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Lasso Renal Occlusive Clamp for Laparoscopic Partial Nephrectomy Surgery

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Client: Dr. E Jason Abel, UW Hospital

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Abstract

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Our client, Dr. Abel, has requested that our team develop a selective renal occlusive clamp for robotic, laparoscopic, partial nephrectomy surgery. Partial nephrectomies are becoming more popular 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 to the other parts of the kidney. This clamp will prevent global kidney ischemia which can lead to tissue damage and complications. This semester, the design will focus on the clamp end of the surgical instrument, with the laparoscopic arm being designed in future. Four different designs were developed: loop, modified bulldog, zip-tie, and crisscross. These designs were analyzed with criteria from the client and from published data about partial nephrectomy. The final design chosen from these criteria was the loop design. A prototype of this design will be constructed and tested.

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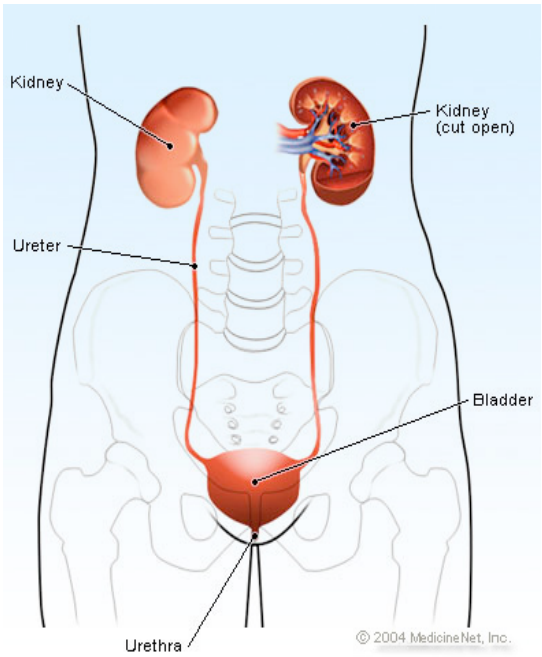
BACKGROUND

Partial nephrectomy surgery is used as a treatment for renal cell carcinoma ("Renal Cell Carcinoma," 2012), which affects 32,000 people in the United States every year (Sachdeva, 2012). The surgery is necessary because larger renal cell carcinomas do not normally respond to traditional cancer treatment methods, such as chemotherapy.



HTTP://IMAGES.EMEDICINEHEALTH.COM/IMAGES/ILLUSTRATIONS/URINARY

Figure 1. Anatomy of the kidneys.

Currently, there are two procedures for partial nephrectomy surgery: open and closed. The open surgery is conducted through a six to seven inch incision within the lateral abdominal region (Landman, 2006). The blood flow to the area of operation in the kidney is occluded using a Satinsky clamp (Abel, 2012). The tumor is then excised and the incisions are closed.

The closed surgery is performed using laparoscopic tools. To begin the laparoscopic procedure, three to four one centimeter incisions are made in the abdomen (Landman, 2006). After the incisions are made, the abdominal cavity is inflated to create an open cavity. A laparoscope is inserted in order to identify the tumors on the kidney. At this point, the renal artery and vein are clamped using laparoscopic bulldog clamps (Martin, 2012). After the occlusion has been performed, the tumor is then excised with the goal of a negative margin, meaning all of the cancerous tissue has been removed (Landman, 2006).

The current procedure for laparoscopic partial nephrectomy requires the use of bulldog clamps to occlude blood flow of the renal artery and vein. This causes global ischemia within the kidney tissues, leading to the release of cytokines (Abel, 2012). The

cytokines will induce an inflammatory response within the surrounding tissues (Furuchi, 2002), which may cause further tissue damage.

In order to prevent global renal ischemia, a partial clamping technique may be used. The open nephrectomy surgery currently uses a Satinsky clamp to apply pressure directly onto the kidney to only occlude blood flow to the areas of operation (Abel, 2012). However, this clamp is not compatible with the laparoscopic procedure.

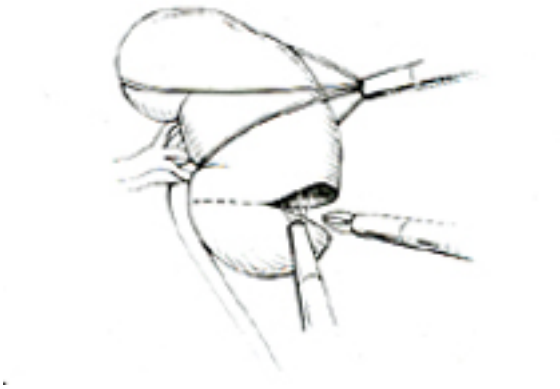


Figure 2. Illustration of a partial nephrectomy.
http://wuphysicians.wustl.edu/graphics/assets/images/FileUpload/3863image.j

CLIENT INFORMATION

Our client is Dr. E Jason Abel, who is a surgeon and assistant professor at UW-Madison Hospital**.** He specializes in the surgical treatment of urological malignancies and has advanced training in many types of cancer including: prostate, bladder, testis, penile and kidney. He is certified by the American Board of Neurology and performs open, laparoscopic, and robotic surgeries. He has special interest in the treatment of localized and locally advanced kidney cancer.

PROBLEM STATEMENT

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.

COMPETITION

Our team came across three methods that compete with our design: traditional open surgery clamps, laparoscopic vascular clamps, and the Simon Renal Pole Clamp.

Clamps such as the Nussbaum, Guyon-Pean Kidney Clamp, Satinsky, and Payr Pulorous Clamp are suitable for obstructing blood flow to the kidney during a partial nephrectomy open surgery. These are all suitable methods, but are not suitable for laparoscopic or robotic surgical techniques (Thompson, 2010). Due to the decrease in complications and post operative recovery time, a feasible option for clamping must be used within the realm of laparoscopic or robotic surgery.

Figure 3. Nussbaum clamp. http://www.rak-phoenix.com/prod_zoom/3107.jpg

For laparoscopic and robotic surgery there are several vascular clamps that are on the market. These clamps can be purchased from several different companies and work well in their application (Kobayashi, 2008). These clamps are used to occlude blood flow to the entire kidney, which is undesirable due to the risk of ischemia in kidney tissue that is not being removed, as mentioned previously.

Figure 4. Laparoscopic Vascular Clamps. http://www.aesculapusa.com/default.aspx?pageid=85

Finally, there is one product on the market, the Simon Renal Pole Clamp, that combines the qualities of both the laparoscopic suitable and partial kidney clamps. This clamp permits normal blood perfusion of the non-clamped kidney during the procedure, which reduces the risk of ischemic damage. It has flexible jaws and linear grooves for safe and atraumatic grasping of the kidney. Its working length measures 37 cm and is attached to a laparoscopic ratchet handle. This product is made by Aesculap (Aesop Surgical Technologies, 2012). However, our client does not like that the force is

Figure 5. Simon Renal Pole Clamp. http://www.tmml.com/Catalogue/SellSheets/A19_INFO_Simon%20Renal

concentrated at the base of the clamp rather than evenly distributed across the kidney.

DESIGN ALTERNATIVES

Through research and multiple brainstorming sessions, four design alternatives were created. Two of the designs, modified bulldog clamp and the crisscross, are modifications of current medical devices. The other two designs, the loop and the zip-tie, are novel designs and would be fabricated out of metal.

MODIFIED BULLDOG CLAMP

Figure 6. Modified bulldog clamp design.

The modified bulldog clamp would be an attachment that connects to the Aesculap Articulating Applicator for Temporary Endoscopic Vascular Clips. The vascular clips already have a bulldog clamp attachment, but it is too small for nephrectomy surgery. A bulldog clamp opens by applying force to the handle against a spring. It closes by removing the tension and letting the spring close the clamp. Three modifications would be performed to make the device meet the client's needs. The length of the clamp would become longer so it can clamp across the length of the kidney. The spring that keeps the clamp closed would have greater stiffness. This would increase the amount of force the clamp can apply. Lastly, a bend in the metal would be added so the force is applied to the right area of the kidney. This clamp would use the vascular clips preexisting mechanisms to open and close the clamp. It would also utilize locking mechanism similar to current vascular clamps to secure the modified clamp to the top of this laparoscopic instrument.

CRISSCROSS DESIGN

Figure 7. Image of a Johns Hopkins Bulldog clamp to be modified for the crisscross design.

http://pillinginstruments.com/images/products/hi-res/SR_353002.jpg

The crisscross utilizes the mechanism of the Johns Hopkins Bulldog Clamp. The Johns Hopkins bulldog clamp works similarly to a bulldog clamp. When a force is applied to the base of the device, the clamp opens. It closes by a spring that is produced by crossing pieces of metal. This design would attach the Johns Hopkins bulldog clamp to a piece of wire that has loose fitting metal tubing surrounding it. The tubing would then be slid down the wire until it applies force to the base of the clamp causing it to open. When the clamp is in the correct position, the tubing is pulled back off the clamp causing it to close. The tubing is removable so that the surgical field can be cleared of additional obstructions.

ZIP-TIE DESIGN

Figure 8. Depiction of the zip-tie renal clamp.

The zip-tie design uses the laparoscopic instruments used in other portions of surgery to thread a wire that is attached to a laparoscopic handle around the kidney. The wire will be a piece of metal modeled after plastic zip-ties. Once the wire has been wrapped around the kidney, it would be placed inside a locking mechanism, which prevents it from sliding back out and allows the wire to be tightened through the handle. As the design is tightened, increased pressure would be placed on the kidney. The handle will also have a quick release function that will release the locking mechanism.

LOOP DESIGN

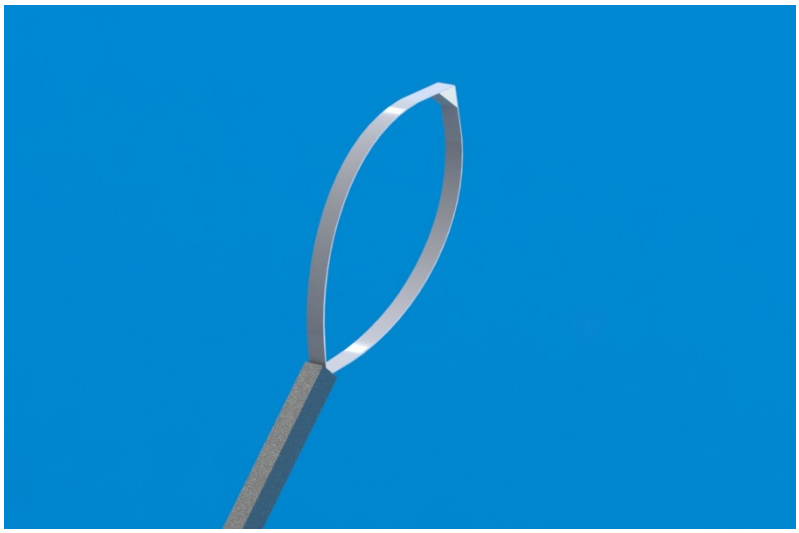


Figure 9. Depiction of the loop design.

The loop design will release a metal loop from a shaft once inside the body cavity. The loop will have a rigid piece of plastic at its tip to encourage the force to be applied against the coronal plane of the kidney. The metal wire will have ridges in it to prevent it from slipping once it is secured around the kidney. The wires on each side of the plastic tip will be able to be tightened independently. The loop will also have a quick release function that will release tension in the wire immediately.

DESIGN MATRIX

Each design was compared against the others through a design matrix to determine the best design. They were compared on the grounds of safety, ease of placement, force distribution, cost, maintenance, manufacturability, and client preference. Each of these categories were weighted on a percentage of 1. Each design was then graded on a scale from one to five with five being the best. Each graded score was multiplied by the weighting factor and summed.

Safety was given the second largest weighting factor of 0.2 because the device will be used during surgery. The device should never add complications to an already tough procedure, because a person's life is at risk. The loop and zip-tie designs ranked highest in this category because they will both have a quick release mechanism. The crisscross did poorly because, in order to remove the force of the clamp, the tubing needs to be slid down the wire. This may take too long and complications could arise.

Ease of placement is important because once the device is in the body cavity, it should be able to quickly and easily secure the kidney. The zip-tie got the lowest score in this section because its design required the doctor to thread a zip-tie around the kidney. With such a tight space and limited vision, this can be difficult for the doctor. The loop scored highly because the loop's size can change to any size needed to accommodate any kidney.

Force distribution was weighted the highest for this design matrix. Existing devices lacked the correct amount of force at the proper place on the kidney. Most of the existing devices applied most of the force at the beginning of the clamp nearest the hinge. This would result in the majority of the force being applied to the edge of the

kidney rather than the middle. The client would like the force evenly distributed across the kidney. The loop and the modified bulldog clamp both received a three because modifications need to be made to the design. The loop has a rigid tip that helps open the loop and keeps it in an elongated shape that keeps the clamp from applying force in the wrong direction. The modified bulldog clamp needs a bend in the metal to insure that the first point of contact isn't at the edge of the kidney. The other two designs received a two because they will not be able to apply enough force.

Cost received the lowest rating in the design matrix. This low rating comes from the cost of existing medical clamps. Existing laparoscopic medical clamps cost upwards of $1000, and these designs are estimated to be in the same price range. The zip-tie received the highest score because it requires very little material, making it easier to produce. The modified bulldog clamp is the most expensive because it needs to be specially manufactured to attach to the Aesculap Articulating Applicator.

Maintenance ranks the designs on their ability to be cleaned. This is important because during surgery a doctor needs to use sterile instruments to prevent infections or other complications. The devices need to be disposable or easily sterilized. The loop received a high score because it would be able to be stripped down to it basic elements then sterilized in an autoclave. The wire would also be replaceable. The crisscross received a low ranking because the hinges of the Johns Hopkins bulldog clamp are tough to be cleaned.

Manufacturability ranks the design on the teams ability to actually create the prototypes. The loop and zip-tie received high scores because those designs can be built using simple parts and little machine work. The crisscross received the lowest ranking because it would be very difficult to create a Johns Hopkins bulldog clamp with the right force distribution at such a small scale.

Client preference was also evaluated in the design matrix. The team needs to deliver a product that meets the client's specifications, so the client was included in the decision process. The loop received the highest score because the client liked the novelty of the design. The client believed this was the new solution that could solve the poor force placement of existing designs. The lack of poor force placement is also the reason that the modified bulldog clamp received the lowest score.

Table 1. Design Matrix

	Weight	Modified Bulldog	Loop	Zip-tie	Crisscross
Safety	.20	3	**4**	4	2
Ease of placement	.15	3	**4**	1	3
Force distribution	.30	3	**3**	2	2
Cost	.05	2	**4**	5	3
Maintenance	.10	3	**4**	3	3
Manufacturability	.10	3	**4**	4	2
Client Preference	.10	2	**5**	3	4
Total:	1.00	2.85	**3.8**	2.8	2.5

FINAL DESIGN

After completing the design matrix, it was determined that the loop design would be the most successful for completing our projects goals. The loop design will be composed of three main parts. There will be a shaft, the loop, and a control system.

The shaft of the renal clamp will be composed of a single piece of stainless steel with dimensions of 1.1cm x 1.1cm x 61cm. These dimensions will allow the shaft to fit inside the trocar during the placement of the device.

The loop of the clamp will be composed of two pieces of stainless steel ribbon. These pieces will have the dimensions of 1cm x 0.1cm x 55cm. These dimensions will allow the loop to be within the shaft during insertion through the trocar. At the distal end of the clamp, the two ribbons will be attached to an equilateral triangular block, which is

also constructed from stainless steel. This block will be 1cm wide and 1cm tall. The proximal end of the ribbon will be welded to the control system. The two ends will be attached at a 30º angle in order to achieve a ballooning effect within the ribbon.

The control system will be constructed with two identical plungers. At one end of the plungers, there will be a 1cm x 1cm pad that the surgeon can depress using a thumb. When the plungers are depressed, the ribbons, which are attached at the other end, will begin to move out from the shaft. In order to keep the plungers in the desired position, a ratcheting system prevents movement toward the proximal end and a spring that resists movement in the distal direction.

Most aspects of the surgical procedure will remain the same; however, in order to achieve proper placement of the parenchymal renal clamp, it is imperative that the connective tissue around the kidney has been sufficiently removed. Next, the clamp will be inserted with the loop enclosed in the shaft. Once through the trocar, the two plungers will be depressed to the point where 7-8cm of the ribbon has been exposed. The loop can then be maneuvered around the peripheral ends of the kidney. The plungers can be retracted to sufficiently occlude flow to the area of operation in the kidney.

When the surgery has been completed, the clamp will be removed by depressing the plungers to decrease contact with the kidney. Then the kidney can be removed from the loop, and the plungers completely retracted to bring the ribbons within the sheath. The entire clamp can then be removed from the trocar.

DESIGN SPECIFICATIONS

The clamp will be a selective renal occlusive clamp for robotic laparoscopic partial nephrectomy surgery. As there is no device that meets the design criteria for laparoscopic partial nephrectomy, a clamp must be designed that successfully occludes blood flow within the kidney and works with a laparoscopic arm. The client has requested that the arm be designed so that it is not in the way during surgery. This semester will focus on designing the clamp mechanism, and next semester will focus on designing the laparoscopic arm.

Most importantly, the clamp cannot cause any harm through its operation to either the operators or the patient, including the kidney and surrounding tissue. To properly occlude the kidney, the clamping end must be able to be apply the necessary

force of 10-15 N for the duration of the surgery, 3.5-4 hours. It must also reliably provide this force for at least 100 applications.

The clamp will be used in an operating room, in a laparoscopic cavity in contact with carbon dioxide gas and living tissues. Since surgical devices are stored and transported before they reach the hospital, and may be stored once they reach the hospital, in a sterile package the device should have a shelf life of at least 10 years without corroding. To be reusable, it must be sterilizable, made with durable and biocompatible materials. For marketing purposes, the device should be aesthetically pleasing.

To ensure that the device can be used in laparoscopic surgery, the clamp end and the laparoscopic pole must fit through a 12mm by 15 cm laparoscopic trocar, and the arm should be 61.00 cm in length. It must be operated with one hand, and the laparoscopic handle should not be in the way after being applied. The laparoscopic handle must be comfortable for surgeons with handbreadth ranging from 6.5-9.5 cm. The weight of the entire device must be comfortable to use, and should not exceed one kilogram.

For proof of concept, only one prototype is required. This prototype for delivery to the client must not cost more than $500. The market price for the device should not be greater than $10,000. The device must adhere to FDA medical device guidelines so that it can be tested in pig models and eventually human patients.

ETHICAL CONSIDERATIONS

The information gathered for the presentation of this paper was done ethically. The thoughts and knowledge that were taken from previously reported studies are given credit via citations when appropriate. The authors of this paper are appreciative for the previous knowledge that allowed us to create the design proposed in this report.

Further ethical considerations should be carefully evaluated during testing. Our client currently does research on pigs and would like us to test our prototype during a live surgery. We will be conducting this testing as part of an existing IRB. It has been decided by our client and team that the proposed methods of testing are appropriate.

FUTURE WORK

To continue with the project many goals need to be accomplished. Materials need to be ordered and a prototype needs to be assembled. Once this is accomplished, the device needs to be tested to ensure it applies the correct force. After proving the concept, the design needs to be created for laparoscopic uses next semester. The client has suggested that the device be tested in a one of his animal trials. Investigation into the clients IRB or obtaining a separate IRB needs to be done to ensure we can legally use the device in trials.

Materials need to be gathered and purchased, so that a prototype can be assembled. For the first semester, the goal is to create a large-scale model. This larger scale model will prove the concepts of the design. Working with a larger model will also allow for easier modification of the device during each iteration of the design. This will ensure that the best design is brought into next semester.

Once a large-scale model is created testing needs to be done to demonstrate functionality. The tests need to demonstrate that the force is evenly distributed across the whole kidney and that enough force is being applied. Using a pressure gauge and a rigid balloon will allow us to determine the force being applied by the device. Testing upon an actual kidney will be beneficial as well. Buying a kidney from a grocery store will allow the team to determine how the device works with the actual tissue. Eventually using the device in actual surgery will provide the team with the best feedback, but an IRB must be obtained first.

After this first semester, the goal of the remaining semester will be to produce our model for laparoscopic surgery. This means taking our design and shrinking it so it fits the constraints of the trocar and the body cavity. At this point, the device will need to be either disposable or made out of stainless steel. This will make it ready for surgery and ensure it is hygienic. Testing will still be needed, to show that the device still has the same functionality as the larger scale model. At the end of the second semester a product should be produced that is ready for the market.

The team needs to also investigate the rules for institutional review boards (IRB). The client would eventually like to test the device during actual animal trials. Before that can be done, the team needs to determine if they need their own IRB or if the device can be legally used under the client's IRB. Testing on actual humans also needs to be done before moving to market, but this needs to be done under IRB guidelines as well.

Once arriving at a final design, streamline production of the device needs to be

performed. Manufacturing at a large scale will lower the cost of the device, making it more competitive with other devices. This will also allow the device to get to a large market.

CONCLUSIONS

The creation of an innovative clamp that evenly distributes force during a partial laparoscopic nephrectomy is needed in the surgical field. This design will allow kidney tissue to be preserved without ischemia and lessen surgical recovery time. Dr. Abel is optimistic about our loop design and feels that with further calculations, prototyping, and testing a novel clamp can be created by the end of the year.

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Appendix A. Project Design Specifications

Optimizing selective renal occlusive clamp for robotic surgery

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.