PHOENIX ANALYSIS & DESIGN TECHNOLOGIES

We Make Innovation Work

Project Name: Tissue Expander Project
Application: Tissue Expander Concept Development Work
Customer: Dignity Health / Barrow Neurological Institute

NOVEL TISSUE EXPANDER TO MINIMIZE TISSUE DAMAGE DURING MINIMALLY INVASIVE SURGERY

In 2012 PADT worked with Barrow to develop a concept feasibility prototype for a novel tissue expander.

BACKGROUND AND PROJECT CHALLENGE

This novel device improves access for minimally invasive surgeries (i.e. laparoscopic surgical procedures). Current surgical techniques use a small incision followed by metal dilators that are inserted one over the other to widen and hold the opening throughout the procedure. Stabbing these metal dilators down into the incision can cause tearing, nerve damage, increased pain, and an increased potential for post operative infections.

The tissue expander improves surgical access during minimally invasive surgeries by creating, and maintaining, an enlarged surgical corridor through more gentle radial expansion instead of a downward stabbing motion. The device uses a thermally responsive tube that can be stretched to a desired size and shape when heated above body temperature and becomes rigid when cooled to body temperature. These properties allow a heated and cooled balloon to shape the tube into a stable and rigid cylinder through which surgery can be performed.

PADT's challenge was to develop a compelling prototype to prove the viability of the technology, and find out if the device could be packaged within an enclosure that would lend itself to the surgical environment (size, weight, noise and portability).

PROCESS AND SOLUTION

Doctors from the Barrow Neurological Institute / St. Joseph's Hospital & Medical Center developed and patented the technology to insert a balloon catheter into an incision and use a controlled thermal system to expand

DISCIPLINES EMPLOYED

Mechanical Engineering

Electrical Engineering

TESTIMONIAL

"I found there to be great benefit in going through PADT's disciplined steps for the development of an updated prototype of our device. Restarting with a more systematic approach, and analyzing each component fresh, made me feel confident about every aspect of the new design."

Neil R. Crawford, PhD

Associate Professor, Spinal Biomechanics

Barrow Neurological Institute

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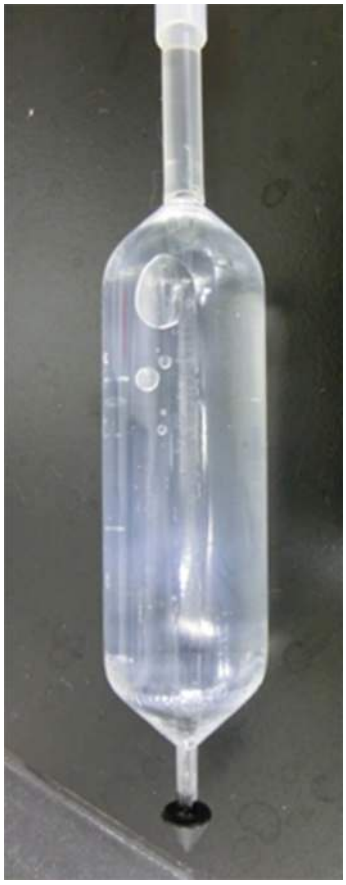
a compliant tube in the incision thus providing surgical access to the site. They came to PADT to develop the first functional prototype to assess the technological challenges and commercial viability.



TASK 1: PADT's first task was to document the preliminary product requirements for the product; including system and subsystem requirements, procedure requirements, usability / ergonomic considerations, and to evaluate the technical concepts.

To streamline the concept development process the most promising concepts were selected based upon calculations, system block diagrams, and schematics for the 2 major subsystems; the Expander System (ES) and the Balloon Catheter (BC).

The Balloon Catheter development work included a detailed analysis of the hydraulic system including thermal, flow & pressure calculations, hydraulic block diagrams, and material evaluation and manufacturability.

The Expander System development work evaluated and integrated all of the components associated with the control subsystem, including temperature controllers, solenoids, pumps, heaters, coolers, and the programmable logic controller (PLC).

The results of the preliminary development work for the ES and BC subsystems, the BOM's, hand sketches, and cost estimates were all evaluated for feasibility prior to the initiation of CAD models and prototype fabrication. Key areas of concern that were identified during the preliminary development analysis were also brought forward for discussion; primarily the cooling system cost and size requirements.

TASK 2: The second task was to design and prototype a cost effective "brassboard" prototype to confirm the overall system operation. The prototype system was designed for easy modifications and adjustments using simple, easily constructed, and cost effective components.

The brassboard prototype allowed the system to be tested over the full range of operating pressures and temperatures, and allowed for the evaluation of balloon inflation and evacuation. This functional prototype also addressed, and identified concerns regarding the size and weight constraints, mobility, noise generation, condensation, product cost estimates, and OR feasibility.

CONCLUSION

The detailed system analysis and functional prototype of the Tissue Expander proved the viability of the technology and identified the action items to be addressed to advance the technology toward detailed design development and commercialization.

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