Product Design Specifications (PDS)

Synthetic Bowel for Resident Assessment

BME 402

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Function: Design a synthetic bowel tissue incorporating the two distinct layers of the small bowel (the mucosa and the muscularis) that replicates animal tissue both physically and aesthetically. This model is designed as a simulation model on which residents can be assessed in their knowledge of procedures such as bowel repair, resection, and anastomosis. This small bowel design will employ a user-friendly fabrication protocol and packaged kit to aid in mass production and accessibility.

Client Requirements:

- Medical students need to able to perform a resection and/or an anastomosis, in which a portion of the small bowel is removed and the remaining ends are sutured together. An important feature of this design must highlight the importance of the *decision making* skill that residents must have in choosing which action is best for the case at hand (ie. this model should be modifiable).
- The tissue needs to tear if the procedure is performed incorrectly, such as if sutures are placed too close or too far away.
- There are 4 anatomical small intestine layers, but this model only needs to incorporate the visible/structurally relevant layers of the bowel: the innermost mucosa and the muscularis.
- Materials should mimic the mechanical properties and aesthetic nature of the bowel.
- The entire model should represent the surgical environment, ie. need for lubrication or some model of peritoneal fluid, a small bowel that is not structurally rigid but rather deforms to the shape beneath it.
- The small bowel model should be easy to fabricate and replace, making it a worthy replacement for the use of the short-lived cadaveric animal tissue that is currently being used in medical schools.

Design Requirements:

1. **Physical and Operational Characteristics:**

    a. *Performance Requirements:* Above all else the synthetic bowel must respond to repair, resection, and anastomosis as live human bowel would respond. This model is meant to replace the animal intestines that residents currently "operate"

on to test their competency with those surgical procedures. Along with this, the model must be easy to assess a pass or fail of competency, meaning the educator could pull at the stitching and know whether or not the procedure was done correctly or not.

b. *Safety:* Safety is a factor that must be considered for all engineering design projects. The synthetic bowel design cannot use live tissue or cells. The goal of this project is to create a bowel of *synthetic* materials with properties comparable to that of live intestinal tissue but to move away from the need for animal intestines. As such, all the designs we develop will have equal safety designations.

c. *Accuracy and Reliability:* The key aspect of this design will be to accurately convey the procedures of repair, resection, and anastomosis of live bowel tissue. To do this the materials that we employ will have to be proven to act and respond to surgical procedures in the same way that live tissue would. Failure of this model to accurately and reliably simulate live tissue would inaccurately test a resident's competency with the procedures and yield disastrous events when performed in the operating room. It will also be necessary for the model to possess accurate tensile strength due to the way residents' are assessed. The material strength is very important in insuring the bowel will not tear under the appropriate tension. Therefore, it is necessary for the product to have a tensile strength of 0.9 MPa [7]. The accuracy and reliability of our model will be assessed through a survey at UW Hospital where residents will practice small bowel procedures with our model. These survey results will then be quantitatively assessed.

d. *Life in Service:* The synthetic bowel tissue should remain functional until it has been utilized in simulated medical procedures, such as resection and anastomosis. Mr. Kwan does not expect the product to be reused after simulation. However, if the model is 6-12 inches long, it should easily be able to undergo another simulation farther down from the previous site of suturing/resection.

e. *Shelf Life:* The synthetic bowel tissue should maintain its structure and mechanical properties when stored at 25ºC.

f. *Operating Environment:* This synthetic bowel will be used in a clinical lab setting. Sterility would not be necessary since the materials will be plastic derivatives of different consistencies of silicone, but the model itself will undergo

a “surgery” and so the resident will be operating as such Iie. needles, sutures, clamps, lubricating fluid, etc.)

g. *Ergonomics:* The synthetic bowel tissue should be easy to handle and store in a lab environment. The user should not have to worry about fragility of the material as it is transported. For the fabrication kit, the directions should be clear and concise and packaging easy to handle. For the survey, the language must be clear and in no way “lead” the resident to answer a specific way.

h. *Size:* The size of the synthetic bowel tissue is not specified, but must be within an anatomically acceptable range. The gastrointestinal tract is typically between 7.5 and 8.5 meters in length. Unless client specifications change, the product will model a portion of the bowel, so the size will not exceed 7.5 meters in length. Additionally the small intestine has a diameter of approximately 1 inch, so that specification must hold in our synthetic model as well.The overall thickness is 1.080 ± 0.25 mm^2, and the thickness of each tissue layer is as follows: mucosa & submucosa = 500-1000 microns; muscularis = 850 micron; serosa = 50 microns [7].

i. *Weight:* The weight of the product will depend on the materials chosen and the percentage of bowel that will be represented in the final product. It is not necessary that the weight be identical to that of the bowel in vivo.

j. *Materials:* The synthetic materials used will possess similar structural, mechanical and aesthetic qualities to the human bowel. All materials must be synthetic and non-living.

k. *Aesthetics:* The synthetic bowel needs to be a red-pink color and have a smooth texture, similar to a human bowel. It should also have similar flexibility and morphology of a human bowel, meaning it should be pliable and deformable. The mesentery should be translucent and fatty-colored. The small bowel tissue thickness (see above) should be accurate. Anatomical landmarks should also be represented when possible, although a working vasculature is not required for this semester’s work.

2. Production Characteristics

a. *Quantity:* Only one proof of concept synthetic bowel is required for this semester, but in the future our design will be intended to be scaled up so that numerous models could be on hand for residents to practice at any time.

b. *Target Product Cost:* Mr. Kwan gave us a budget of $300, which could be easily increased in the future should the design demand it.

3. Miscellaneous

a. *Standards and Specifications:* Our model must be comparable to the dead animal tissue that the residents are currently using for the assessment process. Mr. Kwan did not put any importance on whether the model includes additional pieces of anatomy (like the stomach) but said his primary concern was the authenticity of the small intestine and its physical properties like texture/mechanics, diameter, color, etc.

b. *Customer:* The customers that will be handling the synthetic bowel are medical students at University of Wisconsin School of Medicine and Public Health.

c. *Patient-related Concerns:* The model should possess a high degree of anatomical and mechanical accuracy so that the medical students using the product will be sufficiently prepared to perform this surgical procedure *in vivo*.

d. *Competition:* There are several products on the market that mimic synthetic bowel tissue in strictly a mechanical sense. Currently, the two most popular products on the market are Syndaver Lab's Double Layer Synthetic Bowel Tissue and SimuLab's Large Intestine Tissue. Both are used for practicing resection and anastomosis, but neither are anatomically accurate because they lack the anatomical landmarks that our client is seeking.