-loop life-cycle [8]. This is particularly informative in medical device design where there is little consideration for recycling and reuse due to the entrenched legacy of single use products. As with dialyzers, many products may already have a well-developed design that utilizes a linear, cradle-to-grave life-cycle rather than a closed-loop life-cycle. While the life-cycle analysis serves to direct design goals by analyzing the full impact of materials and processes used, the functional analysis serves to bring to light the designs that have the most practical and significant room for improvement. For example, our life-cycle analysis revealed that the polycarbonate components of the dialyzer had the largest impact, while the functional analysis determined that polycarbonate was also one of the most feasible components to change. The remaining two phases of our project, geometric and stress analysis, were determined only after the design goals were decided based on the life-cycle and functional analyses. Likewise, in the LCA-driven designs of other products, subsequent analyses will be determined based on the specific design goals determined. In this way, LCA serves as a method for directing appropriate design goals that are based on a broad understanding of a product’s lifelong impact, promoting sustainable and responsible design.

REFERENCES

[1] Yan L. 2007. Reuse vs. single use: Is the tide shifting? In *Nephrology News & Issues.*

[2] Frenay R. 2006. *Pulse*. New York: Farrar, Straus and Giroux. pp. 545.

[3] McDonough W, Braungart M. 2002. *Cradle to Cradle: Remaking the Way We Make Things*. New York: North Point Press. pp. 193.

[4] Boettnew EA, Ball GL, Weiss B. 1973. “Combustion Products from the Incineration of Plastic,” EPA report EPA-670/2-73-049.

[5] United States Environmental Protection Agency. 1994. Chemical Summary for Acetaldehyde. Available: http://www.epa.gov/chemfact/s_acetal.txt.

[6] Huff J. 2007. Benzene-induced cancers: abridged history and occupational health impact. *Int J Occup Environ Health* 13 (2): pp. 213–21.

[7] Agency for Toxic Substances and Disease Registry. 2007. ToxFAQs™ for Styrene. Available: http://www.atsdr.cdc.gov/tfacts53.html.

[8] *Environmental Management – Life Cycle Assessment – Principles and Framework*, ISO Standard 14040:2006