Medical Device for Correction of Short Bowel Syndrome

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EXECUTIVE SUMMARY

SBS is a serious and often fatal condition that occurs when the small intestine is too short for sufficient nutrient absorption. Current treatments of SBS include parenteral nutrition (PN), the use of growth hormones, intestinal transplantation, and bowel lengthening surgery. However, complications are associated with all of these treatments including infection, sepsis, and even death. The success rates of current treatments are low and the mortality rate of SBS exceeds 30%, so it is necessary for alternative treatments to be explored[15].

Currently, researchers at the University of Michigan Mechanical Engineering department, led by Professor Diann Brei, Dr. Jonathan Luntz and Brent Utter have teamed up with pediatric surgeons from Mott Children's Hospital, led by Dr. Daniel Teitelbaum, to study a new method of correcting short bowel syndrome (SBS) using mechanotransduction. Mechanotransduction is the biological response to an applied physical stress. In many biological tissues, an applied load will stimulate the tissue to grow in response to the load. Two devices have been developed: a hydraulic actuated design and a shape memory alloy (SMA) ratchet design. The hydraulic device has been tested in pig bowel and proven effective in causing the tissue to grow with the extension of the device. The SMA device has been tested in ex-vivo pig bowel to test its functionality. However, these devices need several improvements in order to be used in human applications. For example, neither of these devices is fully implantable nor do they produce the fourfold extension that is desired.

A quality functional deployment (QFD) was developed and used as a tool to quantify customer requirements for a new implant design. The most important customer requirements were: fourfold extension, fully implantable, and fits inside the abdominal cavity without causing harm to surrounding organs. Linear extension of the implant device (and therefore the bowel) is limited by the size of the abdominal cavity. Therefore, another customer requirement is that the device should be compliant or curvilinear, which would allow the device to bend or be multidirectional. Once the customer requirements were determined, they were converted to quantifiable engineering specifications. The most important specification to quantify was the size of a typical pediatric abdominal cavity. To quantify this, successive two-dimensional CT scan images were stacked and traced using Solidworks. Then, a three-dimensional surface of the abdominal cavity was created and dimensioned.

A functional decomposition and brainstorming were used to develop several design concepts which were organized into a concept tree. These design concepts were evaluated using a selection matrix and concept scoring. The Crawling Bowel Extender was chosen as the alpha design because it scored the highest on the selection matrix and concept scoring.

A prototype of the Crawling Bowel Extender was manufactured and tested and is capable of meeting all of the customer requirements and engineering specifications. Specifically, the crawler can traverse the entire track including the curved portions, it can withstand a retention force of 200 g, and it can apply 20 gf on the bowel. Furthermore, the device is capable of extending the bowel to more than three times its original length.