Aspiration Containment System for Large Ovarian Cyst Removal

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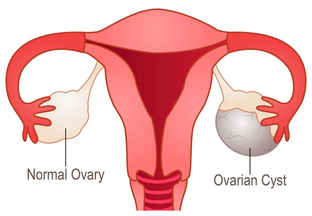
Need Statement

Surgeons require a simple solution for aspirating large ovarian cysts via a small surgical incision and without any content leakage. Such a solution will significantly reduce post-operative recovery times and risk of cancer metastasis.

Background

Clinical Problem:

- Nearly 21,000 women in the United States develop a cancerous ovarian cyst annually, resulting in 14,500 deaths a year.
- Ovarian cysts can grow to be upwards of 30L in volume.
- There is no reliable method to differentiate between a malignant and benign ovarian cyst in vivo.
- It is critical to remove cysts without leakage of content into the abdomen, thereby eliminating the potential for metastasis and need for chemotherapy.



https://www.sitarambhartia.org/blog/gynecology/ovarian-cystectomy/

Current Technology: There are two main surgical techniques:

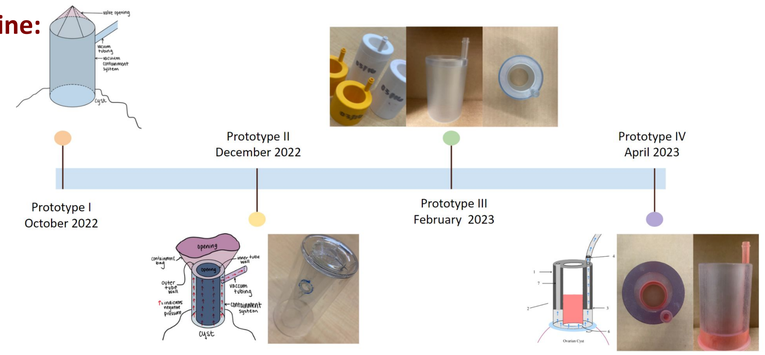
1. **Laparotomy:** An incision is made from the pubis to the sternum and the cyst is removed whole from the body (i.e. without puncture).
2. **Laparoscopy:** A small incision is made and a containment bag is maneuvered around the cyst. The cyst is aspirated in the open bag using the Neptune 3 Waste Management System.

Extensive post-op recovery times

Technical challenges and high risk of leakage

Prototyping

Timeline:

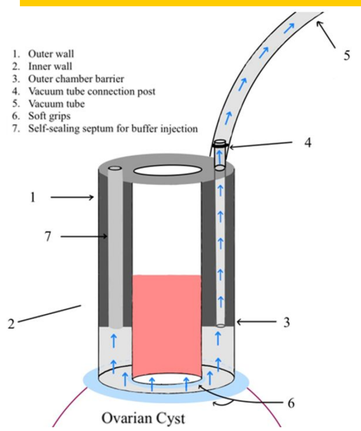


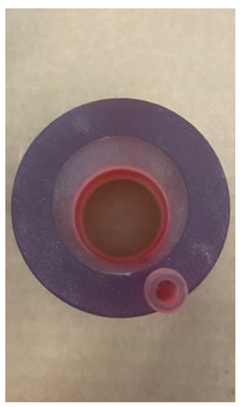
Process: Several iterations were created between prototypes:

- Single and dual chamber systems
- With mesh (bottom) and containment bag (top)
- Varying device heights
- Varying locations of vacuum connection post

Prototypes were initially made from scratch materials, then later 3D printed with PLA, ABS, and finally PolyJet material.

Device Design





The ACS utilizes negative pressure to create an airtight seal with the surface of a cyst. The device is composed of 2 chambers:

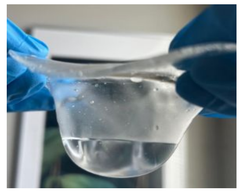
- **Inner Chamber:** allows the surgeon to place and utilize aspiration tools they are well acquainted with (e.g. scalpel & yankauer suction tip) in a comfortable-to-maneuver space.
- **Outer Chamber:** hosts a pathway for negative pressure to be delivered from a surgical vacuum to the device base.

The soft bottom ensures a smooth interface that promotes cyst adhesion. The septum serves as an area for which sterile buffer solution can be injected to clean the outer chamber.

Preliminary Results

Cyst Modeling:

- Initially, water-filled balloons and plastic Ziploc bags were used.
- Ballistic Gel #1 from Humimic Medical was molded into a hollow spherical sack, then filled with red-dyed water.
- VOC feedback indicated that ballistic gel realistically mimics cyst material properties!



Device Testing:

- **Leak Tests**
  - No leakage of fluid occurred during or after aspiration.
  - Device creates a strong, airtight seal with cyst surface.
- **Compressive Force Tests**
  - Device body can withstand 80 lbf (avg. hand grip = 60 lbf).
  - Vacuum post can withstand 35 lbf.
- **VOC Tests**
  - Device is intuitive to use, compatible with multiple removal techniques, and provides adequate visualization.

Future Research Directions

1. Incorporation of a pressure release valve
2. Selection of an autoclavable, non-cytotoxic, and biocompatible device material
3. Modification of the vacuum tubing for compatibility with the Neptune 3 Waste Management System
4. Further evaluation of device ergonomics

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