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Aspiration Containment System for Large Ovarian Cyst Removal

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Abstract

In order to minimize healing times, prevent possible metastasis, and avoid the need for chemotherapy in the future, surgeons require a method for removing large ovarian cysts without any content leakage. To address this need, we have developed a functional prototype that utilizes the readily available Neptune 3 Waste Management system in the operating room to aid in the removal of large ovarian cysts.

Background

Clinical Problem

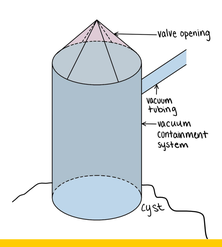
Annually, about 21,000 women in the United States will have a cancerous ovarian cyst develop, which leads to approximately 14,500 deaths a year according to Mobeen and Apostol, affiliated with Coney Island Hospital. However, there is currently no way to accurately differentiate between a cancerous and non-cancerous ovarian cyst. Thus it is critical to remove the cysts without spilling the contents of the cyst and potentially metastasizing the patient's cancer.

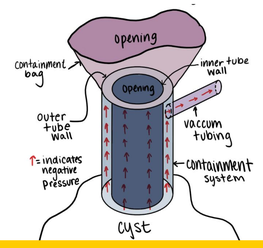
Ovarian cysts that are larger than 15 cm cannot be removed using traditional procedures that do not require the draining of the cyst as Dr. Mattson at M Health Fairview stated. Currently there are two main options for large ovarian cyst removal. The first is to create an incision from the pelvic bone to the abdomen and remove the cyst from the body without puncturing and draining the cyst. This method requires a long recovery time, however it ensures that there is no risk of leaking the cyst contents to the patient's body. Another method that is used to remove large cysts is to create a much smaller incision in the patient. Then, using a needle, a small hole is made in the cyst and a vacuum is placed inside the cyst to drain the cyst. This method requires a shorter healing time, but there is an increased risk of leaking cyst contents.

The goal of this project is to design a device to be used for the removal of large ovarian cysts through a smaller incision without exposing the patient to cyst contents.

Prototyping

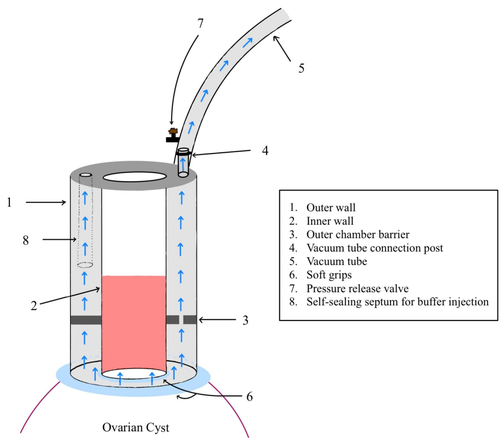
Device Model: Throughout the development of this device, several iterations have been designed and made, as shown in the images below. The original concept of the design was containment tube with a valve that opened to allow surgeon tools to access the cyst. The next iteration included the necessary components to create separate vacuum and tool access chamber, along with a mesh and containment bag components that did not make it into the final design. Once the design was mostly settled on, the group switched from creating scratch prototypes to 3D printed prototypes.





Current ACS Design

The device consists of 2 stiff clear plastic tubes, both the same length, and one with a smaller diameter than the other. The smaller tube will sit concentrically inside the larger tube. The tops of the two tubes will be connected, but the bottoms will not. This will create a chamber between the two tubes where a vacuum is formed when placed on a cyst. One end of the vacuum tube will attach to the connection point, which enters the vacuum space, and the other end will be connected to the standard vacuum machine in the OR. Once the vacuum is created, surgeons will insert their tools into the inner tube to drain the cyst. While the device is suctioned to the cyst, any contents that escape into the inner tube will not be able to exit the device. Additionally, there is an emergency pressure release valve and a buffer injection point included for device and patient risk management.



Preliminary Results

Cyst Model: Originally, the model used for the cyst was a plastic ziplock bag filled with colored water, however, the team wanted to create something more realistic to test on. To create the new cyst model, Ballistic gel #1 from Humimic Medical was molded into a uniform hollow sack. The sack was then filled with water mixed with red dye.

Testing: The device was tested on the new cyst model. It was able to create a seal and suction sufficiently to the cyst. During and after aspirating the cyst model, we observed that there was no leakage of fluid, indicating that our device prototype can aid in the aspiration of large cysts.

Future Research Directions

In the future, there are changes that can be made to the device, especially before moving to clinical testing and FDA approval. This include determining the material to be used for the containment system. The material must be see through, autoclavable, non-cytotoxic and not irritating to human tissue. The material currently being used only meets the first requirement. There are also some other human factors that need to be considered, such as ergonomics of the device, vacuum tube, and stop valve.

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