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Design of a Catheter-Based Device for Performing Percutaneous Chordal-Cutting Procedures

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Abstract

This paper focuses on the design and implementation of a percutaneous catheter-based device to provide physicians with an externally controlled tool capable of manipulating and cutting specific chordae tendinae within the hear to alleviate problems associated with some forms of mitral valve regurgitationt. In the United States alone, approximately 500,000 people develop ischemic or functional MR per year, and the chordae tendinae cutting procedure and device are needed because many patients do not have the required level of health necessary to survive open-heart surgery. A deterministic design process was used to generate several design concepts and then evaluate and compare each concept based on a set of functional requirements. A final concept to be alpha prototyped was then chosen, further developed, and fabricated. Experiments showed that the design was capable of locating and grabbing a chord and that ultrasound imaging is a viable method for navigating the device inside of the human body. Once contact between the chord and an RF ablator tip was confirmed, the chord was successfully ablated.

Keywords

Percutaneous; catheter; mitral valve; minimally invasive; heart; chordae tendinae

1. Introduction

Minimally invasive percutaneous techniques hold much promise for the treatment of heart disease. These include a reduction in trauma to the patient's anatomy, and reduced patient recovery time. They provide a much needed option for patients who are unfit for open heart surgery. Percutaneous techniques involve advancing catheters and other devices into the human body via incisions in major blood vessels.

The results of recent medical studies have generated interest in the use of percutaneous techniques to treat ischemic mitral regurgitation (MR). MR is symptomatic of a poorly functioning mitral valve, which can be indicative of a damaged left ventricular wall. MR currently affects 2.8 million Americans [1,2]. A healthy MV opens to allow oxygenated blood to fill the left ventricle (LV), and then the MV closes as the LV contracts and pumps blood out through the aorta. Normally, a valve's leaflets close with an appropriate amount of coaptation so as to create a surface that prevents blood backflow, or regurgitation, through the valve. This is illustrated as “Normal” in Figure 1.

A bundle of chordae tendinae attaches the MV leaflets to papillary muscles that are anchored to the inferior wall of the heart. The chordae prevent the leaflets from moving beyond their closed position during LV contraction. A heart attack or myocardial infarction (MI) often weakens the heart muscle to the point where the inferior ventricular wall bulges outwards enough to pull the leaflets into the ventricle and prevent adequate coaptation [3]. This is illustrated in Figure 1 as “Post-Infarct”.

Basal chords are thick chords that connect the middle of the valve leaflets to the papillary muscles. There are also numerous, thinner chords that are connected to the tips of the leaflets [4]. After an MI, the ventricular wall bulges out. The basal chords tethering the anterior leaflet of the valve to the papillary muscles (and in turn the ventricular wall), pull on the leaflet and cause it to bend. These changes in heart geometry act to reduce coaptation of the valve leaflets, and lead to MR [5].

The resulting MR can decrease the patient's ability to breathe properly, and may more than double patient mortality [6]. By cutting the basal chord, it is possible to improve leaflet coaptation and thereby reduce MR [7]. Conventional surgical treatments for ischemic MR, for example annuloplasty, have been shown to have high MR recurrence rates [8]. Recent insights into the mechanism of this dysfunction have led to a novel surgical approach that involves the cutting of specific chords in order to relieve MR.

Researchers have demonstrated that cutting two of these basal chords releases the tension on the valve leaflets and leads to a greater range of motion. This in turn improves coaptation of the valve leaflets [1,6,7]. In Figure 1 this is illustrated as “Chord cut”.

Clinical studies indicate that the chordal cutting procedure, in combination with traditional annuloplasty, reduces the recurrence of MR without any deleterious effects on LV function [2,9].

Despite its efficacy in treating ischemic MR, the chordal cutting procedure in its present form has had limited impact due to the fact that it is performed open-heart under direct vision. Most MR patients lack the physical stamina to undergo open-heart surgery [7]. A comparable, minimally invasive procedure will reduce risk, procedure duration and patient recovery time. The new procedure will also increase the number of patients that may be treated. A minimally invasive, non-surgical approach will facilitate the adoption of this technique by enabling a broader range of physicians, for example cardiologists and interventional radiologists, to perform the procedure.

Existing devices for various types of percutaneous mitral valve repair procedures are not appropriate for chordal cutting [10]. This technique will require a new catheter-based tool that-will manipulate the basal chord, as required by the procedure. Percutaneous access to the left ventricle can be achieved by making an incision in the groin, inserting a catheter into the femoral artery and advancing it through the aorta, through the aortic valve, and finally to the chordae tendinae. This process is illustrated in Figure 2.

Development of the required medical instrumentation presents engineering challenges for several aspects of the procedure. The three main engineering challenges that the project must overcome are as follows:

1. Guidance of the catheter towards the chord via 2D and/or 3D ultrasound imaging,
2. Grabbing and confirmation of contact with the chord,
3. Cutting the chord.

These are not trivial tasks to perform. Herein, we describe efforts to satisfy and overcome these challenges.

2. Methods

The primary goal for this project was to create a better method for performing an established surgical procedure via development of a new surgical device. There are several design goals with which we concerned ourselves. First, the procedure must involve advancing all required tools into the heart via percutaneous techniques. The tools that we would end up developing must comply with industry-standard guide catheters, as well surgical standards.

Second, the procedure should, if at all possible, utilize existing imaging technology to maintain simplicity of implementation. Lastly, the procedure must solve the problem at hand: *safely and reliably cut only the targeted basal chordae.*

Existing catheter technology provides physicians with the tools needed to advance small instruments into the heart. We found several catheters that are capable of accessing the left ventricle. However, we did not find a suitable package that could enter the left ventricle and selectively cut a specific basal chordae.

In catheter based systems there exist a few ways to cut and remove tissue. Mechanical cutting is most commonly done using a blade. Another method is to cut tissue using heat, as is the case with RF-ablation. For this application RF-ablation was considered to be very promising for cutting the basal chordae. because there is essentially no cutting force associated with ablation, and there are no macro-scale moving parts. Additionally, there is precedence in the field for a functional RF-ablator unit contained within a small, catheter-sized package.

When using RF-ablation, it is desirable to minimize the amount of time that the ablator is transferring energy to tissue. This is due to the negative impact that an intense heat source in general has on the human anatomy. The beating heart is a dynamic system. Currently-available steer-able catheters are relatively imprecise in nature. Simply advancing a steer-able catheter with an RF-ablator into the left ventricle would not suffice to reliably cut a single specific chord.

A tool is thus needed to enable a catheter guided RF-ablator to grip a specific chord and then cut it. The most critical module for this project is the device which will be performing the grabbing operation. Effective integration of the grabbing mechanism into a currently-available, steer-able catheter platform with capabilities for RF-ablation was the overall goal.

3. Design

Selecting a Design Concept

The first step in the Deterministic Design Process [11] was to establish a set of functional requirements for the device (Table 1).

The design of the gripping mechanism was driven by the geometric constraints of the heart, as well as existing catheter technology. The key focus was on the development of “grip before cut” mechanisms that could be integrated with an existing steer-able catheter. Team members individually generated numerous concepts, and through the use of the Peer Review Evaluation Process (PREP) [12], the team narrowed our range of concepts to four.

Concept 1: Forceps

The first concept was a "forceps" mechanism. The action of the forceps is illustrated in Figure 3. The forceps first clamp the chord between the two "fingers". It is pulled towards the catheter-mounted cutter mechanism, and then cut. The advantage of this approach is the precision with which the chord can be grabbed.

The use of forceps reduces the chances that the operator might grab neighboring chords. Unlike some other concepts, the forceps can approach the chord from multiple angles. There are two important disadvantages which should be noted. First, it is difficult to fabricate small, precise components for this moderately complex mechanism. Second, integrating the cutting tool with this design is not as simple as it is with other concepts. Further details on other advantages and disadvantages may be seen in the weighted criteria concept comparison chart in Appendix A.

Concept 2: Clamshell Grabber

The second concept, shown in Figure 4, was inspired by a clam shell, and could be considered as an evolution of the forceps concept. It should be noted that our "clamshell" is spherical, not planar. The mechanism of actuation was not actually specified, but it was initially assumed to be similar to that of the forceps. This concept has many of the same advantages and disadvantages of the forceps mechanism. The main advantage is that it is easier to integrate a cutting mechanism. The inside of the "clamshell" is hollow; therefore the cutting mechanism may be easily placed inside of the clamshell and then utilized to cut a chord which the jaws of the "clamshell" have gripped.

Note that it would be possible to actuate the clamshell using a cable system and simple pivots which would make its actuation simpler than the forceps; hence this design was kept in reserve as a contingency plan should no other simpler mechanism arise.

Concept 3: Hook

The third concept was based on a hook which can be seen in Figure 5. The hook was intended to grab the chord and pull it towards an ablation catheter. An advantage of this is that the hook and catheter may be oriented such that anything that the hook grabs will be pulled directly over an ablation catheter, or as a contingency, a blade; where in the safety position, the hook straddles and shields the blade. In addition, the hook is fairly simple geometrically and kinematically. The biggest disadvantage with the hook design is the risk of grabbing additional or incorrect chords. As noted above, the nearest chords are a significant distance from the basal chordae (~1cm) and therefore the risk of grabbing the wrong chord(s) is small.

Concept 4: Disk grabber

This concept was a "disk grabber" or "360° Hook", as seen in Figure 6 This concept clamps a chord between a plate and the corresponding flat surface of the tool body. One advantage of this approach is that the mechanical actuation of this mechanism is much simpler due to radial symmetry which eliminates the need for a specific rotational orientation in order to be able to grab the chord. An important disadvantage is that the cutting mechanism may require additional structures or surfaces to perform effectively and efficiently, although an ablation wire or cutting blade could also be circular beneath the disk grabber. Nevertheless, we thought that it would be more difficult to integrate a cutting mechanism into this concept.

4. Concept assessment

The concepts discussed above were evaluated and compared using a weighted criteria concept comparison chart. The comparison was relative to a baseline concept, the "360° Hook". The evaluation criteria were:

1. Flexibility of approach
2. Manufacturability
3. Ease of cutter integration
4. Required precision in the φ direction
5. Required precision in the θ direction
6. Chord grabbing precision.

Each criterion was also weighted to capture the relative importance of each. The criteria comparison chart gave the “forceps” and “clamshell claw” designs identical scores. This was not surprising due to the similarity between the two concepts. The criteria comparison chart shows that the “hook” design is the most appropriate for the needs and constraints as defined by the percutaneous chordal cutting procedure.

The main benefit to using the hook design was the potential simplicity of ablator integration. The hook introduces some risk associated with overshoot, but it was shown that such a risk is small due to the heart geometry. The chord was isolated from other chords by approximately 1 cm of open space inside of the heart.

5. Modeling

Geometry

The primary constraint on the hook design is the small size, and therefore it was logical to begin the design by setting the geometry. As illustrated in Figure 7, the available space for the hook and bearing mechanism consists of a 7mm diameter, 20mm long cylinder. Allowances were made for minimum wall thickness (0.5mm) and for the diameter of ablation catheter (2.67mm). The resulting space is labeled in light blue in Figure 7. Note the mounting hole for the ablation catheter is not concentric with respect to the cylinder.

Hook Shape

An appropriate hook shape can be determined using the geometry outlined above. For a hook design, the critical dimensions are the “width” and the “throw”. The diameter of the workspace limits the width of the hook to 4mm. Given that the largest chords are ~2mm in diameter, the distance is more than sufficient. The small width of the hook serves as a safety feature because larger objects, such as muscles will not fit into the hook.

Assuming that the hook's position may be adjusted more finely than the position of the catheter, it is desirable to maximize the throw of the hook. This assumption is based on the fact that the hook may be finely controlled using a pull cable while the catheter itself must be pushed “in” and “out”. In a coarse motion, as the length of the mechanism is limited, the “throw” of the hook was limited to 5mm. Figure 8 shows an illustration of the hook “width” and “throw”.

Hook Mechanism

A cable was used to actuate the hook, and was chosen for three key reasons. First, cables are flexible when not tensioned. Therefore, the ablation catheter will be able navigate the curves of the vasculature and the heart. Second, cables may be made to very small diameters, thereby satisfying the size constraints. Finally, cables allow remote actuation because the device cannot be actuated directly.

Catheters with cable mechanisms are commercially available. An example of this is the Microvasive Polypectomy Snare, seen in Figure 9. This uses a catheter to push and pull a short wire lasso. Interestingly enough, testing showed that this device provided suitable performance. A Microvasive Polypectomy Snare was modified to actuate the hook in our alpha prototype.

The use of a cable mechanism to actuate the hook is suited for low force applications; a cable can provide little compressive force. Using a cable mechanism provides safety benefits due to the fact that there will never be stored mechanical energy that could be released accidentally, possibly damaging adjacent tissue. In addition, should the cable mechanism break, the hook could be easily disengaged by pulling or pushing on the ablation catheter.

Hook Stiffness

The stiffness of the hook was evaluated based on the assumption that the hook is mounted to the base as a cantilevered beam. There were two loading conditions. The first is a side load normal to the main shaft of the hook, and the second is an axial load on the front face of the hook. These two loading conditions are modeled as cantilevered beams, as shown in Figures 10, 11a, and 11b.

For $\boldsymbol{F_1}$, the deflection is given by Equation 2.1. For $\boldsymbol{F_2}$, the deflection is given by the Equation 2.2. Simulated values of $\boldsymbol{\delta_1}$ and $\boldsymbol{\delta_2}$, for a given set of parameters, may be seen in Tables 2 and 3, respectively.

$$\delta_1 = \frac{-F_1 L_1^3}{3EI_{circ}} \tag{2.1}$$

$$\delta_2 = \frac{F_2 L_2 (L_2)^2}{6EI_{sq}} \tag{2.2}$$

A Homogenous Transformation Matrix (HTM) was constructed and used to estimate the overall deflection of the tip of the catheter with loads F1 and F2 equal to the estimated peak cutting force of 0.6 lbs (all values are in mms). Figure 12 is the HTM reference diagram; the HTMs can be seen in equations 2.3a, 2.3b, and 2.4. Equation 2.4 shows the overall HTM for the system deflection.

$${}^{A}H_{B} = \begin{bmatrix} 1 & 0 & 0 & 0 \\ 0 & 1 & 0 & 1.95x10^{-4} \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{2.3a}$$

$${}^{B}H_{C} = \begin{bmatrix} 1 & 0 & 0 & 0.294 \\ 0 & 1 & 0 & 1.13x10^{-4} \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{2.3b}$$

$$ {}^{A}H_{C}=\begin{bmatrix} 1 & 0 & 0 & 0.294 \\ 0 & 1 & 0 & 3.08x10^{-4} \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{2.4} $$

When the summed deflections are considered (dominated by deflection from $\boldsymbol{F_2}$) the hook deflection is found to be approximately 10% of the hook size. This is relatively large for the small applied force, therefore the model points toward the need to use a low-force cutting method, e.g. RF ablation if possible.

Bearing Constraints

Only one translational degree of freedom (opening/closing) was required for the hook, with no rotational degrees of freedom. This means that all of the other degrees of freedom must be constrained. The use of a concentric circular constraint, in this case similar to a plastic bushing, removes two rotational degrees of freedom and two translational degrees of freedom. A keyway was introduced to prevent rotation of the hook about the longitudinal catheter axis. In order to properly constrain the shaft, 2 bearing surfaces were used, spaced 9mm, ~4 diameters, apart. Figures 13, 14, and 15 show other views of the design and assembly.

Stress Analysis

Finite element analysis (FEA) was used to evolve the design details once basic dimensions were determined from basic closed form equations. Sample results of the FEA, as shown in Figure 16, illustrate that the stress stays below 20 MPa at all points in the hook when a 22.24 Newton tensile force was applied, so a molded plastic device can be achieved. Since the yield strength of the material (DSM Somos 18420 Resin) is 42 MPa, this gives a safety factor of 2. In order to ensure proper safety, all future designs must employ cables that break at or below 22.24 Newtons of force, or higher strength materials are to be used. It is important that the cable breaks before the hook. This is to guarantee that no plastic parts break free inside the body. Final versions of the device will most likely be injection molded rather than fabricated using SLA material, and so the production material will be stronger and tougher than that used within the current design because it can also use a filler such as carbon fiber.

Manufacturing

The small size of the parts, some ~0.25mm, precludes the use of many traditional one-off fabrication methods. Therefore, the initial designs were fabricated by Vaupell Corporation using a high resolution stereo-lithography (SLA) apparatus. The device was produced in three pieces to allow for proper assembly, and the final assembled version can be seen in Figure 17. Figure 18 shows an overall view of the entire mechanism.

6. Experimental Results

Two experiments were performed to test the capabilities of this device:

1. Percutaneous entry and location/grasping of the device
2. Ultrasound guidance and chordal cutting

Percutaneous Entry and location/grasping of the device

The device was inserted ‘percutaneously’ into an experimental setup that consisted of a tube that emulated the geometry of the Aorta and a porcine heart, as shown in Figure 19. The Mitral Valve Chordae Tendinae was isolated as shown in Figure 20. The device is shown open and about to grip the targeted chord. Direct visualization of the internal structures of the heart was used in place of ultrasound imaging.

It is well-known that intimate contact between tissue and an RF ablation element is sufficient to cut chords. In this first test, a chord was not cut as the device was not powered at that time, but Fig. 21 shows the chord captured and pulled against the location of the RF ablator.

Ultrasound guidance and chord cutting

The next experiment in our bench-level testing had two goals. The first was to test the feasibility of utilizing ultrasound to navigate the left ventricle and locate the basal chordae. The second goal was to grip the chord and demonstrate that RF ablation is a feasible means of cutting the basal chord.

Figure 22 shows the device positioned within the heart in an ultrasound image. However, it would require skill beyond that of what was available to us at the time the experiment was run to successfully locate and cut the chord simply with ultrasound feedback. Figure 23 shows chords that were cut gripped and then cut via RF ablation using the device (visualized directly via dissection of the left ventricular wall.)

7. Conclusions and Future Work

We have shown that we can introduce the device into the left ventricle of a heart, locate, and grab a chord attached to the mitral valve. We have also shown the Ultrasound imaging is at the very least makes navigation with this device feasible. Additionally, we have also shown that it is possible to cut the basal chord utilizing RF ablation. At the present time, a patent application for a device and method has been submitted by Dr. Levine, and is pending with the U.S. PTO (Patent Application Number 10/523,096).

Acknowledgments

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Appendix A

	Flexibility of approach	Manufacturability	Ease of ablator integration	Phi-precision motion	Chord-grabbing precision	Theta-precision	Score
Weight	**2**	**1**	**2**	**2**	**2**	**2**	**N/A**
Forceps	-1	-1	-2	-1	2	1	-3
Clamshell Claw	-1	-2	-0.5	-1	2	0	-3
Hook	-1	0	2	0	0	0	2
360 Grabber	0	0	0	0	0	0	0

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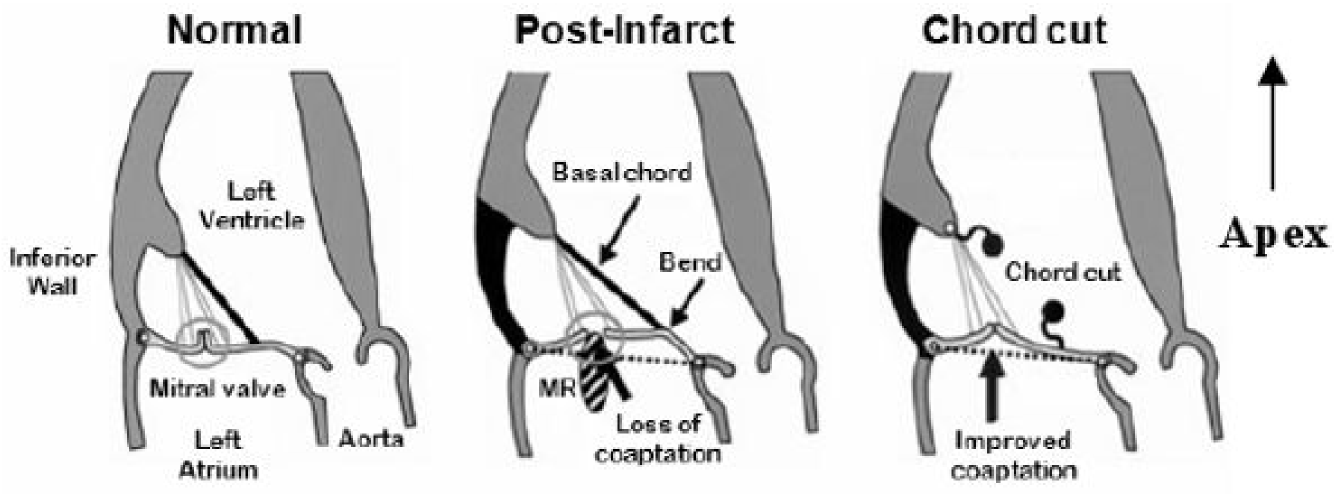

Figure 1. Cross-section of normal (left), post-infarct (center), and post chord-cut heart (right)[1]

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[1] *Messas et al. Circulation. 2006; 114:524-528*)

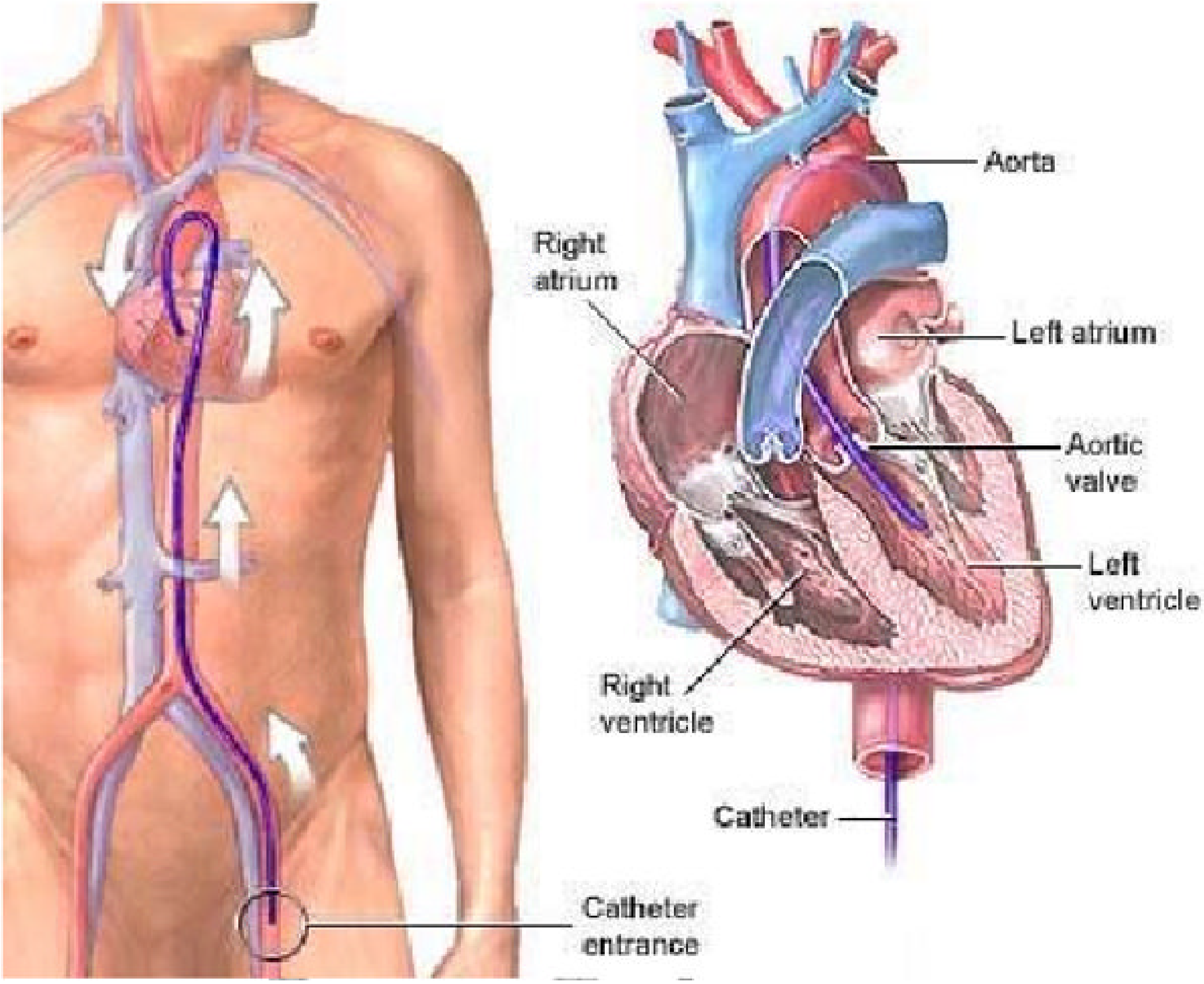

Figure 2. Diagram of current percutaneous procedure[2]

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[2] Image source: http://medicalimages.allrefer.com/large/left-heart-catheterization.jpg

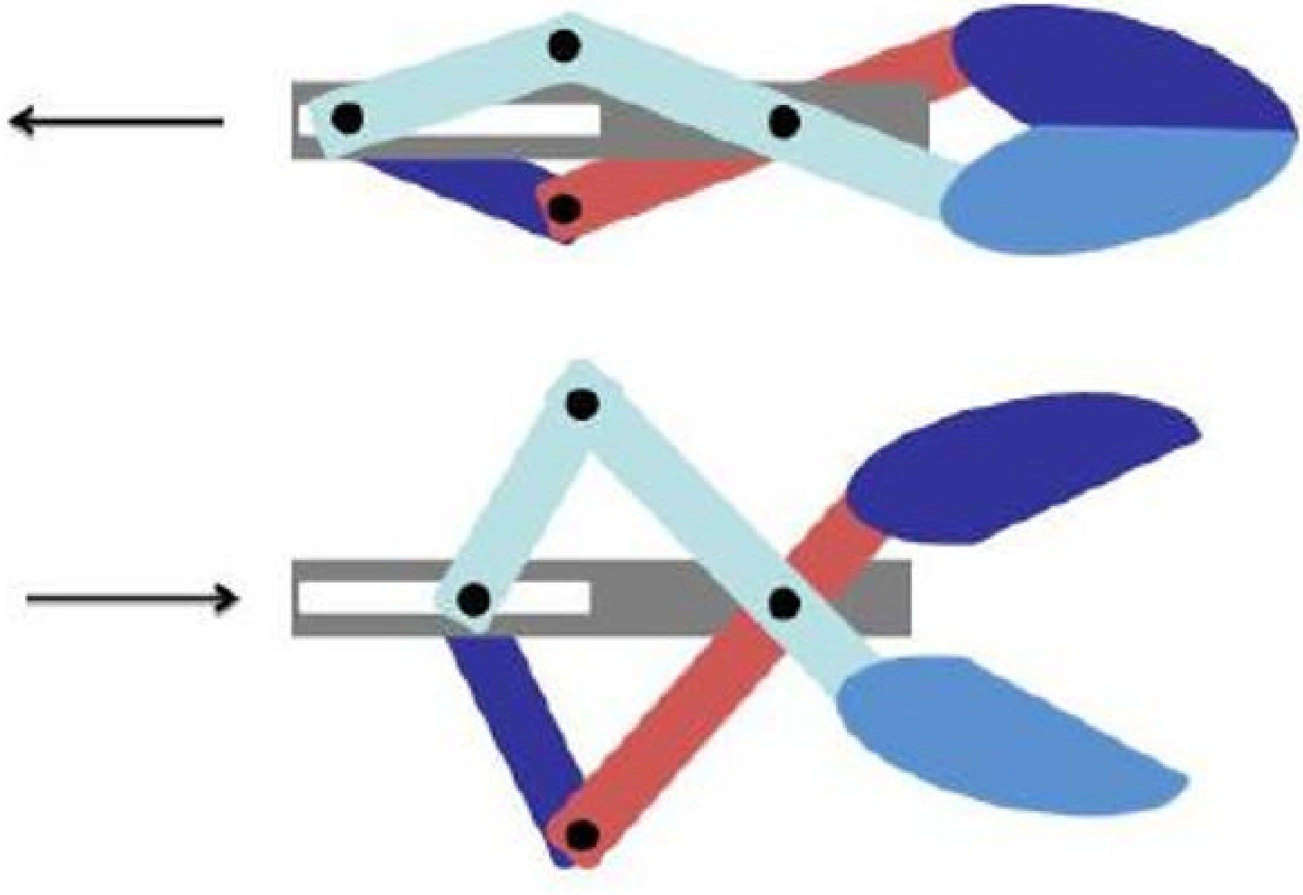

Figure 3. Forceps design concept

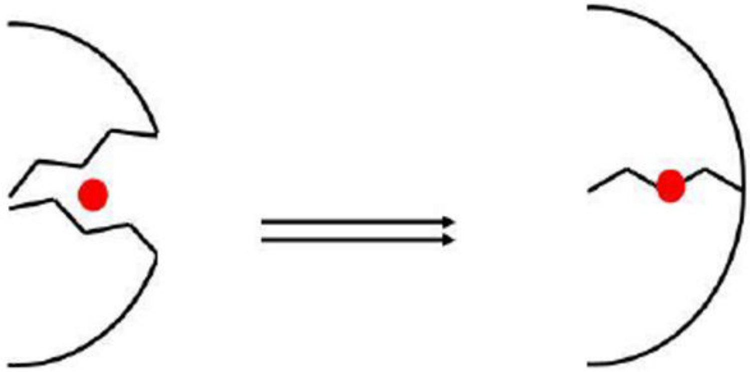

Figure 4. Clamshell design concept

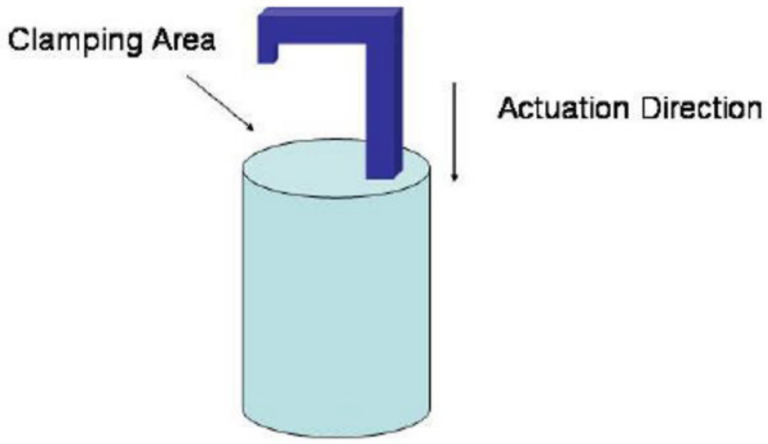

Figure 5. Hook design concept

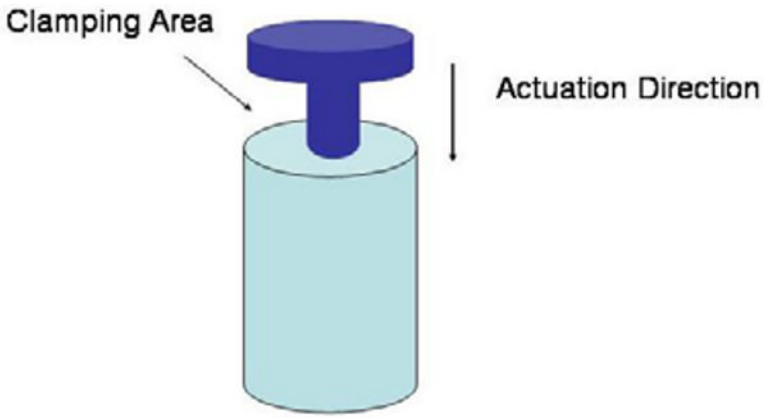

Figure 6. 360° Hook design concept

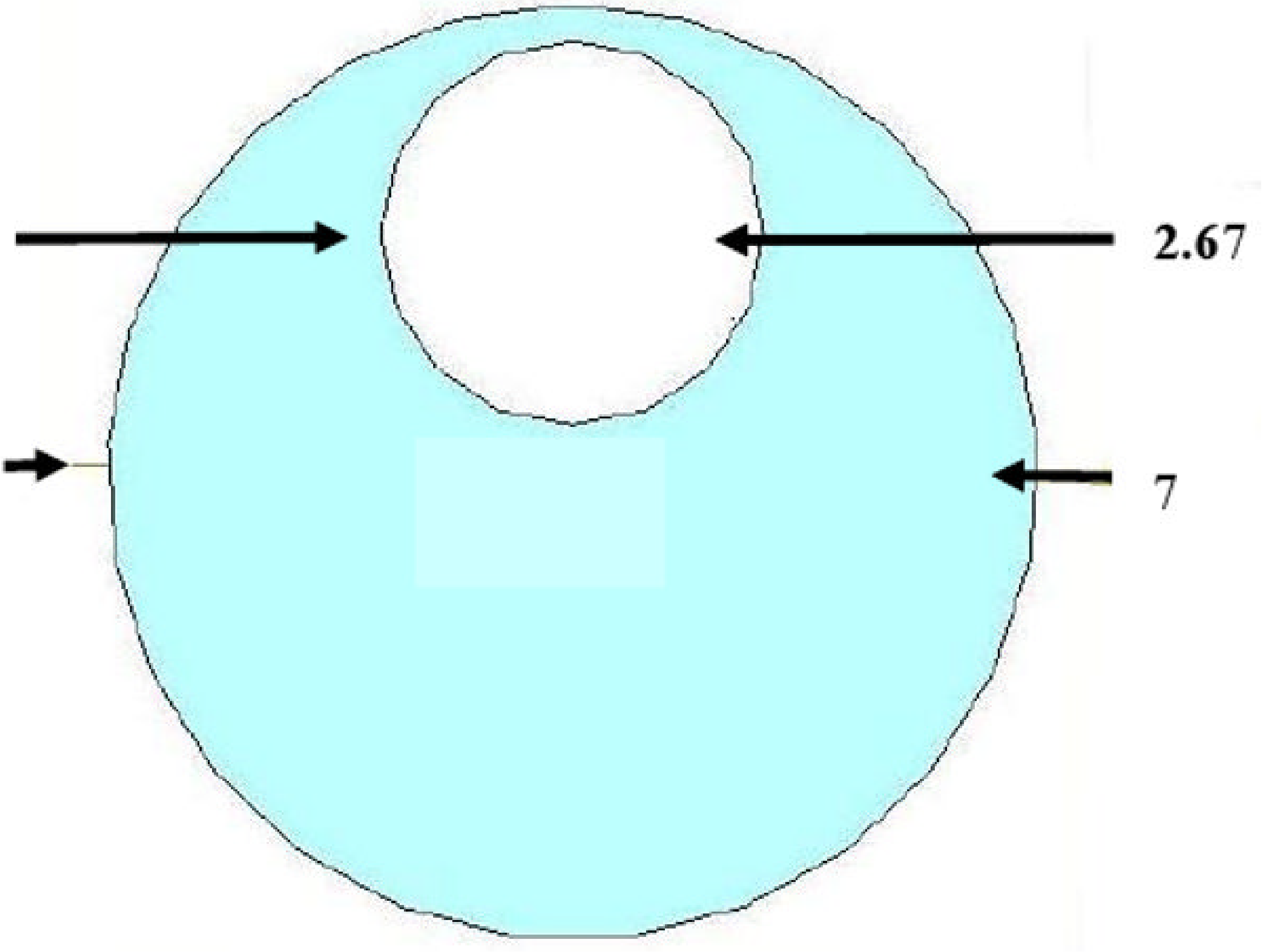

Figure 7. Cross-section of hook body design. Note non-concentric hole for existing RF ablator (units in mm)

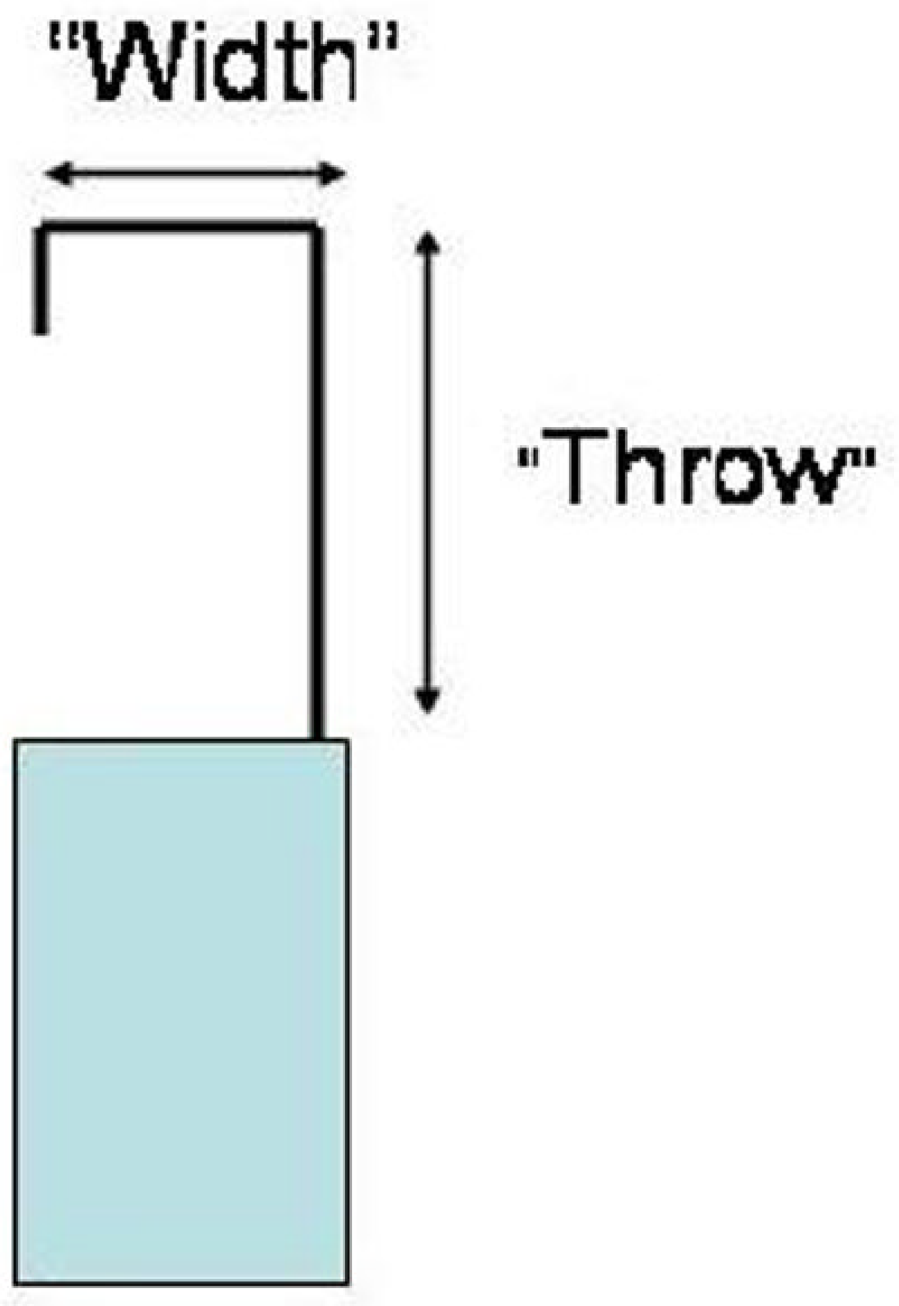

Figure 8. Characteristic dimensions of the hook mechanism

Figure 9. Microvasive Polypectomy Snare[3]

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[3] Image Courtesy of: http://cookmedical.com/esc/content/thumbnail/esc_as.jpgAIN

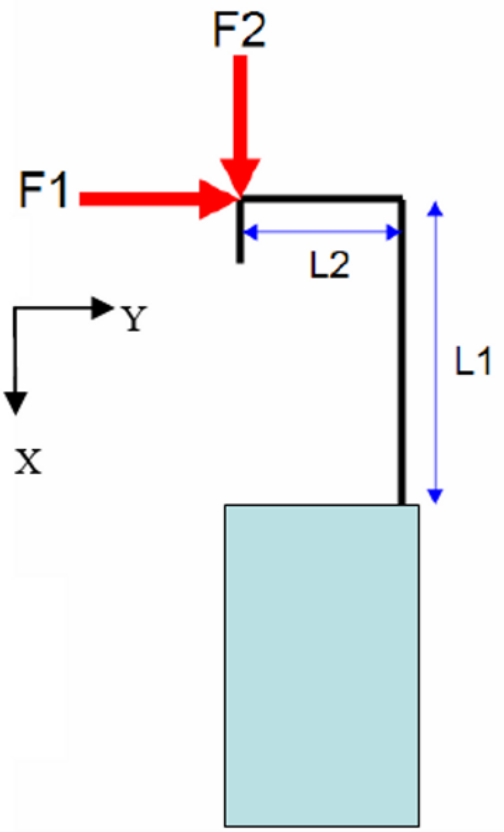

Figure 10. Hook loading diagram

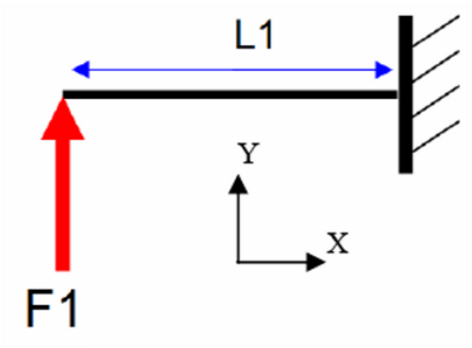

Figure 11a

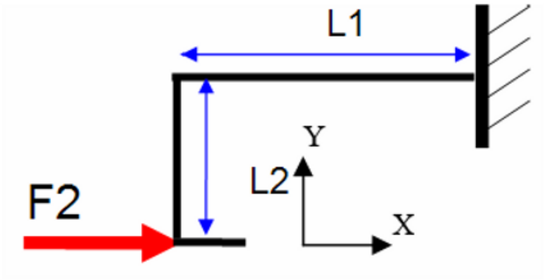

Figure 11b

Figure 11.
Figure 11a: Model for loading condition 1.
Figure 11b: Model for loading condition 2.

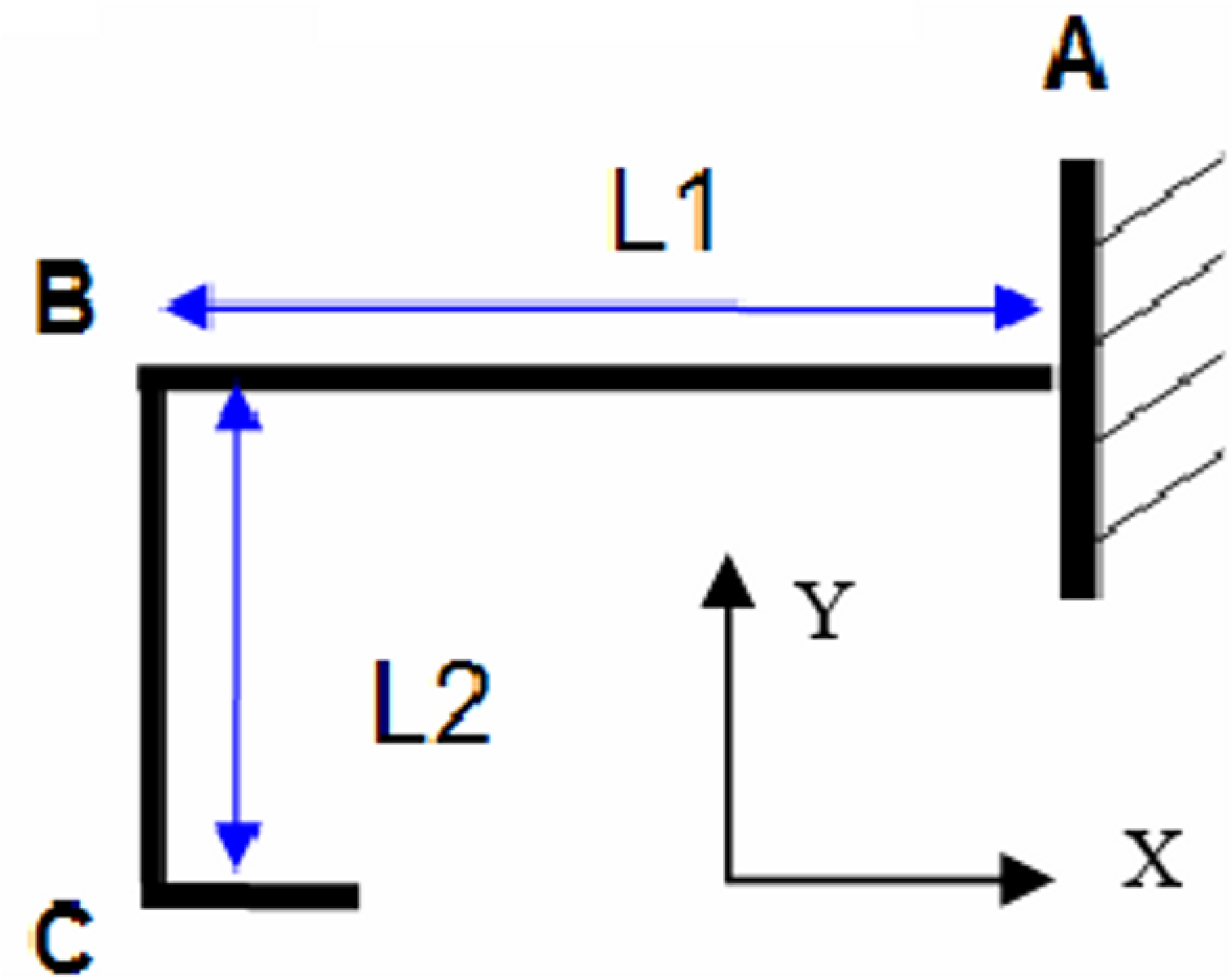

Figure 12. Our HTM reference Diagram

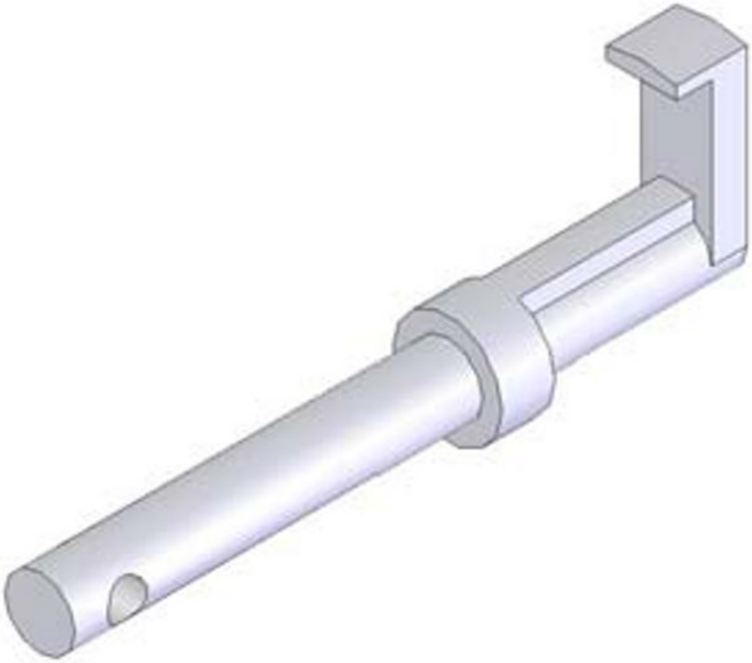

Figure 13. Hook used to grab chords

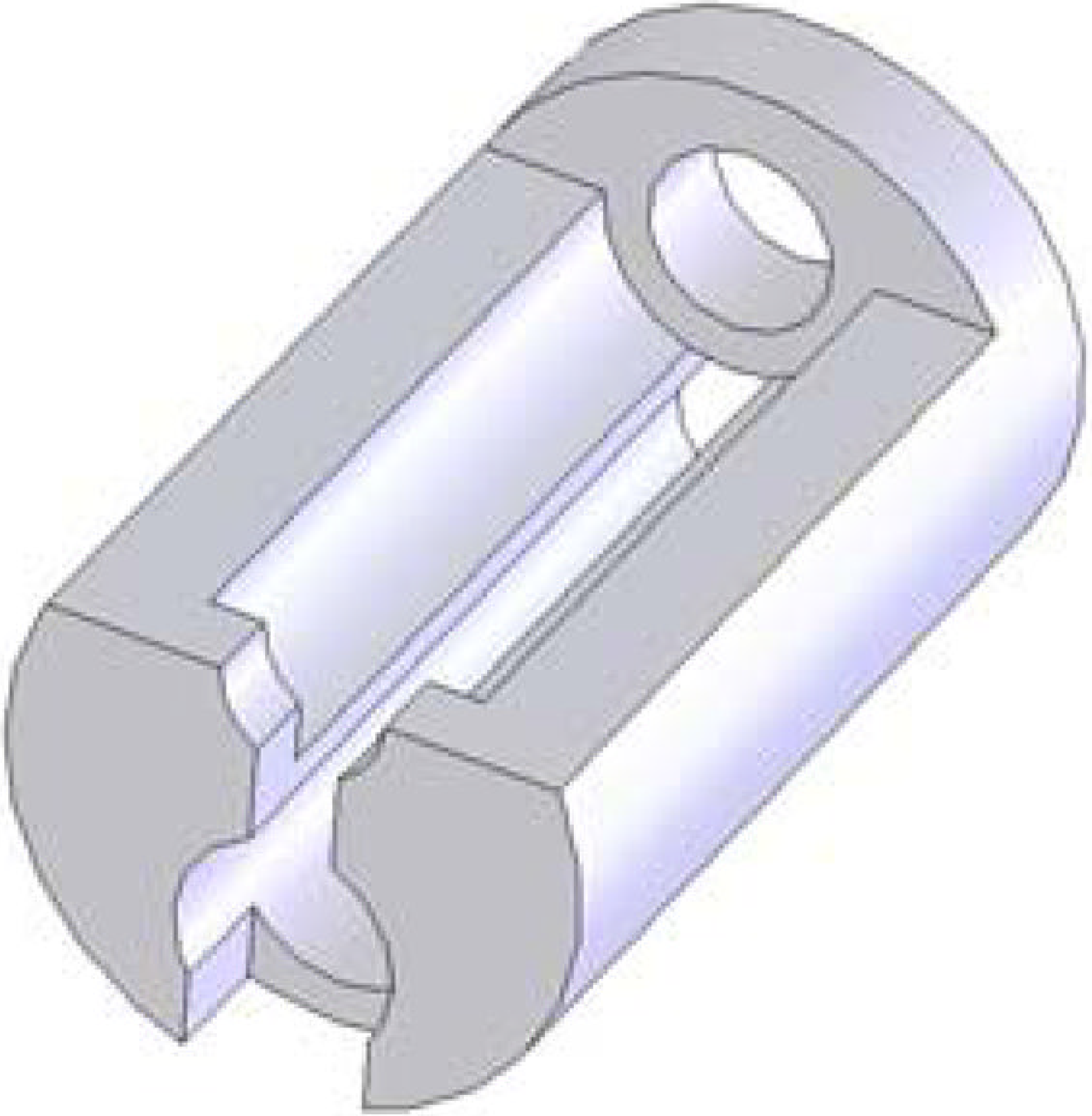

Figure 14. Hook mounting structure
Figure 1: Hook assembly.

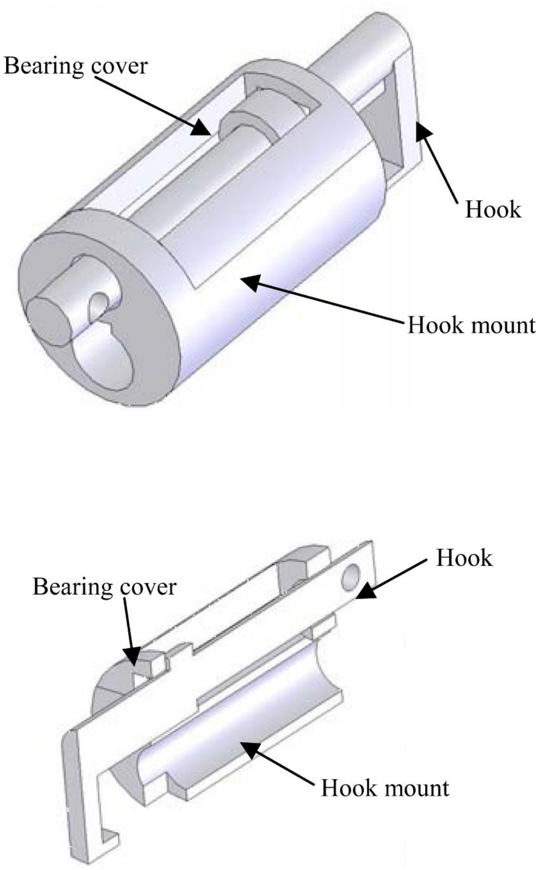

Figure 15. Cross-section of hook assembly

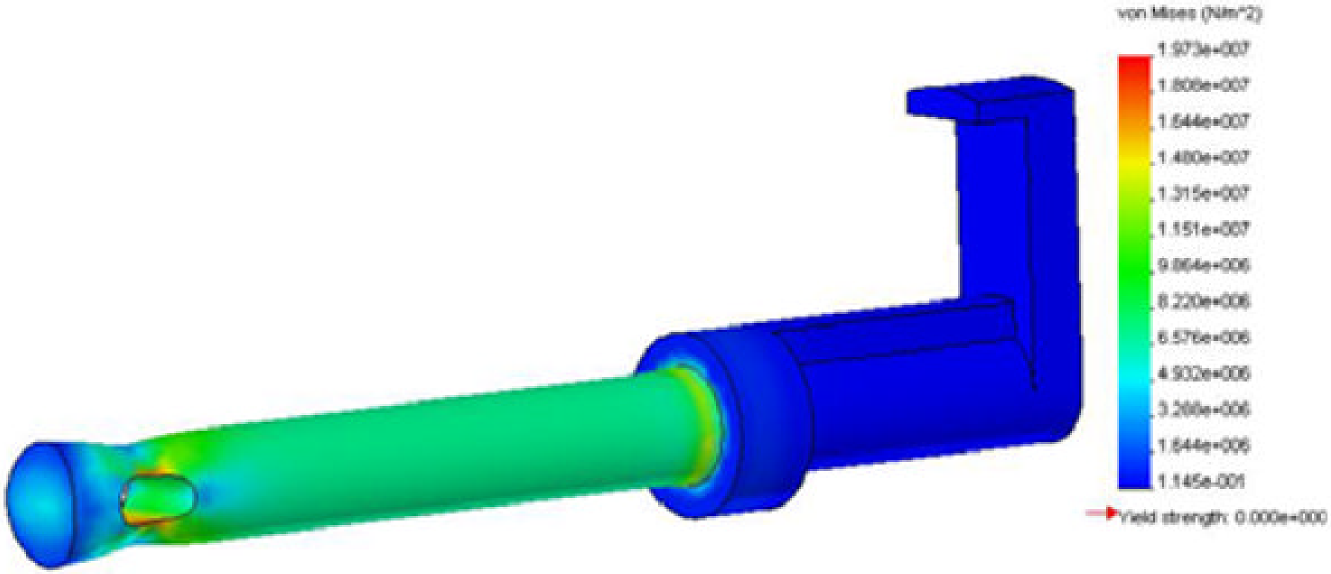

Figure 16. Finite Element Analysis of the hook

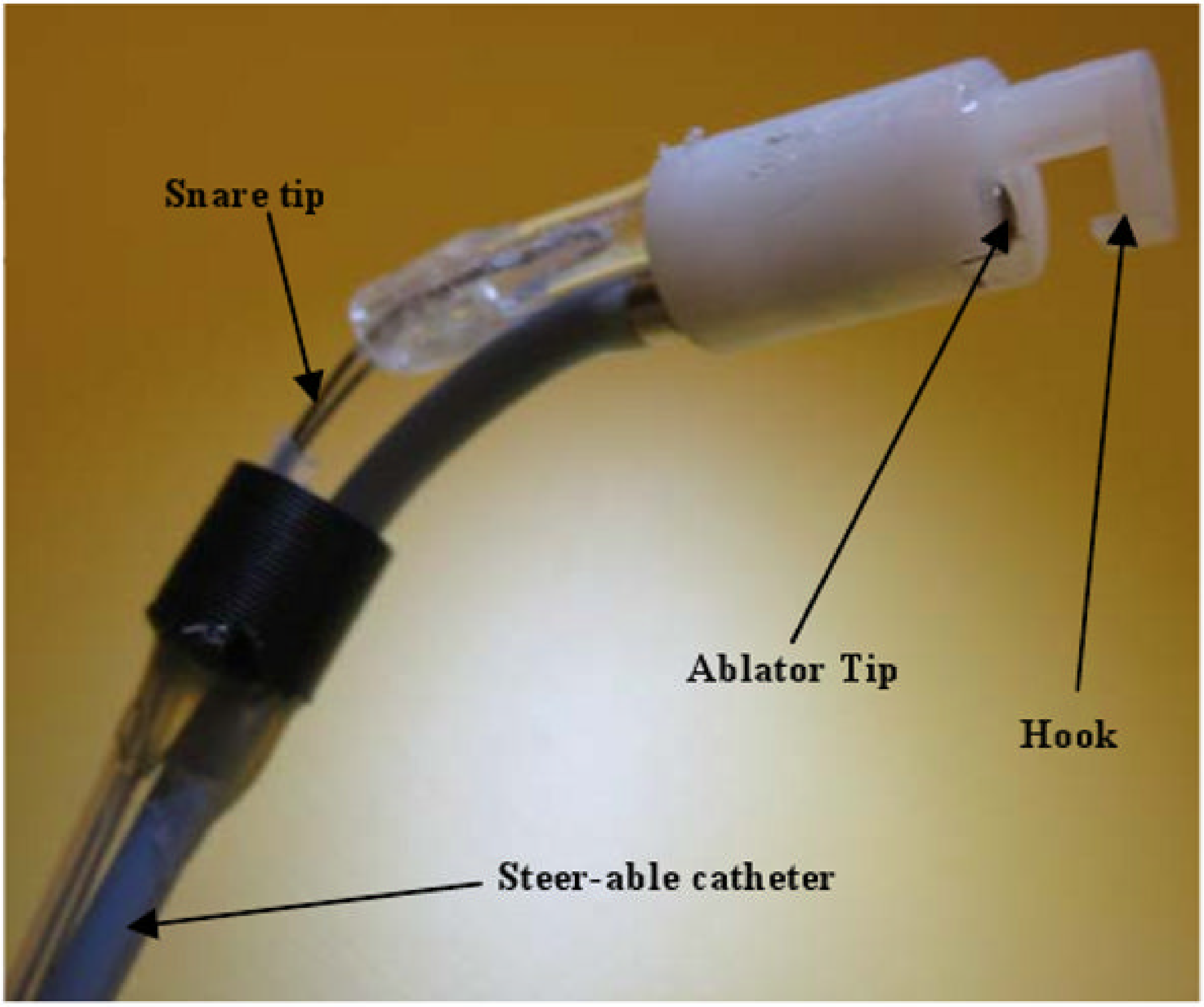

Figure 17. Detailed view of mechanism

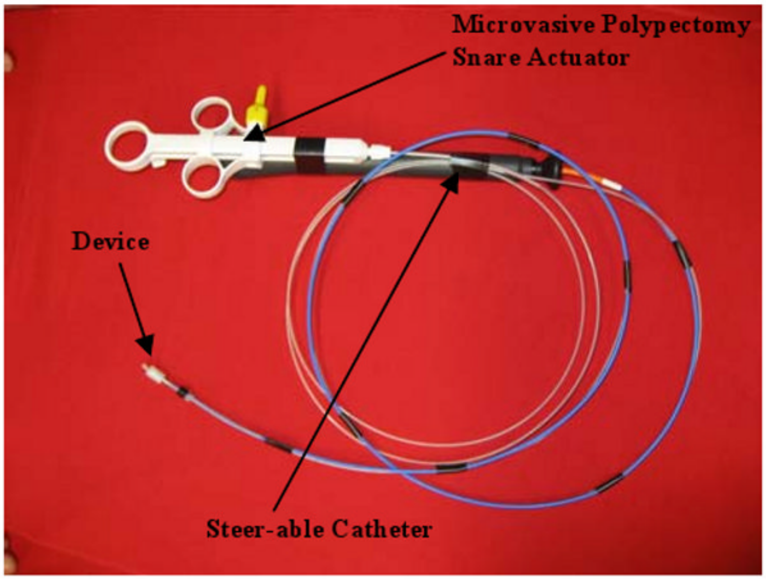

Figure 18. The mechanism, including the Microvasive Polypectomy snare, and steer-able catheter

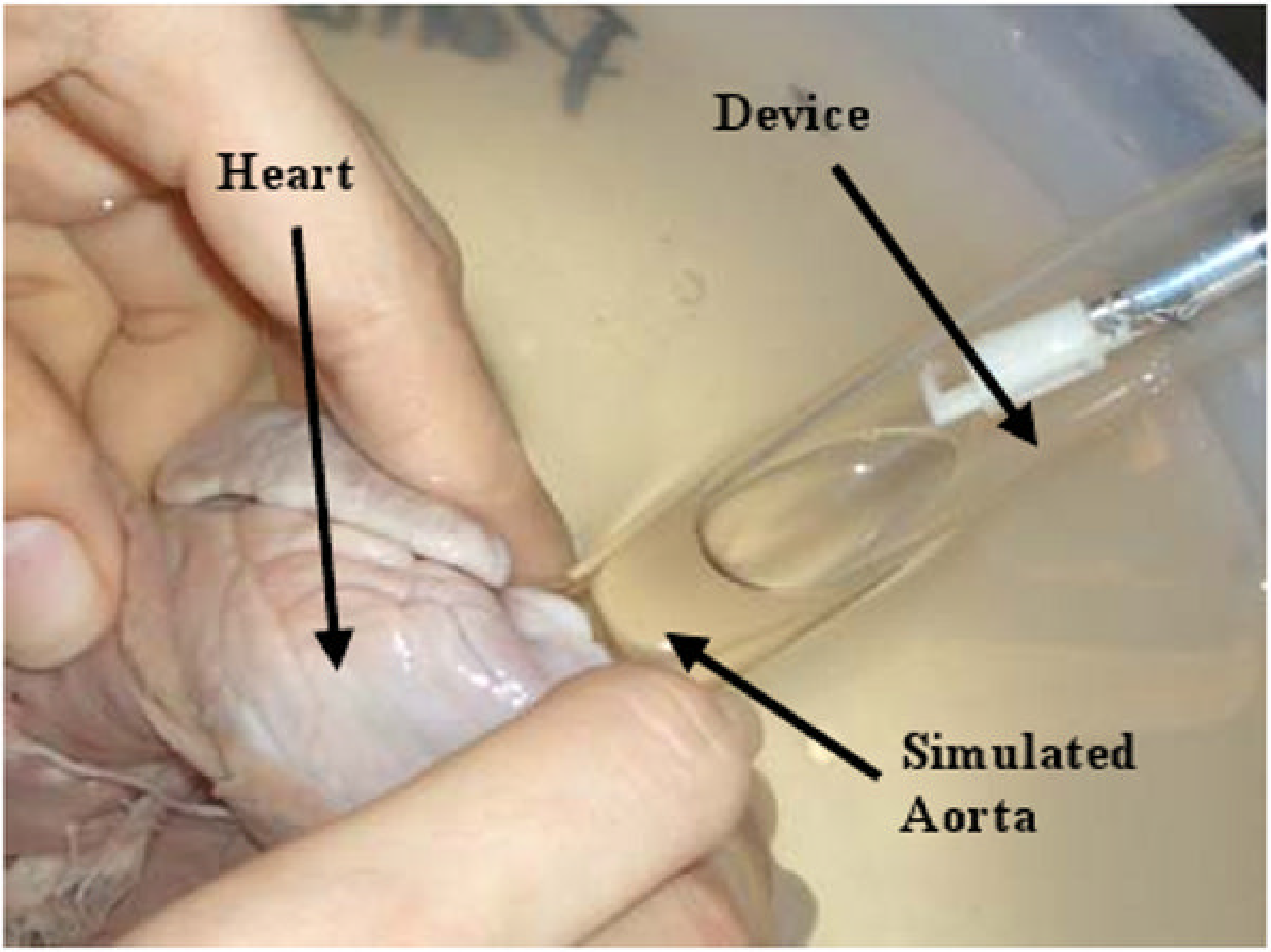

Figure 19. Our experimental setup, with the simulated femoral artery and porcine heart, and the device inserted into the simulated vessel

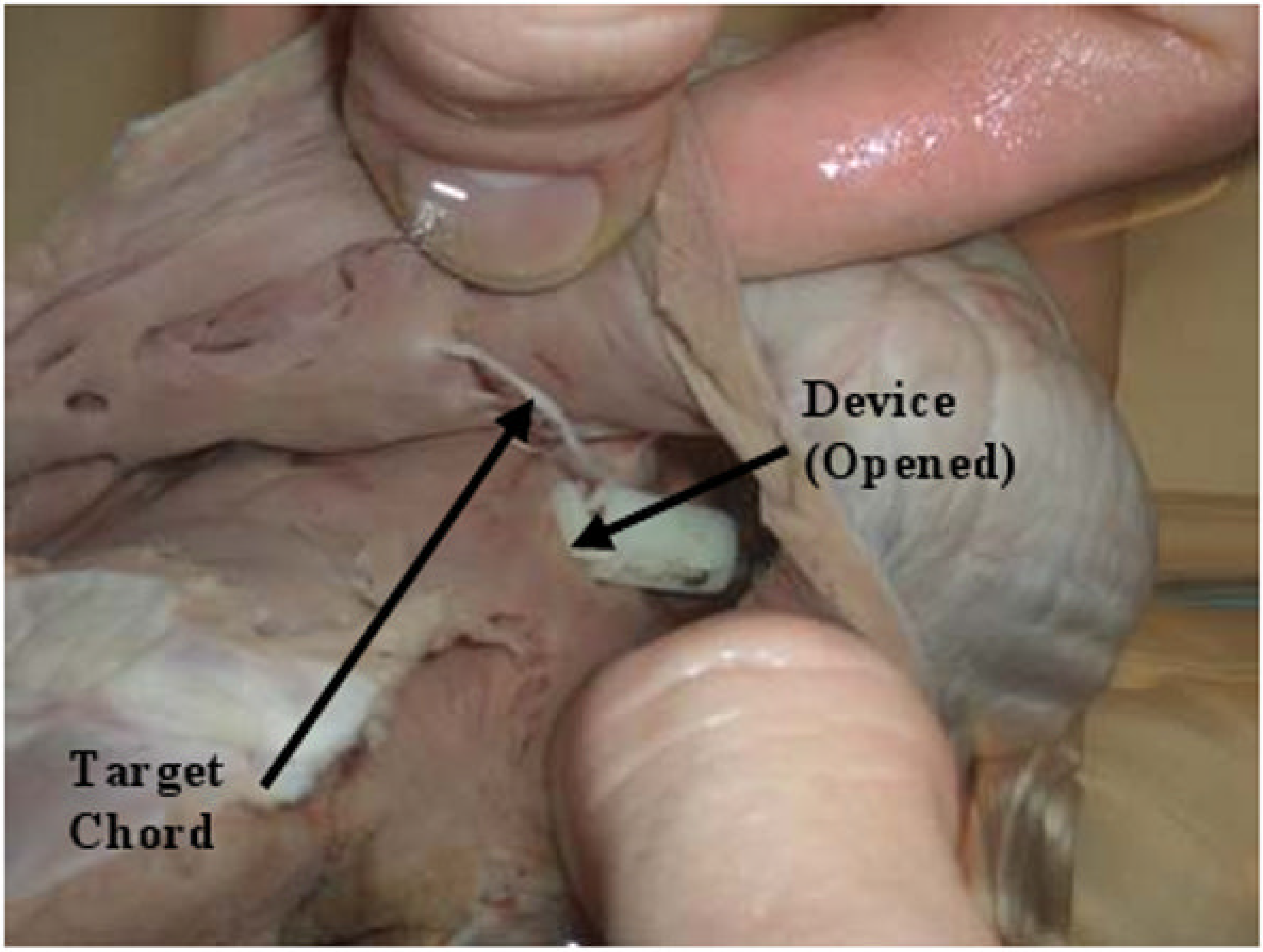

Figure 20. The device in position to grip the mitral valve chordae tendinae

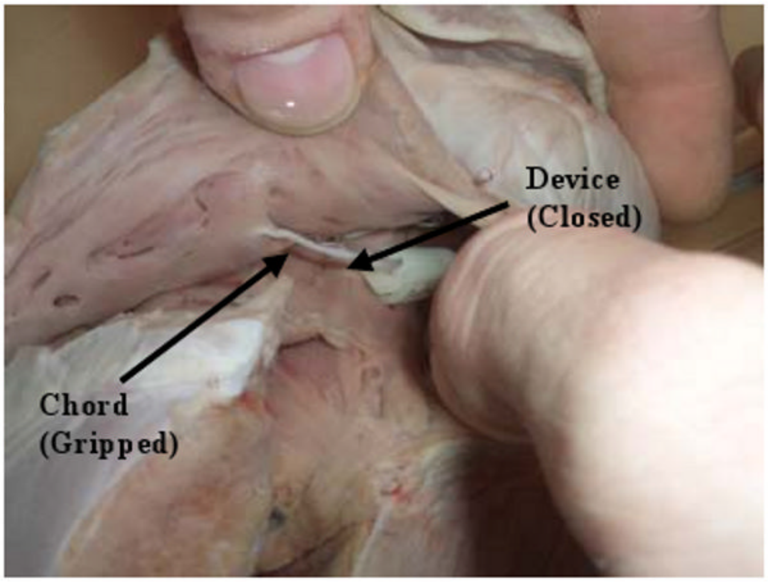

Figure 21. Device (with RF ablator on board) gripping Mitral Valve Strut Chord

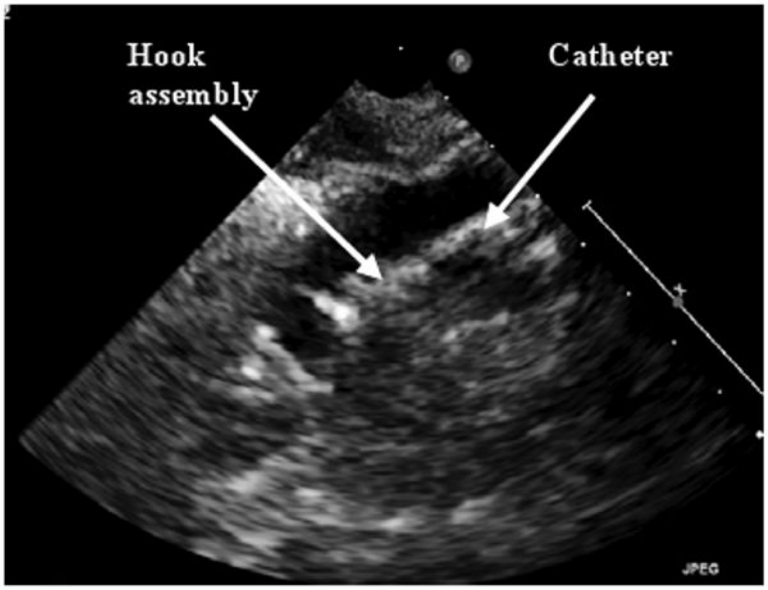

Figure 22. Echo image of catheter device

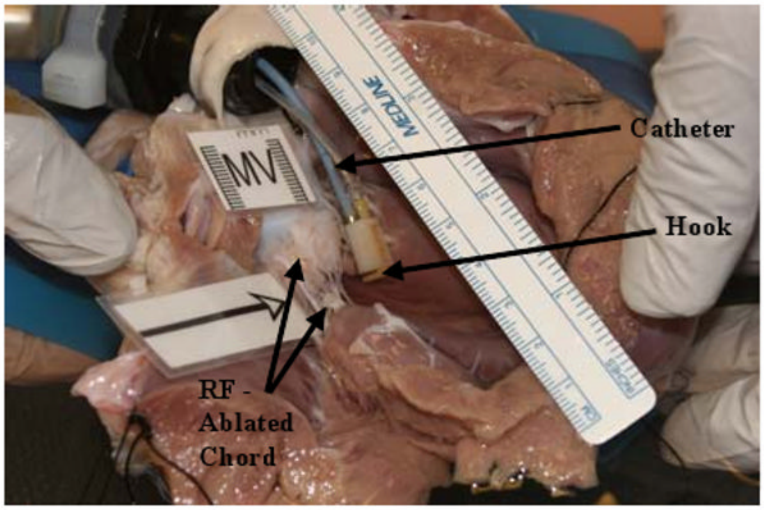

Figure 23. Basal chord cut using RF-ablation

Table 1
Device Functional Requirements

Grab and orient 1.5 mm (±0.5 mm) basal chord.
Chord ripping mechanism must be able to maneuver inside of a 23 French catheter (+5/-0 Fr).
Cut basal chord (the tolerance here is a Boolean, either cut the correct chord, or cut nothing).
The device must be compatible with ultrasound imaging (Material density = 1 g/cm^3 ± 0.125 g/cm^3).

Table 2

Deflection due to *F1*

Parameter	**Value**	**Units**
L_1	6	mm
Radius	2.0	mm
Young's Modulus	2.0×10^{9}	Pa
F_1	0.6 [14]	lbf [mN]
δ_1	2.0×10^{-4}	mm

Table 3

Deflection due to *F2*

Parameter	**Value**	**Units**
Length of Beam	5.0	mm
Radius of Beam	2.0	mm
Length of Hook	3.0	mm
Thickness of Hook	0.2	mm
Width of Hook	0.5	mm
Young's Modulus	2.0×10^{9}	Pa
F_2	0.6 [14]	lbf [mN]
Applied Moment	0.68	N-mm
δ_2	1.1×10^{-04}	mm
Hook Deflection	0.29	mm