**Initial Design Considerations:**
- Keeping patients safe and providing maximum comfort
- Device for physicians to increase access to the gallbladder
- Most common disorder affecting the biliary system (25 million people in the United States)
- Characterized by stone formation, which can lead to painful symptoms and potential duct blockages
- Subset of patient population has comorbidities, making them unable to undergo general anesthesia
- Current Treatments/Options
  - Cholecystectomy: surgical removal of the gallbladder (requires general anesthesia)
  - Percutaneous drainage: current solution to help relieve painful symptoms and formation, characterized by stone in the biliary system (25 million people)

**Problem Statement**
1. Base problem: A better solution to remove gallstones from non-operative patients suffering from gallstone disease is needed
2. Meetings with physicians and extensive research to determine:
   - True root of the problem
   - Available tools
   - Physicians’ needs and desires
3. Main problem identified to solve: The lack of access to the gallbladder that is limiting the use of current tools to remove gallstones in a minimally invasive manner

**Goals and Preliminary Design**
- Overall Project Goals: Develop an easy to use and reliable device for physicians to increase access to the gallbladder, while keeping patients safe and providing maximum comfort
- Initial Design Considerations:
  - Wire mesh with similar function to finger trap toy mechanism
  - Force and safety factor (SF) calculations were done to discover that a stainless-steel mesh would be able to withstand the pressures of the body

**Design Objectives**
- Prototype 1: Established mechanical functionality (objectives 1-7)
  - Handle rotates to change sheath diameter
  - Sheath diameter size can be seen on handle through a small window on housing
  - Wire mesh rigidly attaches to bearing
- Prototype 2: Improve usability, patient safety, and patient comfort (objectives 1-11)
  - Handle moves bridge along threads of housing to change sheath diameter

**Prototype 1**
- Overall Prototype 1 Goal: Establish mechanical functionality (objectives 1-7)
  - Handle rotates to change sheath diameter
  - Sheath diameter size can be seen on handle through a small window on housing
  - Wire mesh rigidly attaches to bearing

**Prototype 2**
- Overall Prototype 2 Goal: Improve usability, patient safety, and patient comfort (objectives 1-11)
  - Handle moves bridge along threads of housing to change sheath diameter

**Percutaneous Access**
- Galbladder with gallstones
- 1. 18-G needle punctures the abdominal wall, liver, and gallbladder
- 2. Guidewire is placed through 18-G needle
- 3. 18-G needle is removed, and device is placed over guidewire
- 4. Guidewire is removed, and device is kept in place
- 5. Device is upsized to increase sheath diameter
- 6. Tools are placed through the expanded device to remove gallstones
- 7. Sheath is fully expanded, and gallstones are removed
- 8. Sheath diameter is decreased over time
- 9. Device is removed
- Note: All placement done with pre-established imaging modalities

**Objectives and Results**
- Design Objectives
  - Prototype 1: Threaded physician interface
  - Prototype 2: Threaded physician interface
- Prototype 2: Locked control wires
  - Bearing between bridge and mesh
  - Bearing between bridge and mesh
  - Iris and iris tab
- Prototype 1: NA
  - Drain attachment
  - Suture eyelets
  - Spring-loaded lock
  - Detachable housing

**Impact and Conclusions**
- Current Impact
  - Raises awareness of the lack of options for the target patients
- Future Impact
  - Provide patients with options and has potential to be used in other procedures – increasing patient care across many fields
  - Decrease follow-up procedures – decreasing waste and financial burden for both hospitals and patients
- Conclusions and Accomplishments
  - Determined the root problem to be lack of access
  - Proved mechanical feasibility of device
  - Filed provisional patent
  - Created a foundation for project continuation
  - Collaborated with individuals across professional fields
  - Maintained a positive team dynamic

**Future Work**
- Immediate Plan: Compile tentative testing procedures, extra ideas, & current problems into a document for project pass off
  - Develop to-scale, working prototype
- Future Work: Obtain patent and consistently producible product

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