Pediatric Kidney Transplant Surgical Instrument Development

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BME 200/300 Design Project

Lab 309

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Function

End-Stage Renal Disease (ESRD) is a condition affecting more than 808,000 people in the United States [1]. Approximately 5,645 of those with the condition are under the age of 18 [2]. Renal transplantation is currently considered the best and most cost-effective treatment for ESRD [3]. A major challenge that arises while performing kidney transplants in children is the lack of appropriate surgical tools and instruments. Current surgical instruments are designed with adult bodies in mind. These instruments are often too large to be used on children's smaller bodies, among other issues. Our clients, Dr. Kelly Collins and Dr. Jennifer Phillips, face this challenge consistently while performing pediatric surgery and asked the team to create a design of a vascular clamp that could be used during kidney transplant surgeries in pediatric patients. The device will be adjusted to more easily access the lesser wound depth corresponding to the body of a pediatric patient while still avoiding a large-sized tool that may obstruct the surgical field. Compared to current designs on the market, the model should also have less clamping strength to prevent any lasting damage to the targeted blood vessels, as pediatric patients often have smaller blood vessels and lower blood pressure [4] than adult patients.

Client requirements

- Instrument should have all features of a standard vascular clamp found in renal transplant surgery, including
    - Appropriately sized and ergonomic finger rings
        - Adult surgical handles should have slightly oval-shaped rings with an internal diameter matching average adult thumb and index finger widths
    - Atraumatic jaws to avoid damage to vessels and any surrounding tissue
    - A strong and maintainable locking mechanism tight enough to stop all blood flow from the objective vessels during anastomosis while preventing any long-lasting crushing or damage to the vessels
    - An overall small enough size to avoid obstruction of surgical field
- The prototype should be adjustable for blocking blood flow in all vessels involved in anastomosis, including
    - An average size adult donor renal artery
        - Typically ranging from 5-6 mm diameter, with an average of 5.6 mm [5]
        - This size range may be subject to change depending on statistical measurements found in the provided CT scan database
    - An average size iliac vein for a recipient of each age group
        - These size ranges will be determined based on statistical measurements found in the provided CT scan database
- Final product should be composed of a safe and biocompatible metal and should be latex-free

- Final product should be autoclavable or able to withstand chemical sterilization with commonly used compounds, and should follow all clinical grade safety standards
- Model should be reusable or produce a framework that is publishable in a research journal and can be adjusted to create a standard medical-grade OR instrument
- Final product should be within the budget of $200-500

Design requirements

1. **Physical and Operational Characteristics**
    - **Performance requirements**
        i. The clamp shall accommodate the full range of iliac vessel depths measured from pediatric CT imaging of patients aged 0–18 years. The required working depth shall be determined from the imaging dataset.
        ii. The clamp shall maintain a jaw width of approximately 1.6 mm and a jaw length of approximately 58 mm [6], equivalent to the reference adult DeBakey vascular clamp used in kidney transplantation, while reducing the overall instrument depth to accommodate pediatric anatomy.
        iii. The clamp must remain securely positioned on the vessel to avoid any unintended movement or loosening during use.
        iv. The clamp shall generate an adjustable clamping force within the range of approximately 2–5 N [7], sufficient to achieve complete vascular occlusion while minimizing endothelial injury. The final target force will be validated through benchtop testing using simulated pediatric vessels representative of the transplant procedure.
        v. The clamp must withstand the mechanical loading associated with repeated operation and vessel clamping without permanent deformation or failure.
        vi. The final design shall be compatible with fabrication from surgical-grade, autoclavable metal.
    - **Safety**
        i. The final instrument must be made from medical-grade, non-toxic, latex-free materials suitable for use during pediatric kidney transplantation.
        ii. The instrument must provide enough clamping force to temporarily stop blood flow without damaging or excessively compressing the blood vessels.
        iii. The designs should avoid sharp edges, pinch points, or other features that could cause injury to the patient, surgeon, or surgical staff.
        iv. Standard hospital sterilization procedures
        v. Reusable and durable

vi. Clinical-grade safety and surgical instrument standards
vii. Sterile, medical-grade surgical instrument

- **Accuracy and Reliability**
  i. The clamp must consistently reach and engage the target vessel across the expected range of pediatric vessel depths.
  ii. The final design shall be reusable and capable of withstanding repeated steam sterilization cycles (121–134 °C) [8] without loss of mechanical performance or structural integrity. The minimum validated number of reuse cycles will be determined during testing.
  iii. The prototype shall demonstrate reliable performance in the kidney transplant simulation model across the range of wound depths and vessel diameters representative of the target pediatric population.
- **Life in Service**
  i. The prototype surgical clamp(s), ideally composed of 3D-printable plastic, should successfully withstand at least one full operation of the kidney transplant simulation model
     1. The material must not break down or degrade during the simulated operation
     2. The clamp(s) must effectively block the blood flow from the vessels without causing excessive vessel tissue damage
  ii. The final surgical clamp(s) composed of sterile and medical-grade metal must consistently complete the required function without any material breakdown, corrosion, or failure
     1. The model should withstand an estimated 300-900 cycles of sterilization, as is consistent with the lifespan of a typical surgical instrument [9]
     2. While a standard kidney transplant surgery can range from 3 to 4 hours, the anastomosis phase at which the vascular clamp is actively applied should span under 40 minutes [10]
        a. This time limit is in place to avoid any prolonged blood flow restriction or permanent damage to surrounding tissue
     3. UW Health Transplant Center reports conducting about 273 to 350 kidney transplant surgeries annually, with about 4% (or 10 to 15 of those surgeries) focusing on pediatric patients [11]
     4. As such, the total active operational time for the clamps should range between 200 and 600 hours (to accommodate sterilization restrictions) or 20 to 90 years (to accommodate allowed surgical use)
- **Shelf Life**

i. The instrument will most likely be stored in aluminum, double linen wraps, polypropylene, or a sterilization pouch. [9]
ii. The instrument may be stored for up to 96 weeks in a room that should ideally be double the assembly and decontamination areas combined. [9]

- **Operating Environment**
  i. The instrument must be capable of undergoing the process of cleaning, disinfecting, and sterilizing for a surgical instrument. This includes cleaning with water, using an enzymatic transport gel or foam, and being plunged into a bath of detergent for 5 to 20 minutes. [12]
  ii. The instrument surfaces should be resistant to typical sterilization methods of surgical instruments, which could include dry heat, autoclave for up to one hour, or chemicals such as ethylene oxide, hydrogen peroxide, chlorine dioxide, peracetic acid, or aldehydes. [12]
  iii. The instrument must be able to go through approximately 300-900 cycles of sterilization. [9]
  iv. The instrument must be able to function in standard operating room environments, which are recommended to be 20 to 23 degrees Celsius, but can get as low as 17 degrees Celsius or as high as 27 degrees Celsius, and have a humidity from 20%-60%. [12]
  v. The instrument must be able to handle occasional jostling without misaligning.
- **Ergonomics**
  i. The instrument should be comfortable for the surgeon to use for long periods of time.
  ii. The instrument should require minimal hand force to open, close, and adjust while still providing sufficient clamping force to securely occlude the vessel.
- **Size**
  i. The instrument must be appropriately sized for pediatric kidney transplant patients, while still allowing access to an adult-sized donor kidney and vascular structures.
  ii. The design should account for differences in surgical depth, since depth does not necessarily correlate directly with the patient's age or overall size.
  iii. The instrument should not simply be scaled down from an adult instrument, as reducing the size may prevent it from reaching or properly accommodating the adult kidney and vascular system.
  iv. The design should consider multiple sizes or adjustable dimensions to accommodate the wide range of pediatric patient anatomies.

v. The instrument must be long enough to reach the necessary surgical structures while remaining compact enough to provide adequate access within the pediatric surgical field.
vi. Dimensions should be informed by cross-sectional CT imaging of pediatric kidney transplant patients rather than relying solely on age-based measurements.

- **Weight**
  i. The instrument should be lightweight enough for comfortable handling and precise manipulation by the surgeon during a delicate kidney transplant procedure.
  ii. The weight should be minimized without compromising the strength and rigidity required for safe surgical use.
  iii. The instrument should be appropriate for a metal, reusable surgical instrument, while the initial prototype can be lighter or made from other materials for testing.
  iv. The weight should be balanced with the required clamping force, ensuring the instrument is strong enough to stop blood flow without unnecessarily increasing its size or weight.
- **Materials**:
  i. Prototype clamps can be fabricated with 3D-printed plastic materials, which allows the team to make rapid and low-cost alterations.
  ii. Materials like PLA and PETG will be used as long as they provide equivalent or sufficient durability and force.
  iii. Final products will be manufactured from a medical-grade metal by a qualified manufacturing company.
  iv. This final material must be appropriate for surgical use and should provide sufficient strength, durability, and reusability with the sterilization process.
  v. Materials that deform, corrode, or release harmful substances during surgical use or cleaning should not be used for the final product.
- **Aesthetics, Appearance, and Finish**:
  I. The surgical clamp(s) will have a compact design that allows them to be easily positioned and used in the small abdomen of pediatric patients.
  II. The jaws should have a smooth and curved shape without any sharp edges or surfaces that could damage the tissue or vessel.
  III. The final clamp will be medical-grade that is smooth, and polished, allowing for easy cleaning and sterilization.
  IV. The different clamp sizes will have a consistent design while having different scaled dimensions for various vessel sizes.
  V. The prototype appearance and surface may vary due to limitations of 3D-printing.

2. **Production Characteristics**
   - **Quantity**:
     I. The number of prototypes will be determined based on the CT scan analysis and how much the team adjusts the design.
     II. The scans will provide the information required to identify the number of different-sized clamps needed.
     III. A design and specification will be made for each size, but to save money on prototypes, a select few sizes will be chosen for testing.
     IV. The final product quantity will be determined by the manufacturing company based on the required clamp sizes and demand.
   - **Target Product Cost**:
     I. The total cost of designing and prototyping should remain within the $200-$500 budget range provided by the client.
     II. Prototype clamps will be primarily made using 3D-printed plastic to minimize the cost during the design and testing phases.
     III. The clamps will be constructed from a medical-grade metal by a qualified manufacturing company. Their production cost is expected to be greater than the team's prototypes, and that cost will be covered separately by the hospital.
     IV. Commercial vascular clamps such as the DeBakey and bulldog-style typically cost between $150-$350 or more per piece depending on the manufacturer and design [13].
     V. The final product does not need to be less expensive than the existing clamps; however, the manufacturing cost should be reasonably similar to the other surgical clamping instruments.

3. **Miscellaneous**
   - **Standards and Specifications**

     i. While metal, non-powered surgical instruments are usually exempt from the FDA 510(k) premarket notification, this device requires consideration of this standard as it is a novel device with a new design and new intended clientele [14] under the limitations of regulation 21 CFR 878.9.

     ii. This device will be classified as a Class I medical device due to being a manual device with basic and general controls [14] and hence must follow regulations of 21 CFR 878.4800.

iii. This is a novel medical device and hence must follow the FDA regulation 21 CFR Part 820, which sets good manufacturing practices to ensure good quality.

iv. The FDA requires that all regulated medical devices be labelled; hence, the device must follow regulation 21 CFR Part 801, which specifies what exact labels the device must have regarding the name and place of business of the manufacturer.

v. ISO 7153-1:2016 specifies what materials are safe to use for the manufacture of metal surgical instruments, and the device must be made of a metal on the approved list to be permitted for global use.

vi. ISO 13485 specifies rules for quality management, manufacturing, and lifecycles of medical devices, and the device will need to meet the requirements of this standard to be sold in global markets.

vii. ISO 7151 is a standard that lays out rules for non-cutting surgical instruments. Since the vascular clamp is a non-cutting tool, this standard must be followed.

- **Customer**
  - i. This model is necessary for providing a precise and adjustable tool or set of tools intended to efficiently block blood flow in vessels without resulting in long-term damage for the patient.
  - ii. The potential customer(s) for this vascular clamp set are pediatric transplant surgeons specializing in the renal and urinary system.
  - iii. Aspects that customers would value most include
    1. An atraumatic mechanical grip that is tight enough to prevent any loosening or slippage of the vessel but gentle enough to avoid causing endothelial tearing or structural damage to pediatric arteries and veins.
    2. Interchangeable or adjustable jaws of varying sizes to effectively accommodate several vessel diameters found in pediatric patients ranging from infants to adolescents.
    3. An easily maneuverable and lightweight vascular tool that allows for precise clamping without heavily obscuring the encountered surgical field.
    4. Material that can maintain structural durability through a minimum of 300 to 900 high-heat autoclave or chemical sterilization cycles.
  - iv. Design features that the clients have expressed dislike for and should be avoided include

1. Excessive force caused by a rigid closure mechanism that poses the risk of crushing vessels and causing surrounding tissue damage or necrosis.
2. Extreme friction, jaw misalignment or mechanical failure at the hinge of the clamps during progressive use
3. Material degradation or corrosion after continued life in service.

- **Patient-related concerns**

  i. This device will be used invasively during surgery and therefore needs to be sterilized between uses.

  ii. This device has mechanical actuation and has no electrical components or data storage capabilities, due to which there is no risk of patient data leak.

- **Competition**

  i. Competing Design #1: Pediatric DeBakey Vascular Clamp[6]

  - The pediatric DeBakey vascular clamp is designed for pediatric vascular surgery and features a reduced overall size while providing atraumatic temporary occlusion of blood vessels during vascular anastomosis. The clamp improves maneuverability in smaller surgical fields compared to standard adult vascular clamps.
  - While the pediatric DeBakey clamp is better suited for pediatric anatomy, scaling down the entire instrument also reduces the jaw dimensions. As a result, it may not adequately accommodate the adult-sized renal vessels encountered during pediatric kidney transplantation.

  ii. Competing Design #2: Standard Adult Vascular Clamp[7]

  - Standard adult vascular clamps, such as DeBakey and Satinsky clamps, are routinely used during adult kidney transplantation and provide reliable temporary vessel occlusion with jaw dimensions appropriate for adult donor renal vessels.
  - Although these clamps effectively accommodate adult vessels, their overall length and working depth are optimized for adult anatomy, making them difficult to maneuver within the smaller operative field of pediatric kidney transplant recipients.

  iii. Competing Design #3: Atraumatic Vascular Clamp Designs [15]

  - Existing patented atraumatic vascular clamps incorporate features such as resilient jaw surfaces, optimized jaw geometry, and interchangeable

components to improve vessel contact while minimizing tissue injury during temporary vascular occlusion.
- While these designs reduce vessel trauma and improve clamping performance, they do not address the need to modify the overall instrument geometry for pediatric surgical access while maintaining adult-sized jaw dimensions.

iv. Competing Design #4: Enhanced Vessel Grip Vascular Clamps [16]

- Several patented vascular clamp designs improve vessel grip and clamping consistency through modified locking mechanisms, jaw profiles, and force distribution, allowing secure vessel occlusion with reduced risk of slippage.
- Although these designs enhance clamp performance, they are intended for general vascular surgery and do not address the unique challenge of pediatric kidney transplantation, where the instrument must combine a pediatric working depth with compatibility with adult-sized vessels.

Current vascular clamp designs are optimized either for adult vascular surgery or general pediatric vascular procedures. None of the identified devices are specifically designed for pediatric kidney transplantation, where the clamp must preserve adult-sized jaw dimensions while reducing the overall working depth to improve access within the smaller operative field of pediatric recipients. This gap motivates the development of a specialized pediatric transplant vascular clamp, which represents the primary design opportunity for our project.

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