Product Design Specifications

Optimizing selective renal occlusive clamp for robotic surgery

Members

Kelsey Duxstad - BWIG
Naomi Humpal - Communicator
Andrew Pierce- Team Leader
Michael Stitgen - BSAC

Advisor

Professor Paul Thompson

Function

Our client, Dr. Abel, requests that our team develops a selective renal occlusive clamp for robotic, laparoscopic, partial nephrectomy surgery. Surgeons are performing more partial nephrectomy surgeries in order spare functional tissue. Our product will optimize the partial nephrectomy by selectively occluding blood flow to part of the kidney, while allowing normal blood flow in the other parts of the kidney. This clamp will prevent global kidney ischemia which can lead to tissue damage and complications.

Design Requirements

1. **Physical and Operational Characteristics**
    - **a.** Performance Requirements: The product must be able to be applied for the duration of the surgery (3.5-4 Hours) and must be reusable for future laparoscopic procedures.
    - **b.** Safety: The product cannot cause any harm to the operators nor the kidney and the surrounding tissues
    - **c.** Accuracy and Reliability: The device must be able to apply 10-15 N of force across the entire kidney for a maximum time of 30 minutes. Additionally, it must reliably provide this force after at least 100 applications.
    - **d.** Life in Service: The device must be able to operate for the duration of the surgery (approximately 3.5-4 Hours)
    - **e.** Shelf Life: The device must be able to remain in storage in a sterile package without corroding for at least 10 years.
    - **f.** Operating Environment: The expected environment for use is in an operating room in contact with living tissues.
    - **g.** Ergonomics: The device must be easily sterilized, operated with one hand, accommodate hand breadth ranging from 6.5-9.5 cm, and not cause discomfort to the user.
    - **h.** Size: The device must be able to fit through a 12 mm by 15 cm laparoscopic trocar and the arm should be 60.96 cm in length. The clamp should be 5 cm long.
    - **i.** Weight: Weight should not exceed one kilogram
    - **j.** Materials: The device should be made of materials that are durable and biocompatible.
    - **k.** Aesthetics, Appearance, and Finish: For marketing reasons our final design should be aesthetically pleasing.
2. **Production Characteristics**
    - **a.** Quantity: One prototype is required

   b. Target Product Cost: The marketable price for the device should not exceed the cost of a commercially available surgical clamp, $10,000. Our prototype should not exceed $500.

3. **Miscellaneous**
   a. Standards and Specifications: The device should adhere to FDA medical device guidelines.
   b. Customer: The final product is intended for use by Urologists performing Laparoscopic Partial Nephrectomies.
   c. Patient-related Concerns: The device is intended for use on patients needing laparoscopic partial nephrectomy. The device will need to be sterilized before use on subsequent patients.
   d. Competition: There are no commercially available laparoscopic, kidney parenchymal clamps. The Satinsky laparoscopic clamp has been used in this manner, but it is only designed for arterial clamping.