Articulated catheter tip to manipulate end effectors in minimally invasive surgery

by

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ABSTRACT

Different catheters are built with tools at the tip (end effectors) for cutting, snaring, measuring, and probing tissues in the heart. Current end effectors are very simple and their effectiveness is limited because they must be extremely compact for traveling through a patient's cardiovascular system. Developing better catheter end effectors would enable clinicians to do a wider range of procedures in a minimally invasive way.

This project involves building a "wrist" at the end of a catheter for clinicians to better interact with tissue. More specifically, it is the creation of a working articulated joint near the tip of the catheter with multiple degrees of from machined components, which must be small enough to fit inside the vein and controllable once inside the body. This is especially important for minimally invasive heart surgery, where both the surgical manipulation of tissue during valve repair and inspection of heart tissue require a device that has many degrees of freedom to move once inside the heart. This is also important for delicate surgeries such as beating heart surgery, where an articulated catheter tip can reduce damage to surrounding tissue.

A 2:1 steerable pin joint prototype for use in catheters is presented herewith. The prototype joint, made by 3D printing from polyurethane, has a 6 mm outer diameter with a 4 mm inner channel and can bend from 165.7 degrees from left to right (n=7, SD: 6.03 deg.) via actuation by two antagonistic pull wires. Furthermore, the joint can withstand high axial forces relative to its size, especially when bent, as well as deflection from lateral forces against the side of the tip. High lateral forces can also be applied at the tip with small tension on the pull wires due to a 4 to 5x mechanical advantage of the joint in bending.

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CHAPTER 1. INTRODUCTION

1.1 Problem Statement

This ES100hf senior thesis project aims to build a steerable joint, similar to a wrist, close to the catheter tip to enable surgeons to finely control a catheter end effector in minimally invasive surgery.

1.2 Background

Minimally invasive surgery, where small catheters are fed directly to the region of interest through small (<5 mm) incisions in the body, has become a popular tool for cardiac surgery. It enables complex procedures to be done on the beating heart without opening of the chest, which prolongs healing times and increases the risk of serious complications. [1] Over 1.1 million procedures are performed annually in catheterization labs across the country, and cardiac catheterization has replaced more than 15 types of heart surgery.[2, 3]

Different catheters are built with tools at the tip called end effectors for extracting, snaring, measuring, and probing tissues in the heart.[1] Current end effectors are very simple and their effectiveness is limited because they must be extremely compact for traveling through a patient's cardiovascular system. For example, balloon catheters, which can expand when inflated with a fluid or with air, are used to expand stenotic arteries and valves, and are helpful for inserting stents to dilate narrow passageways. Ablation catheters, used to destroy plaques in coronary arteries and remove arrhythmic heart tissue, deliver high intensity light or heat to areas of the heart through a conductive tip. Biopsy catheters, used to collect tissue for analysis from inside the heart, for instance, in cases of myocarditis, consist of a sharp-tipped gripper which can be opened and closed via a guide wire.[1, 4]

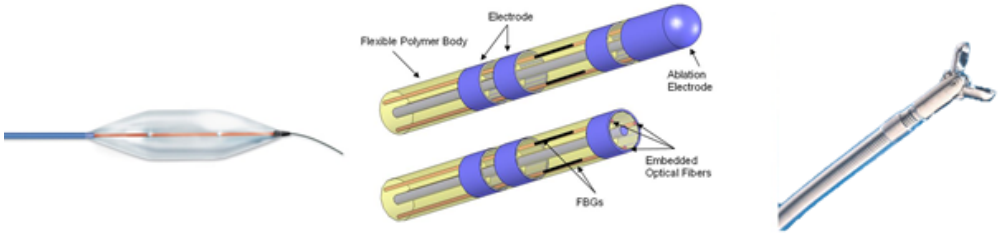

Figure 1. Different catheter designs: (left) a balloon catheter, (center) an ablation catheter, (right) and a biopsy forceps catheter.[5-7]

To access the heart, doctors make incisions either in the femoral artery in ether of the legs or the jugular vein in the neck; infrequently, the procedure can also be done through the wrist. Surgeons will guide the catheter inch by inch through the body, either by ultrasound or fluoroscopy using radioluminescent dyes, until it reaches the heart.[4] Because the catheter must travel through smaller veins and arteries, the diameter of the catheter must be around 18-24 French (5-8 mm) for adults, 10 French (3.1 mm) for small children, and 4-6 French (1.2-2 mm) for infants and toddlers.[8] It also must be reasonably flexible to bend around turns while still remaining rigid enough to apply a strong force, usually up to 4 N / cm2, at the tip when inside the heart.[8] This is done by bonding multiple segments of plastic tubing of different stiffnesses rating until reaching the tip.[4] An example is a simple coronary catheter, used for injecting contrast dyes to the heart, made of three segments of plastic that is 72 durometer on the proximal end, 63 durometer in the central segment, and 35 durometer at the tip.[4] Depending on the type of catheter, stiffer plastics may be used, up to 70 durometer at the tip.

To steer the catheter to the correct region of the heart, surgeons can bend and rotate the catheter tip, allowing a very limited degree of freedom.[9] Most catheters require bending of the tip before insertion, but sometimes can be controlled using pull wires inside the catheter or electronically using NiTi shape memory alloy actuators[10].

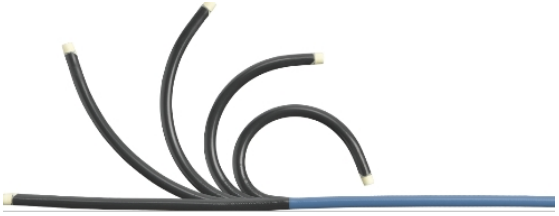

Figure 2. Range of motion of a bent tip catheter [11]

1.3 Motivation

Even with good visualization such as fluoroscopy and ultrasound, targeting end effectors to a location of interest in the heart is difficult[4], leading to higher costs of cardiac procedures and lower success rates. This is due to, first, a lack of fine control of the bending of the catheter tip, and, second, limited maneuverability of the catheter tip location inside the heart. This research project aims to solve the first problem by developing a steerable joint, similar to a wrist, close to the catheter tip to finely control the end effector.

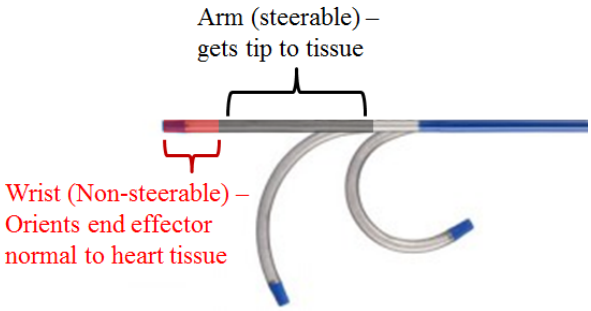

Figure 3. Illustration of current steerable catheters, with 'wrist' region highlighted.

While current catheter end effectors are limited, the Biorobotics Lab is currently developing robots to steer catheters in minimally invasive cardiac procedures[12]. A system is under development which will allow an ultrasound feedback-control system to compensate for the beating motion of the heart during surgery to both stabilize the catheter and apply force to areas of the heart, enabling surgeons to perform more surgeries by a minimally invasive approach. This improvement in precision will allow more useful end effectors to be developed for heart surgery.

1.4 Overview of State of the Art

Cardiac catheters are both steerable and non-steerable in one, two, or multiple degrees of freedom.[13] They can be rotated along the central axis of the catheter by applying a torque to the inner guide wire of the catheter as well as deflected in bending by applying a corresponding tension along one side of the catheter tip. Most catheters have a predefined shape that is useful for reaching challenging anatomy inside the heart during different minimally invasive heart surgery. [13]

From inspection, current steerable catheters are imprecise and difficult to use. First, bending happens over a large distance, making it difficult for the doctor to maneuver in tight inside the heart. Bend distance is important due to the dimensions of the heart. Two standard dimensions that are used to measure the available space inside the heart are the left and right ventricular end-diastolic dimension (LVEDD and RVEDD, respectively).[14] On average, the LVEDD is normally between 36 to 56 mm while the RVEDD is 10 to 26 mm. [14] Measures of right and left atrial dimension are also comparable (24 to 40 mm).

This is significant because current steerable catheters bend over a much larger distance than is available for maneuvering, making it difficult to control the location of the catheter tip. For instance, the Radia Steerable Diagnostic Catheter (Bard Electrophysiology) is one commonly used brand of steerable catheter that suffers from this issue. It requires at least 70 mm between the wall of the heart and the catheter lumen to bend the tip by 90 degrees.[15] As in this example, bending is achieved by pull wires over a large distance in the 'arm' region of the catheter leading to the tip.

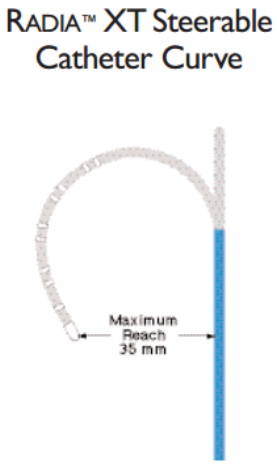

Figure 4. Radia XT Steerable Catheter Curve[15]

Second, doctors cannot change the angle of the tip when at a particular spot in the heart – making it difficult to align the tip normal to heart, important for the effectiveness of many heart procedures. The NIOBE magnetic catheter navigation (MNS) system (Stereotaxis, St. Louis, MO) sidesteps this issue by using an external magnetic field to control the position and angle of a ferromagnetic catheter tip attached to an elastomeric lumen when inside the heart.[16, 17] MNS is already used to successfully perform many

types of catheter ablation procedures; however, the upfront cost of the externally-controlled system is in upwards of $3 million.[18]

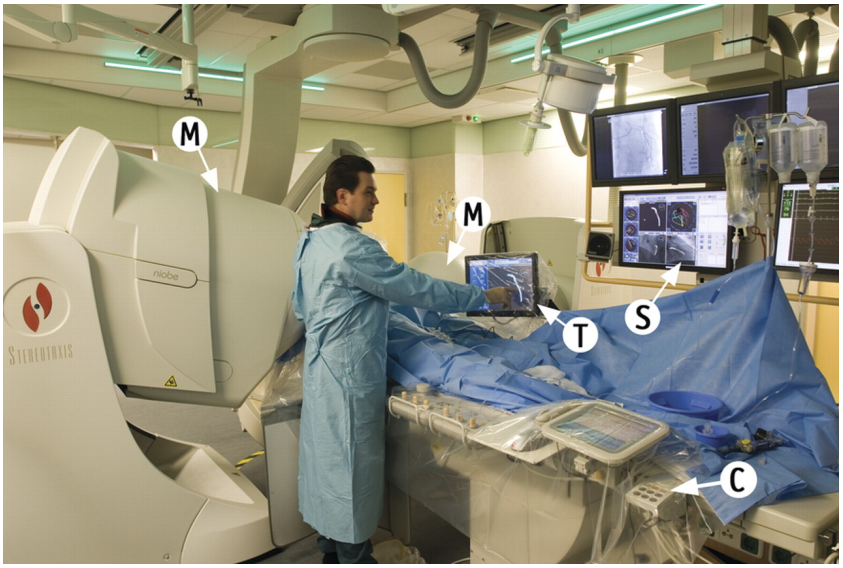

Figure 5. NIOBE Magnetic Navigation System[17]

1.5 Need and Potential Use

Developing a catheter wrist would enable clinicians to do a wider range of procedures by cardiac catheters and greatly reduce the risk of serious complications during minimally invasive cardiac procedures.

For instance, perforation of the heart wall occurs in 2-3% of minimally invasive procedures due to poor control of the catheter tip.[19]

Poor targeting of the catheter tip is also responsible for incomplete catheter ablation, a serious issue in tachycardia correction procedures.[20] For one, catheter-based cardiac ablation is a time-consuming and difficult procedure which may take up to 4 hours.[21] Damage to tissue nearby the phrenic nerve (PN) or in the electrical connections between the sinoatrial (SA) and atrioventricular (AV) nodes can cause tachycardia.[22] To correct this, an ablation catheter is used to remove the damaged tissue responsible. Issues resulting from incomplete ablation include injury to the PN, SA node dysfunction requiring a permanent pacemaker, loss of AV synchrony, and recurrence.[20] To protect the heart during this procedure as well as help steer the tip of the ablation catheter to the site of interest, doctors deploy a steerable balloon catheter near the site where ablation is required.[20] Serious

complications as well as the use of additional catheters could both be avoided by a steerable tip catheter as it would allow doctors to easily control the position of the ablation catheter during the procedure and direct it to the tissue of interest without needing to inflate a balloon catheter to correct its position.

Correction of ventricular and atrial septal defects (VSD and ASD) can also be improved by a steerable catheter wrist. The risk of serious complications, including damage to the tricuspid valve leading to ventricular failure and death, are largely due to poor catheter placement.[23] Two common ways these defects are corrected is through either an implantable device which can be delivered by a catheter, such as an Amplatzer septal occlude device, or open heart surgery, where cardiac patches or sutures are used to close the defect.[8, 23] In the first case, multiple rigid intra-cardiac guide wires must be positioned at specific locations around the defect to allow the implant to successfully seal off the defect. Placement of each guide wire increases the potential for injury, the time and cost of the procedure, and makes it difficult to place additional catheters due to crowding.[23] The use of a steerable tip catheter would greatly reduce the need for guide wires during the positioning of the implant.

Heart biopsies are often non-specific and have a high false positive rate for conditions such as myocarditis, since it is often difficult to steer catheters to sites of disease tissue; a surgeon may take 8 to 10 samples before reaching diseased tissue.[9] A steerable catheter could reduce the number of attempts to 1 or 2 by going directly to affected areas. Furthermore, steerable catheters could apply greater force during surgery, since the wall of the heart would remain normal to the tip of the device.

CHAPTER 2. DESIGN GOALS

2.1 Variables

Much like a human wrist, the joint near the catheter tip should be flexible within a short distance, strong, and durable for repeated targeting of the end effector. As many catheters are either disposable or used in a limited number of procedures before being replaced, the final approach should be cost-effective and therefore mechanically simple. Along with doctors who perform both open and minimally invasive cardiac surgery from Boston Children's Hospital and a team at the Harvard Biorobotics Laboratory, I assembled a set of required functional characteristics of an ideal joint that can be employed in a variety of cardiac procedures, as shown in the table below and schematic.

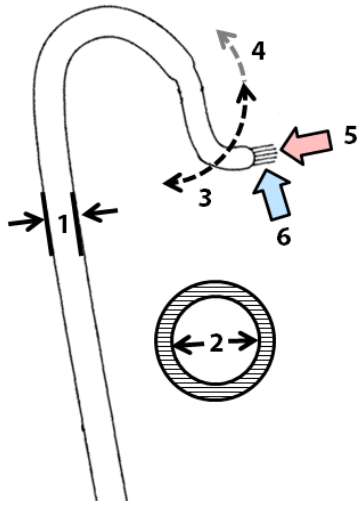

Figure 6. Schematic of catheter wrist design parameters

	Requirements
1. Diameter	< 9 French (3 mm)
2. To manipulate end effectors	Inner channel or other mechanism
3. Range of motion	-90 to +90° pitch, <1 cm bend radius
4. Flexion speed	>90° / sec
5. Axial force	>2 N
6. Lateral force	>1 N
7. Flexion accuracy	10° (Ideal: 5°)
8. Flexion resolution	5° (Ideal: 1°)

Table 1. Functional requirements of catheter wrist

2.1.1 Diameter

Due to the small size of blood vessels leading to the heart, the joint must be no larger than the diameter of typical catheters used in cardiac procedures. For adults, a diameter of no more than 10 French (3.2 mm), including a factor of safety, should be used.

2.1.2 Range of motion

The tip should be able to deflect from left to right through 180° smoothly in a distance of less than 1 cm to precisely target a specific location of the heart wall. It is important to note that this is different than the range of motion of the entire catheter. As the human arm is maneuverable before the wrist, the length of the catheter before the joint may also be steerable.

2.1.3 Flexion speed

To be useful in future computer-guided catheterization procedures, the tip must be able to quickly change position in response to movement of the heart wall. Depending on the heart rate of the patient which can vary from 50 to 120 BPM during a procedure, the joint must be able to move towards and away from the heart at the same rate. A decent approximation of the required actuation speed in bending is around 90 degrees / second, allowing the tip to go from fully extended back to neutral position near the rate of the human heart.

2.1.4 Forces

Catheter ablation and congenital defect repair procedures require at least 4 N / cm2 and a total force of 2 N or more delivered against the cardiac tissue to be effective (Dr. del Nido, 2012). Therefore, the catheter joint must be able to withstand at least a 2N axial force applied to it. Furthermore, it is reasonable to expect the catheter tip to encounter lateral forces of 1 N or more that would cause the tip to deflect from its prescribed pitch.

2.1.5 Accuracy

The doctor performing the cardiac procedure should be able to monitor the deflection of the tip directly within 5° and prescribe positions accurately within at least 10°.

2.1.6 Biocompatibility

While the catheter is not implanted into the human body, the material properties and structure of the catheter should not be harmful to the patient. This means that materials used in the catheter should not leech hazardous organic or soluble compounds into the

bloodstream. Furthermore, pneumatic or suction-based systems should be avoided in case of leakage of air while inside the vascular system, which can cause necrosis, a heart attack, or death. Temperatures should remain near body temperature to avoid damaging sensitive tissues or the blood. Finally, open crevices where blood can collect on the catheter may lead to potentially fatal blood clot formation, so the joint must be sealed from the bloodstream and present a smooth profile for blood to flow over.

CHAPTER 3. FINAL DESIGN

3.1 Overview

A pull wire actuated one degree of freedom pin joint for use in catheters is presented in the figure below. This design for a joint that can be embedded in the tip of the catheter is modeled after the natural construction of a lobster claw, which allows for excellent pivoting and joint strength while maintaining an inner channel. The joint is cylindrical with an outer diameter of 3 mm, an inner channel with diameter 2 mm, and a maximum theoretical bend angle of 174.76 degrees (87.38 degrees in each direction). Tight bending is achieved by a bend radius of 6 mm. Mechanically, the joint can withstand high axial forces normal to the tip and high lateral forces when tension is applied to the pull wires. An inelastic sheath secures the pull wires along the joint, and an elastic sheath covers the open area of the joint to make a continuous outer catheter lumen that is sealed off from the body. Detailed drawings and additional images of each part can be found in the Supplementary Information.

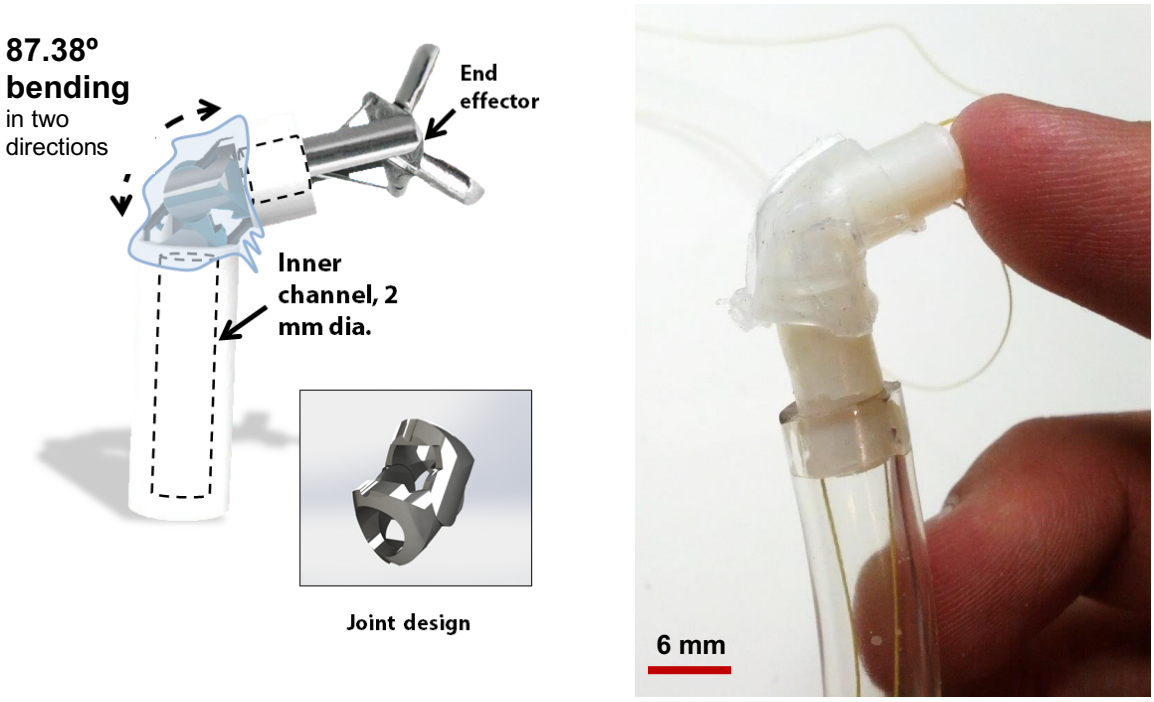

Figure 7. CAD rendering of final pin joint design, with the joint highlighted (left); 2:1 scale prototype (right)

3.2 Joint Structure

The pin joint is made up of a bottom part which is connected to the catheter lumen and makes up the outer section of the joint and contains two 0.5 mm dia. pins which are 0.25 mm tall. A top part connects the bottom part to the catheter tip and contains an inner section with two sockets which the pins rotate within. The pin joint also contains a 2 mm diameter inner channel throughout its length to allow end effectors to be passed through the joint to the catheter tip before or during a catheterization procedure.

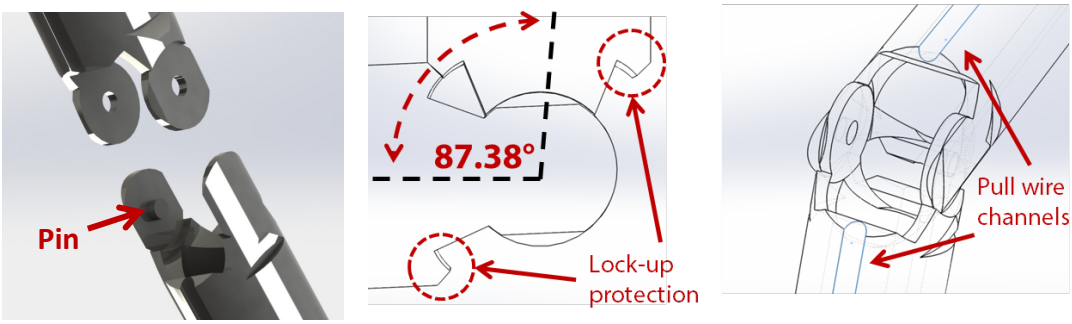

Figure 8. Exploded view of the top and bottom portions of the catheter joint, with the pin highlighted (left); the maximum theoretical bend angle of the catheter as a result of a lock-up protection mechanism (center); pull wire channels integrated into the catheter lumen (right)

The intersecting portions of the top and bottom part of the joint have a large surface area to protect the joint from mechanical failure during operation.

Both segments of the joint also include recessed channels along the outer edge which guide the pull wires over the joint for actuation. Pull wires are made from drawn AISI 302 stainless steel and attached to the top part of the joint by microwelding during manufacturing.

Pull wires pass through the open space of the joint between the two parts. A portion of the channel is extended into the open area of the joint to prevent overextension of the catheter past 90 degrees and subsequent lock-up. Sudden lock-up of the joint occurs past 90 degrees bending since the pull wires pass through the bending axis of the joint, causing the direction of the torque exerted on the tip to reverse. Lock-up does not occur when an end effector is used however, even in cases of overextension, since the bending axis is protected within the inner channel occupied by the end effector. Even without an end effector present, the joint is protected from lock-up by this design.

The joint is made by press molding from AISI 302 stainless steel. This is a general purpose austenitic steel similar to those used in surgical instruments[24]. It has a high tensile strength of 502 MPa which makes it ideal for withstanding high loads. It is commonly used for stamping and drawing into wire. To assemble the bottom and top parts of the joint together, the top part is snapped into the bottom part by force. It is assumed that the force required in assembly does not damage the joint, as demonstrated empirically in prototyping.

A 2:1 scale prototype of the pin joint was created for evaluation. The prototype was created in CAD modeling using Solidworks 2012 and manufactured on a Stratasys Objet350 Connex 3D printer (Eden Prairie, MN) from proprietary VeroWhite polyurethane plastic printing substrate. Kevlar pull wires were used for actuation and attached to the top part of the joint using a zip tie. The bottom part was mounted in a 10 mm outer diameter vinyl tube for testing purposes.

Figure 9. Assembled catheter joint before addition of pull wires and outer sheath (left); close-up view of catheter joint (right)

3.3 Sheath structure

The entire open section of the joint is covered by a durable elastic sheath which adds an additional 0.5 mm to the size of the joint for a total outer diameter of 3.5 mm. The sheath must be highly elastic since it must expand and contract by 100% of its original length on each side when bending the joint.

Additionally, along the closed luminal section of the joint, an inelastic sheath made from extruded polyolefin thermoplastic is fitted around each part to hold the pull wires in place inside the channel. Like the elastic sheath, the inelastic sheath adds an additional 0.5 mm to the diameter of the joint.

During manufacturing, the inelastic sheath and elastic sheath are joined together by molding under moderate heat (70 deg. C) to make one continuous surface that seals off the joint from the human body.

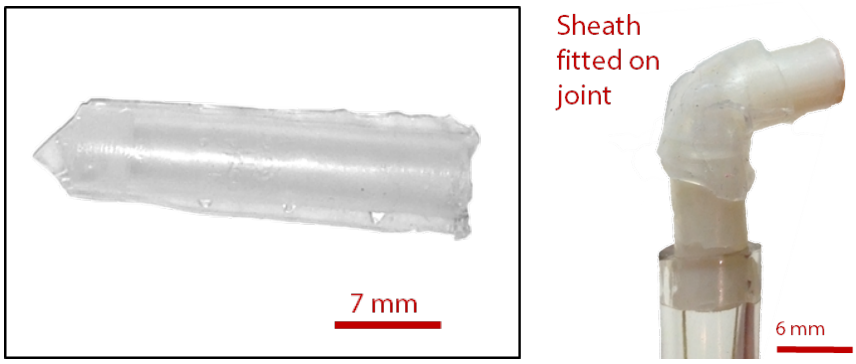

Figure 10. Image of molded sheath made from Ecoflex 0010A silicone rubber pre-trimming (left); catheter with inelastic and elastic sheath fitted on joint (right)

A 2:1 scale elastic sheath for the joint was created from Ecoflex 0010A silicone rubber (Smooth-On Inc., Easton, PA) using simple molding. Elastic sheaths were manufactured to 1 mm thick $\pm$ 0.5 mm and had an outer diameter of 7.5 mm. The molds were formed in steps which consisted of mixing the two-part silicone rubber, defoaming, pouring the rubber into the mold, degasing at low pressure, inserting metal rods into the mold to create the inner space of the sheath, and curing at 70 deg. C for 45 minutes. Excess material was then trimmed from the molded sheaths and fitted mechanically over the catheter joint. Silicone rubber was mixed and defoamed for 3 minutes each on a Thinky AR100 mixer (Thinky Corp., Laguna Hills, CA). Molds were milled from Delrin. Drawings and images for the molds are available in the Supplementary Information.

Additionally, a 2:1 scale inelastic sheath was made for prototyping from clear heat-shrinkable polyolefin tubing. The tubing was fit over the closed sections of the joint and heat applied to make a tight fitting seal around the pull wire channels.

3.4 Mechanical properties

3.4.1 Failure modes

In terms of mechanical failure, there are a number of different possible failure modes which were investigated to determine which failure mode would dominate. Empirically, the

dominant failure mode for the pin joint was separation of the top part from the bottom part due to the pin leaving the socket due to elastic deformation of the overlapping region under high axial or lateral loads. Mathematical models for multiple different failure modes were created to verify that this failure mode is expected. A summary of each model is provided here. CAD simulations of applied force were used to visualize the stress distribution but were not relied upon to accurately determine the stresses from each failure mode.

3.4.1.1 Shear on pin

Due to high axial loads transmitted from the tip of the catheter to the pin, shear failure of the pin is one possible failure mode. Sufficient loads could cause either the pin to break off from the bottom part or to deform enough to leave its socket. A diagram of the loading on the pin is shown below.

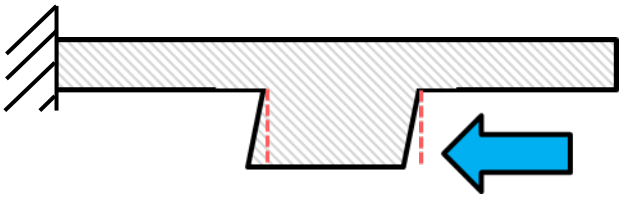

Figure 11. Shear loading on pin

$$force\ applied\ to\ pin = \frac{1}{2}F_{axial} = \frac{\tau\pi d_{pin}^2}{4}$$

$$shear\ stress = \frac{2F_{axial}}{\pi d_{pin}^2}$$

For a 2N force applied at the tip and a 0.5 mm dia. pin, we have:

$$shear\ stress = \frac{2 * 2}{\pi * (0.0005)^2} = 5.1\ MPa$$

From this we can calculate the shear strain for a given material at maximum load:

$$shear\ strain = \frac{\tau}{G} = \frac{5.1\ MPa * 2(1+v)}{E}$$

where E is the Young's modulus of the material and v is Poisson's ratio.

To prevent failure of the pin, a material should be selected for the joint which obeys the following:

$$shear\ stress = \frac{1}{2} * ultimate\ tensile\ strength\ (approx.)$$

Because of this, a safety factor of 49.2 can be achieved with AISI 302 stainless steel (UTS: 502 MPa). Additionally, a safety factor of 8 is achieved for the polyurethane used in the prototype (UTS: 40 MPa).

A CAD model of the force distribution due to a 2N force at the tip of the catheter on the pin is provided in the figure below. Most of the stress was transferred from the pin onto the region connecting the outer overlapping section of the pin joint to the lumen.

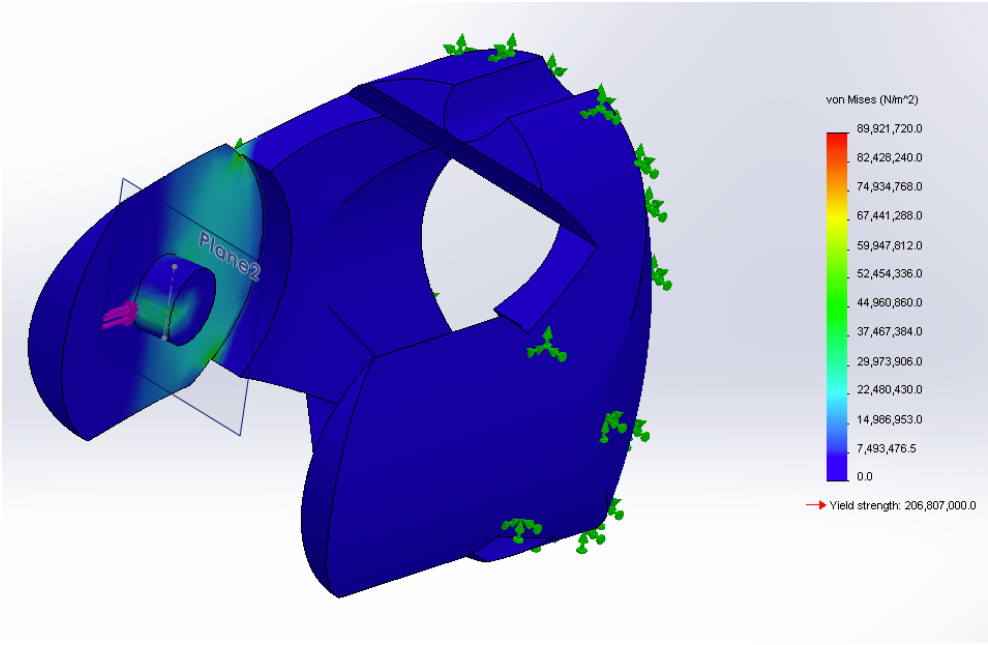

Figure 12. CAD model of 1N force on pin in direction of arrow shown

3.4.1.2 Crushing of joint

Due to forces inside the vasculature of the human body, including the beating of the heart, the joint may be subjected to high loads in compression around the catheter which could damage it. This could result from a pressure difference between the inside and outside of the catheter (for instance, systolic BP) or the contraction of the vascular smooth muscle around the catheter. Assuming a force or pressure is applied at the center of the pin joint (a

worst-case scenario), the deflection of the walls of the joint can be modeled as a simple beam bending model:

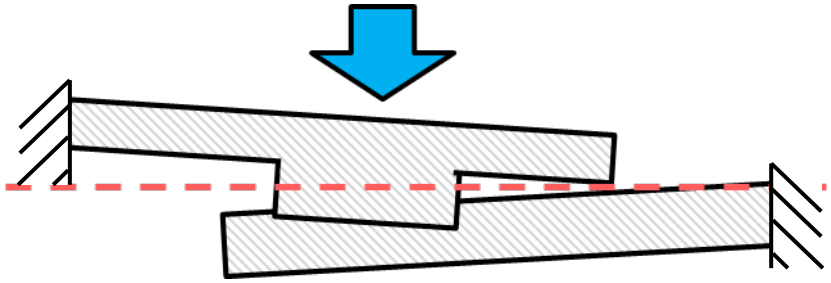

Figure 13. Crushing of joint

$$interarterial\ pressure = P = 4 * F_{bend} * A$$

$$F_{bend} = \left(\frac{3EI\Delta x}{L^3}\right)$$

$$deflection = \Delta x = \frac{4L^3F_{bend}}{Ebh^3} = \frac{L^2P}{Eb^2h^3}$$

where b is equal to the width of the sidewall in contact in the joint, h is the height of the sidewall, L is equal to b since the joint is circular.

The following equation gives the maximum stress inside the joint:

$$stress = \frac{F_{bend}Lh}{2I} = \frac{6F_{bend}L}{bh^2} = \frac{3P}{2b^2h^2}$$

For b = L = 1 mm, h = 0.25 mm, and F = 10N = $4F_{bend}$ and a FOS of 2:

$$stress = \frac{6*2.5*0.001}{0.001*(0.00025)^2} = \mathbf{240\ MPa}$$

This gives a safety factor of 2.1 for AISI 302 steel but a fractional safety factor for polyurethane. This failure mode justifies that the final design should be made from a high strength material such as steel.

A more realistic force distribution of 2 N applied to the entire articular surface of the joint was also considered and modeled in a CAD simulation and shown in the figure below. The maximum von Mises stress for the model was concentrated internally inside the material outer and inner overlapping sections of the joint where they connected to the catheter lumen.

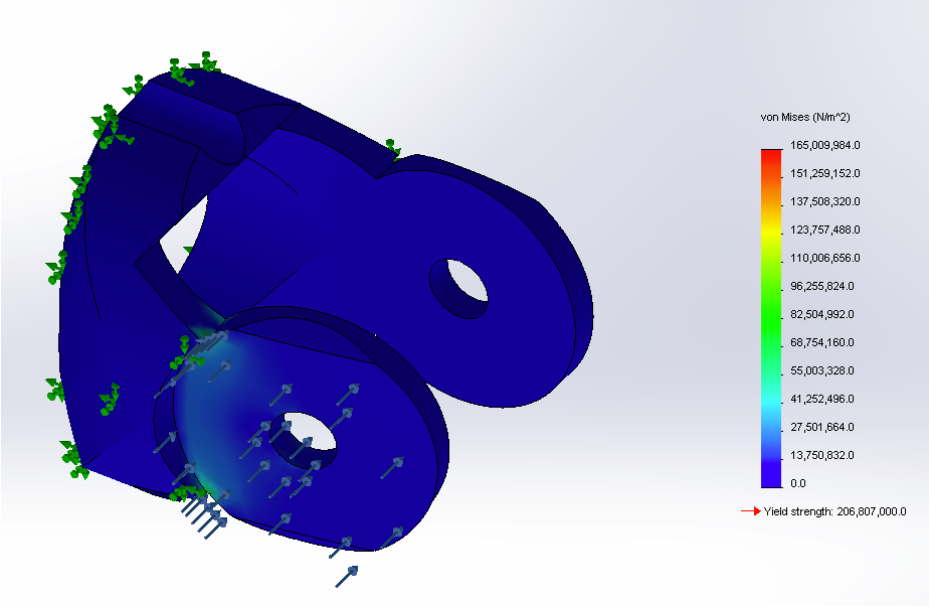

Figure 14. CAD model of ½ N force over the articular surface of the inner socket

3.4.1.3 Lateral force orthogonal to bending

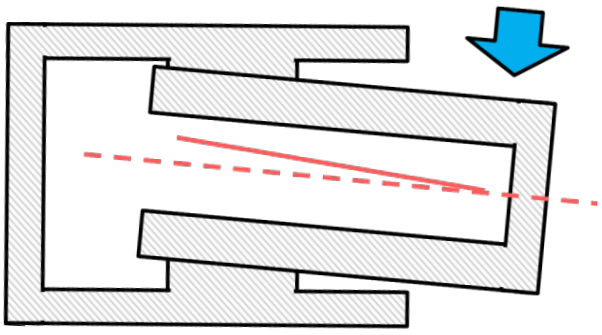

Figure 15. Lateral force applied to tip of catheter

Lateral force may be applied to the tip of the catheter which transfers both a torque and a force to the pin joint which may cause the pin to leave its socket or the overlapping segments to fail.

For a lateral force of 1N on the tip, the force on each overlapping segment can be determined:

$$F_{bend} = \frac{\tau}{4L} = \frac{F_{lateral} d_{joint\ to\ tip}}{4L}$$

$$F_{bend} = \frac{\frac{1}{4} * 0.02}{4 * 0.001} = 1.25\ N$$

$$max.\ stress\ = \frac{F_{bend} Lh}{2I} * FOS = \frac{6F_{bend} L}{bh^2} * FOS$$

$$= \frac{12 * 1.25 * 0.001}{0.001 * (0.00025)^2} = \mathbf{120\ MPa}$$

To understand whether or not the part will separate before breaking by the pins pulling out of their sockets, we can calculate the deflection for ANSI 302:

$$max.\ deflection\ = 0.25\ mm$$

$$deflection = \frac{4L^3 F_{bend}}{Ebh^3} = \frac{4 *.001^3 * 1.25}{193 * 10^9 * 0.001 * 0.00025^3} = 1.66 * 10^{-3}\ mm$$

Therefore, a lateral force of 1N should not cause the pin to leave its socket.

A CAD model of a distributed lateral force of 1N over the entire top part of the joint was created, showing exaggerated displacement of the part for visualization. From the figure, as expected the force distribution is similar to beam bending of the overlapping segments as modeled mathematically, with forces concentrated at the base of each segment.

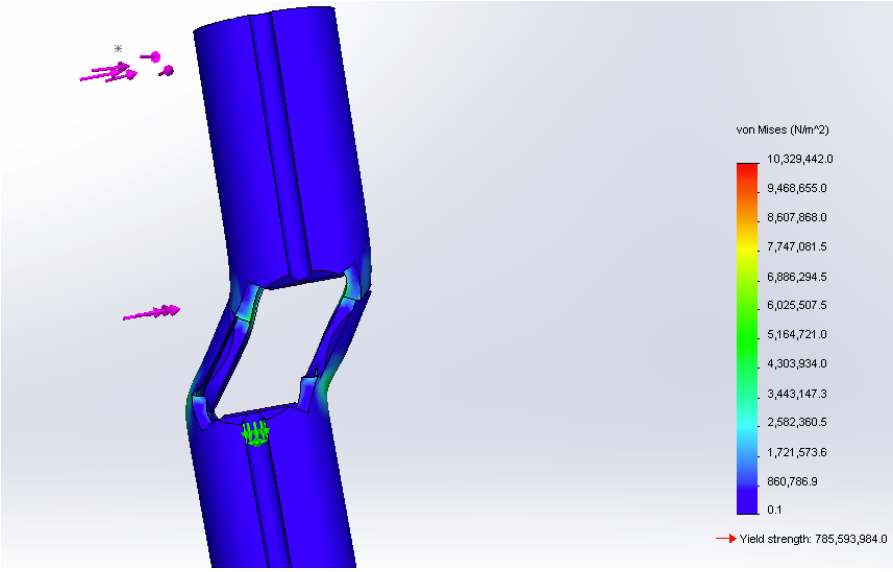

Figure 16. CAD model of 1N lateral force distributed over entire top section of the catheter joint

3.4.1.4 Outer sheath strain

The elastic material which covers the open part of the joint must be able to withstand high strains both in extension (on the left side of the figure below) as well as compression (on the right). Failure of the sheath material would allow blood to leak into the inner channel. Furthermore, if the material is too stiff, the elastic sheath may put high resistive loads on the pull wires during bending or prevent the catheter from achieving its full range of motion.

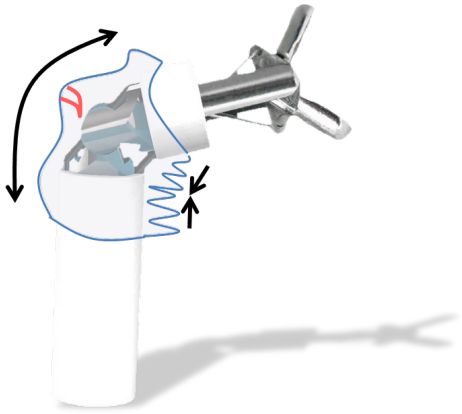

Figure 17. Outer sheath strain

The change in length of the outer sheath between -87.38 degrees to +87.38 degrees is from 0.1 mm to 4.16 mm. The minimum length of the elastic sheath required to cover the joint is 2.085 mm. For the 5 mm long elastic sheath designed for the catheter joint, the maximum strain applied to the sheath in bending is +/- 58.5 percent. This strain is easily achievable by Ecoflex 0010A silicone rubber selected in the final design, which can withstand 800% elongation before break.

3.4.2 Mechanical advantage in actuation

Force on the pull wire is amplified as a lateral force at the tip of the catheter, and applied lateral forces parallel to the direction of bending require only a small tension on the pull wires to counterbalance them. The catheter joint acts as like a pulley system, where the motion path that the joint sweeps through is much shorter than the distance the pull wire must contract to accomplish that motion path. The change in distance amplifies the force applied by the pull wire and gives the joint a mechanical advantage, which is ideal for control of the bend angle of the joint in cases where it is under a high lateral load.

The distance over which the torque is applied to the catheter joint is half of the circumference of the pin, which is $\pi/4$, or 0.785 mm. The difference in length of the pull wires, however, is defined by the change in separation distance of the pull wire channels, which is 3.59 mm. This gives an expected mechanical advantage of 3.59/0.785 or about 4.57 for conversion of the tension on the pull wires to lateral force.

CHAPTER 4. METHODS

4.1 Design Selection

4.1.1 Ideation

I started with over twenty possible designs for a catheter joint, differing in both their actuation schemes and joint structure. Each design was a combination of an actuation scheme and a joint structure.

4.1.2 Actuation

Catheters may use pull wires for simple actuation using knobs or motors outside the body.[13] Most steerable catheters today use a set of two antagonistic pull wires for left and right bending. Pull wires operate by applying a tension to either the left or right side of the catheter lumen which causes it to strain on that particular side. For instance, when tension is applied to the left pull wire, the distance along the left side decreases, causing bending of the catheter tip towards the left. Without a joint, the stress from tension is evenly distributed over the entire catheter lumen. With a joint, the pull wires cause the joint to rotate in the direction of pull to relieve the stress. Additional pull wires may control additional directions of movement, for instance, up and down as well as left and right.[13]

Pneumatics and hydraulics may also be used, similar to soft robotic devices. Negative or positive pressure exerted by air or a fluid may be used to apply a stress to one side of the catheter lumen, causing it to strain in a direction proportional to the applied pressure.[25] These types of actuators require the use of highly flexible elastomeric materials, such as Ecoflex.[25] Because of this, however, they can only tolerate lower pressures and therefore can only apply small forces at the tip.[26]

Shape memory alloys (SMA), which rely on coiled springs of NiTi alloys, can also be used to deflect the catheter tip. Each SMA wire, when heat is applied to it (transition temperature around 70 deg. C), takes on a secondary conformation which is set during manufacture of the SMA wire.[27] Each wire has a different default conformation which it returns to: one wire is a coil bent to the left and the other bent to the right. By applying a voltage across the thin wire, the SMA is heated and tension is applied to the catheter tip in the direction of the SMAs default conformation. By alternating the voltage applied to the two wires, deflection can be achieved. About 4-5% strain can be achieved with SMA actuators, with a maximum frequency of 2 Hz.[27]

Electroactive polymers (EAP) change tip deflection with electric current but rely on a different mechanism than SMAs. EAP actuation is performed by sandwiching an EAP between two flexible electrodes.[28] To be electroactive, the polymer contains trapped Na+ ions in its nanostructure. When the electric field is applied (around 1.5 volts), the Na+ ions

are attracted to the negative electrode, increasing its size. This increase in size on one side of the polymer applies a bending moment to the entire EAP sandwich, causing the actuation.

Finally, gearing mechanisms can be used translate rotational torque from a stiff guide wire which is actuated by a motor outside the patient into tip deflection. This would be the equivalent to a rack and pinion system. The rack, at the tip of the catheter, would control the bending of the tip from left to right.

4.1.3 Joint structure

The simplest joint can be a hollow elastomeric tube, such as rubber, that deflects large distances. Since the joint needs to be able to withstand large strains, specially designed elastomers used in soft robotics are preferable; these include Ecoflex, Dragon Skin, and Elastosil. These materials can undergo a strain of 500-1000% before yielding, making them desirable for a catheter tip deflection as well as sheathing material for other catheter joints.[26]

More traditional mechanical joints can be used in catheter designs, including ball and socket, pin, and hinge joints.

Bellows joints may also be used with more rigid materials where deflection is required. Here, a flexible plastic or metal is cast into a ribbed tube with uniform wall thickness. When tension is applied to one side of the bellows joint, the ribs are uncoiled, much like a spring, allowing higher elastic strain than the original material would provide. A square wave

Bendable drinking straws appear to have a bellows like joint, however, while working very similarly, are manufactured differently and operate using a different mechanism. To make the joint, a hollow plastic tube is compressed in the joint region until plastic deformation occurs, at which point the walls collapse together to form a bellows-like shape. Because the plastic is very rigid, when a stress is applied to one side of the joint, the side in extension pops back to its original shape, while the side in compression collapses closer together. This makes bendable drinking straw joints more flexible than bellows joints, since the side in extension doesn’t undergo deformation over its entire length but more rather a reconfiguration of its shape.

Multiple sliding segments may also serve as a type of joint. In this case, each segment would be free to slide a small angle to the left or the right of the previous segment while remaining in contact with it. This allows the catheter to be made of a rigid material yet still deform when tension is applied to a side, as each segment would slide to the side in tension and deflect the tip.

4.2 Design Narrowing

4.2.1 Overview

From my expansive list of nearly 20 prototypes, I organized them by joint structure and actuation method into a Pugh decision matrix to help me pick the best design. This matrix evaluates each design based on fabrication, functional, and biological concerns. From totaling up the rows of the matrix, an ideal design strategy can be selected. Only the pin joint design and pull wire actuation method stood out from the matrix without any significant drawbacks. Pull wire actuation was determined to be feasible through a review of the available literature and fabrication tools available at Harvard.

The other designs suffered from serious design risks and shortcomings. In terms of actuation, hydraulic devices at 3 mm scale could not be made without micro-scale extrusion molding and would not meet force and inner channel requirements. This includes air muscles and bending actuators which are commonly used in soft robotics. SMAs do not actuate quickly enough or significantly change length over a small distance. EAPs are difficult to acquire and do not bend over a tight radius. From lab testing conducted prior to my thesis project, gearing to convert rotational motion of a guide wire to bending at the tip suffer from lock-up and poor motion control due to high friction between the guide wire and the catheter lumen.

In terms of joint structure, elastomers cannot withstand high forces applied to the tip as they inherently deform easily. Bellows joints can be made from the same material as the catheter and bend tightly; unfortunately, from finite element analysis in CAD modeling, the wall thickness of the catheter is too large at the scale of a catheter to cause significant deflection. ‘Vertebrae’ made out of multiple sliding segments can achieve some bending, albeit only over larger distances such as a few centimeters. Both bellows joints and vertebrae

suffer from poor biocompatibility since blood clots can form inside the interfacial spaces between adjacent segments, leading to serious injury should the blood clot travel through the circulatory system. Ball-and-socket joints do not support an inner channel as it would interfere with the structure of the joint, and are therefore undesirable.

		Machinability	Cost	Bend distance	Range of motion	Inner Channel	Speed	Axial force	Lateral force	Accuracy	Resolution	Complexity	Biocompatibility	TOTAL	*Notes*
Joint structure	Elastomer	0	0	1	1	-1	1	-1	-1	-1	-1	1	0	-1	
	Bellows	0	0	-1	-1	1	0	0	1	0	0	-1	-1	-2	
	Bendable straw	-1	-1	1	1	1	0	-1	0	0	0	-1	-1	-2	Different from bellows joints
	Multiple vertebrae	1	0	-1	-1	-1	0	1	0	0	-1	0	0	-2	
	Ball-and-socket	-1	0	0	-1	-1	1	1	0	1	0	-1	0	-1	
	Pin*	1	1	1	0	0	1	1	1	1	0	1	0	8	Final design
	Granular jamming	0	0	0	1	-1	0	1	1	0	-1	1	0	2	
	Thermoplastic	0	0	-1	0	-1	-1	1	1	1	0	0	-1	-1	
	Square wave	-1	0	-1	-1	1	1	-1	-1	-1	0	0	-1	-5	
	Hinge joint	0	0	1	0	-1	1	1	1	1	0	1	0	5	
	Shear locking	-1	-1	-1	-1	-1	0	0	0	1	-1	-1	0	-6	
Actuation Method	Pull wires*	1	1	0	0	1	1	0	0	1	1	1	1	8	Final design
	Hydraulic	-1	0	1	1	-1	1	1	1	0	0	-1	0	2	
	Shape memory (NiTi)	0	0	-1	-1	1	-1	1	1	0	-1	0	-1	-2	
	Electroactive polymers	-1	-1	-1	-1	0	1	0	0	0	-1	-1	-1	-6	
	Artificial muscle	-1	-1	1	1	-1	1	1	1	1	1	-1	-1	2	Hard to source

Table 2. Pugh decision matrix of initial design ideas, by module category

4.2.2 Alternate Designs

A list of alternate designs and information gathered on each either through prototyping or research is presented in the following pages that highlight their shortcomings.

4.2.2.1 Granular jamming joint

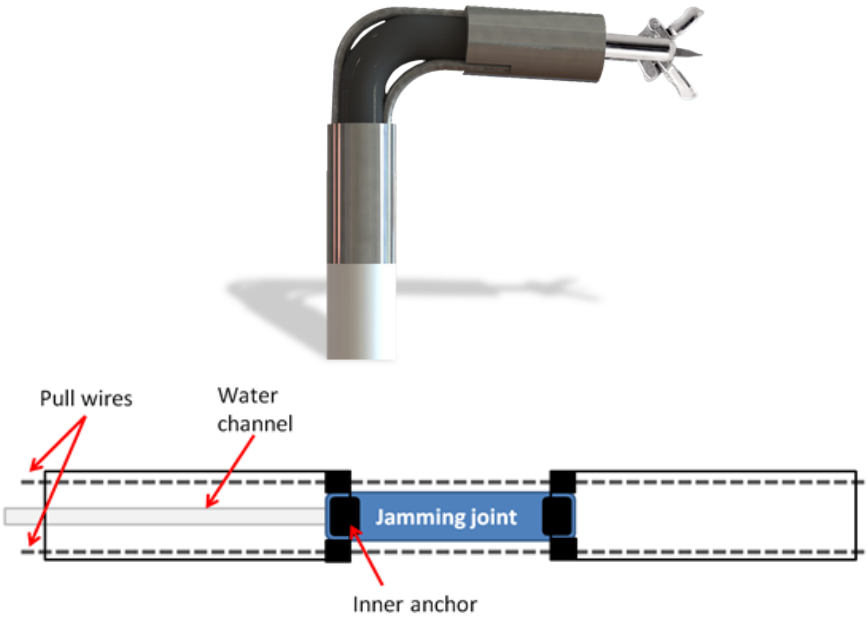

Figure 18. CAD rendering of granular jamming joint design, with schematic

This is a new type of robotic joint which can change the flexibility of a portion of the catheter to allow it to bend via pull wires but also become rigid enough to apply high forces. In normal operation, water and a jamming material inside the joint is flexible to bend over a large angle via actuation by the pull wires. By removing the water from the jamming joint, the joint can be locked into place and force applied to the tip. End effectors can be manipulated when the catheter is rigid, eliminating the need for an inner channel. Theoretically, the joint can bend from -90 to +90 degrees in any direction when flexible, much like a ball and socket joint, and its simplicity means that it can be made very small at comparatively low cost. Furthermore, because the joint becomes rigid, it is possible to use

the same set of pull wires both to control deflection of the catheter tip and the end effector when the catheter is in the locked state.

The part attached to the jamming bag which interfaces with the catheter lumen and end effector, as well as the inner anchor, can be manufactured on a 3D printer. The jamming joint itself is made from an elastomer such as Ecoflex silicone rubber with amorphous silicon (grain size: 500 microns) as one type of jamming material.

Initial testing showed that a jamming joint could be created, as demonstrated by the proof of concept model in the figure below. This proof of concept model was exchanged with the large scale pin joint prototype previously presented. A thin plastic bag filled with coffee grounds was used for the jamming joint. From testing, it was determined that the wall thickness of the bag must be very thin to allow the granular material to compress and lock into place. At scale, a thin-walled bag might be too fragile to achieve this without breaking when under stress. Furthermore, the jamming joint tends to bunch up to a size much larger than the diameter of the catheter as the end effector slides into the space of the jamming joint under load. This might impede movement of the catheter throughout the body as it will come in contact with the walls of the vascular system unless maintained in an initial elongated state through locking of the joint on insertion.

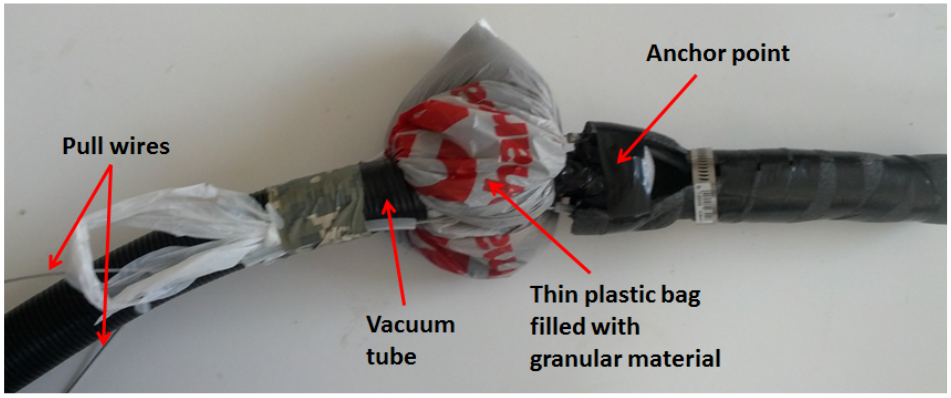

Figure 19. Image of proof-of-concept jamming joint prototype

Small 2:1 scale testing was also conducted on the jamming joint. Table salt was used as the jamming material. Ecoflex 0030A silicone rubber (Smooth-On Inc., Easton, PA) was

used for the jamming bag and molded using the same mold created for the elastic catheter sheath. Inner anchors were 3D printed using the Objet 3D printer at 60 Oxford St. from VeroBlack polyurethane. A cylindrical end effector surrogate made from rolled aluminum plate was added to the tip. Zip ties were used to attach the pull wires to the end effector.

Several issues were discovered relating both to actuation and force requirements. First, because of the smaller scale, the jamming material cannot rigidify significantly to lock the joint at a specific angle or provide resistance to angular and lateral forces. Second, the anchoring system is insufficient to couple the jamming joint to the end effector, as the elastic material deforms away from the desired bend angle under load even when the jamming joint is rigidified. Next, loads applied to the pull wire can cause the jamming joint to bunch up, restricting further actuation. Finally, the jamming material itself can cause small tears in the bag surrounding it when rigidified, causing loss of negative pressure.

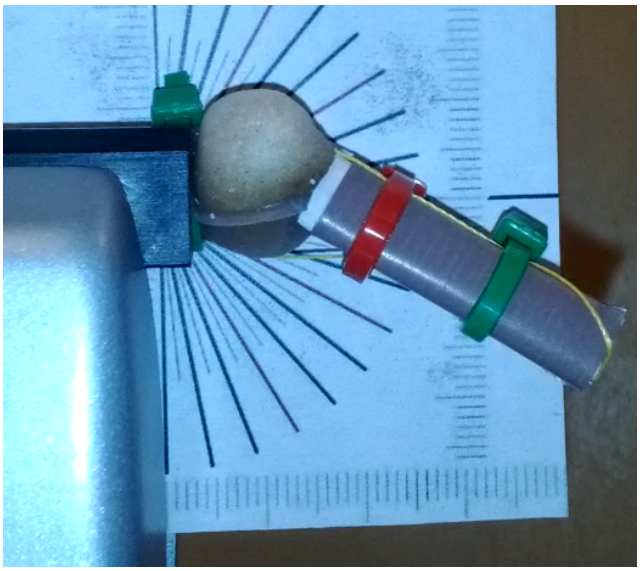

Figure 20. Image of small scale jamming joint prototype in testing

4.2.2.2 Bellows joint

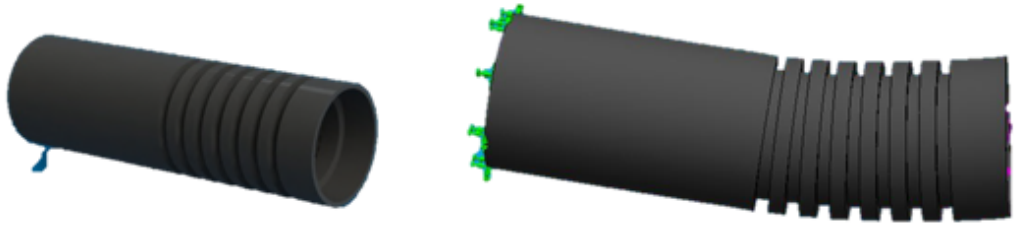

Figure 21. CAD model of bellows joint catheter.

This is a thin-walled flexible tube with a segment that has either square corrugation or has been compressed in such a way that bending in this region of the catheter is greatly enhanced. Using CAD modeling, I was able to create a 3 mm diameter catheter with a 6.7 mm segment that has 0.25 mm tall square channels that ideally would allow the catheter to bend up to 90 degrees in any direction with slightly more bending force than a traditional bending straw, without accounting for material properties of the flexible catheter wall. The benefits of such a design are not only the ease of creating such a design through molding, but also the ability to maintain a large inner channel, its compatibility with traditional pull-wire catheter systems, the added rigidity of the flexible region that protects it from collapsing while also providing necessary force to the tip, and the simplicity of using a single material throughout. Challenges exist, however, determining what the best method of designing the corrugated channels is, and whether or not the geometry scales down to the actual catheter at scale.

Through CAD simulation (not shown), it was determined that the stress applied from deflecting the joint past a few degrees caused the bellows joint to fail.

4.2.2.3 Thermoplastic catheter backbone

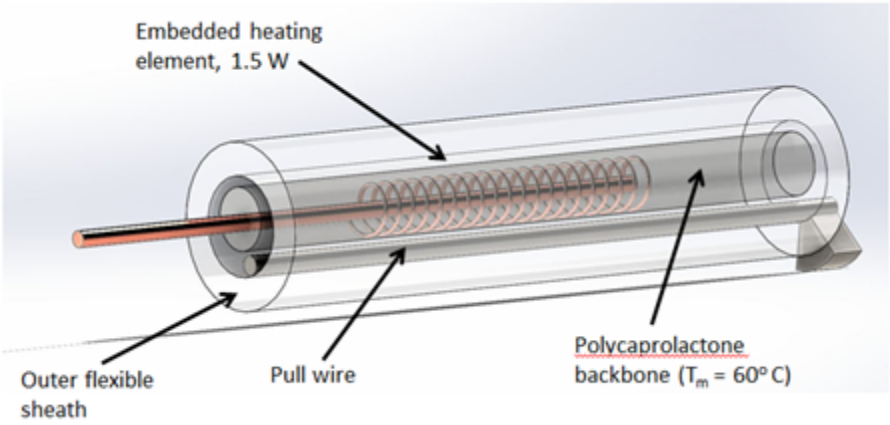

Figure 22. CAD model of thermoplastic catheter backbone inside a catheter lumen

This catheter uses a polycaprolactone thermoplastic inner support backbone that can be heated and bent to a desired shape quickly at low temperatures (60° C) using a pull wire and an embedded heating element. The inner heating element can achieve the required actuation speed by applying 1.5 W of power to the area for less than ½ second, and can be cooled to nylon stiffness just as quickly using a saline coolant that flows through the length of the catheter and out the tip. Polycaprolactone is a biocompatible material used in medical implants and also sold in DIY shops as "InstaMorph" as it is ideal for rapid prototyping. Benefits include the ability to embed multiple bendable segments in the catheter tip, allowing for a very simple, compact multi DOF design, extremely high force generation through a solid backbone, better resistance to outside force, and possibility to be scaled down smaller than 9 Fr. Cons include losing the inner channel, dealing with heating of the blood around the joint, slower actuation times than when using pull wires, and potential brittleness of the inner support material. There are other materials that may be used instead of polycaprolactone, including polybutylene terephthalate, PLA thermoplastic, and PVDC. It is possible that a reshapable outer sheath can be made of polycaprolactone.

However, concerns about safe temperatures in the human body, the high viscosity of the molten thermoplastic, and low actuation speeds of the joint all discovered in initial materials testing made heatable thermoplastics impractical. Furthermore, once melted, the

thermoplastic would not be able to cool to under its crystallization temperature to provide rigidity.

Material Property	Value
MW	80 kg / mol
Melting Point (deg. C)	60-62
Crystallization Temperature (deg. C)	**27.4**
Young's Modulus (MPa)	440-500
Hardness (Shore D)	50
Flexural Modulus	**N.D.**
Viscosity @ 70 deg. C	**12650**

Table 3. Material properties of polycaprolactone[29]

3.2.3.3 Shear locking

This device, instead of using pull wires, uses a semi-cylindrical segment of metal connected to the tip of the catheter which includes notched grooves that allow the user to apply a tension to the catheter tip to cause it to bend and lock into place. The locking arm can be released by a pull wire attached to the locking arm not shown here. This not only allows for the tip to undergo greater bending in a shorter distance due to increases in pull force and stabilization, but also for the tip to maintain rigidity when it is flexed by the walls of the heart. While this design interferes with the inner channel, it is possible to maintain the inner channel by redesigning the locking arm to go around it.

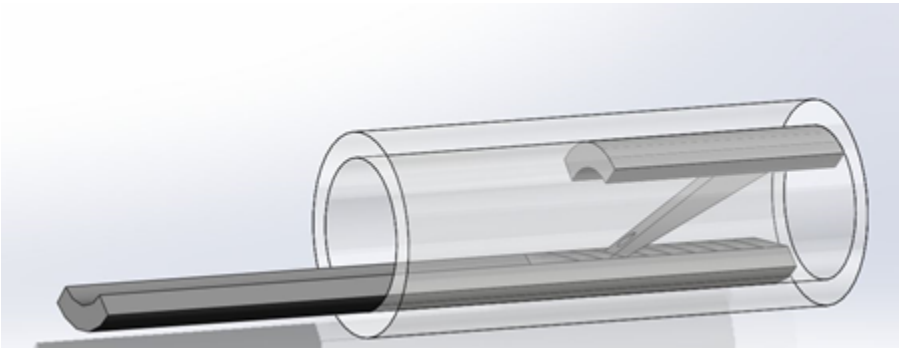

Figure 23. CAD model of elastomeric catheter joint with locking mechanism

4.3 Prototyping of pin joint

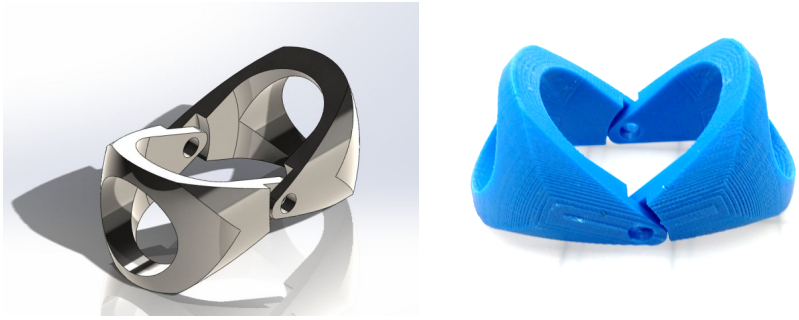

Figure 24. First prototype CAD model (left) and 15:1 scale 3D printed joint (right)

A CAD model as well as a 15:1 scale 3D printed prototype are shown in the figure above. For the first large scale prototype, a ¼'' diameter locking screw (not pictured) was used to attach the two segments of the pin joint together. The catheter lumen was omitted to save material costs. This first prototype served as the template on which I added subsequent modifications as the design process moved along.

This first prototype failed almost immediately upon testing. Upon insertion of the locking pin into the holes in the pin joint, the prototype cracked between the hole and the wall adjacent to the joint. This was likely due to the fact that only a small amount of material surrounds the hole, concentrating any forces between the pin and the joint on a small cross section of material. From this prototype, I redesigned the joint to include much more material around the joint at the loss of its wedge-like shape near the pin.

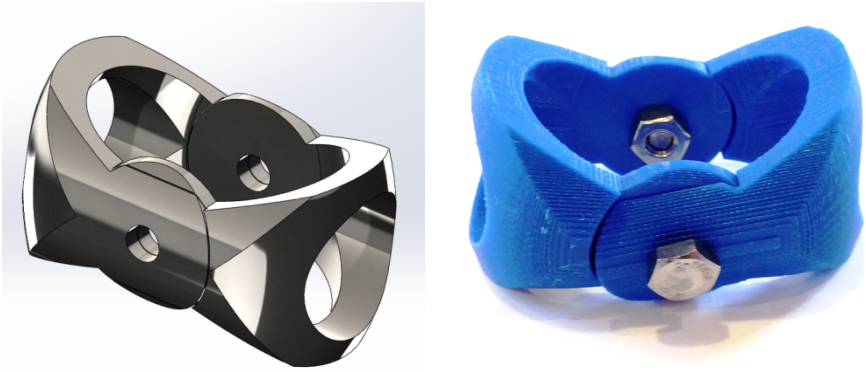

Figure 25. Second prototype CAD model (left) and 15:1 scale 3D printed joint (right)

I increased the material around the pin by adding a disk-shaped volume about twice as large as the diameter of the hole to the joint. To test the performance of this larger articulated surface, I 3D printed a second 15:1 scale prototype of the modified design as shown above. This time, insertion of the pin did not cause the part to fail, and overall stability of the joint, at least from handling, seemed to have increased.

To test the function of this second prototype as a catheter joint, I created a large 15:1 scale prototype using parts I found from a local hardware store and those available to me in the teaching labs. I created a two-walled catheter using a section of 1” dia. vinyl tubing for the inner sheath and pipe insulation for the outer sheath. I used two sections of 1/16” dia. braided steel wire as my pull wires, and made channels between the inner and outer tubing in the design using ¼” polyethylene tubing. Hose clamps connected the catheter joint to the catheter sheath.

Overall, the prototype was functional, traversing the full range of motion with limited tension on the pull wires. One problem I did encounter, however, was lock-up of the pin joint near 90 degree bending. To temporarily solve this problem, I added two additional hose clamps to my model around each section of the joint to prevent the pull wires from crossing the central bending axis. This prevented the catheter from locking by limiting the bend angle. I made modifications to my CAD model to prevent lock up by adding material to the top and bottom of each segment that prevents bending past 87.3 degrees, which is where the pull wire enters the area where the pin is located.

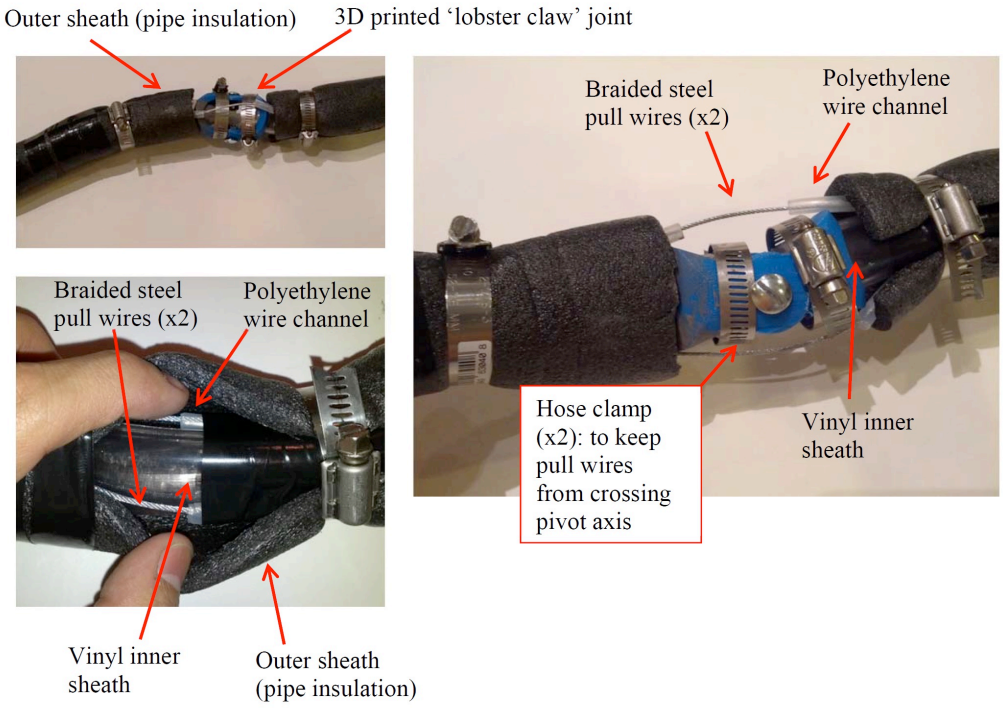

Figure 26. 15:1 scale testing of second pin joint prototype

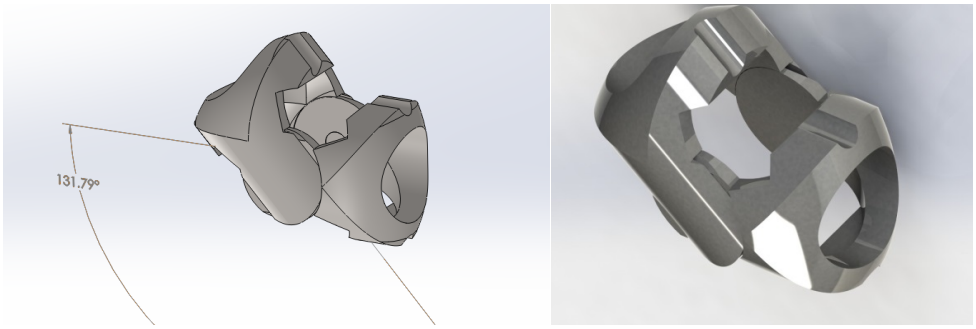

Figure 27. Final prototype joint-only CAD model

I modified my Solidworks model to include pull wire guards (shown above) which ensure that the pull wires never crosses the pivot axis. This also integrates the pins inside the model, so that a locking screw is not needed. The inner part locks into place when forced into the outer part. The force required for assembly is minimal and well under the yield strength of the material.

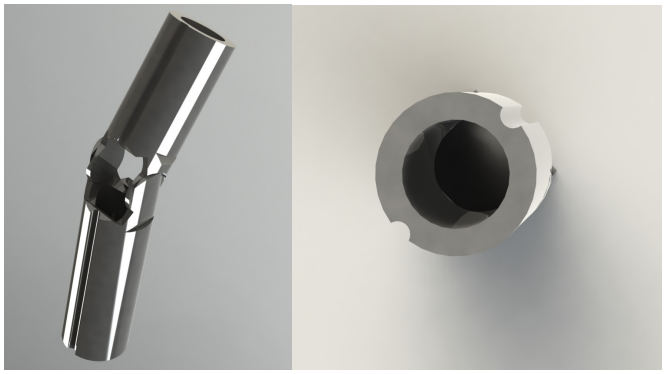

Figure 28. Final prototype CAD model including catheter lumen

This prototype includes two cylindrical sections the same size as the catheter lumen that allows the pin joint to better interface with the catheter lumen and end effector. Small channels running down each side of the two sections help guide the pull wires across the joint for actuation. This CAD model does not include the outer flexible coating.

Small 2:1 scale prototypes of the pin joint without the catheter sheath attachment were first 3D printed to test whether or not the part could be manufactured. The final prototype was then 3D printed, as shown below. Additional images are provided in the Supplementary Information.

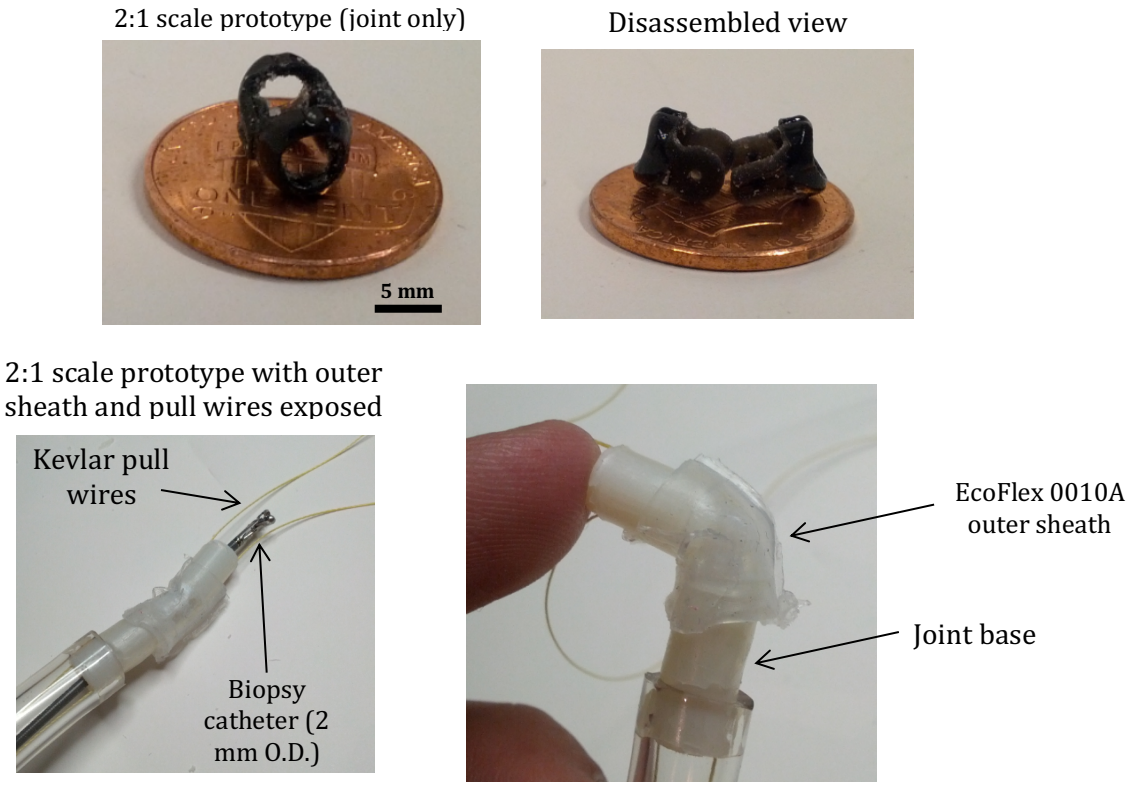

Figure 29. 2:1 scale pin joint prototype

4.4 Testing

4.4.1 Axial force tolerance before failure

Force measurements were made at the Harvard Biodesign Lab (60 Oxford St., Cambridge, MA) using a 3-axis force and torque sensor (FT10517, ATI Industrial Automation, Apex, NC). To test axial force directed normal to the tip of the catheter joint, the tip was aligned to the center of the sensor and force applied by sliding the tip into the force sensor along the X-axis of the sensor. The bend angle of the tip was measured by aligning the catheter to a template corresponding to the desired bend before force application. Failure was defined as mechanical failure of the joint at non-zero load, and was non-specific for the type of failure. The major failure mode of the joint during force application was simply the pin leaving the socket due to reversible deformation of the overlapping segments that make up the joint, which did not affect the mechanical integrity of the joint once the pin was reinserted ($R^2 = 0.09$).

4.4.2 Lateral force tolerance to deflection and failure

Lateral deflection of the catheter end effector occurs when a lateral force against the side of the tip causes the tip to bend. Lateral force can lead to failure of the catheter joint if the force is applied orthogonal to the plane of bending (for instance, if the tip can bend left-to-right, lateral force from the top or bottom could cause the joint to fail). If the force is applied parallel to the plane of motion, however, lateral deflection occurs when the tension applied to the pull wire is lower than the required torque to keep the tip from deflecting. Lateral deflection decreases the accuracy of joint bending.

Lateral force was measured by aligning the side wall of the catheter tip along and normal to the X-axis of polyurethane shaft connected to the force sensor in a way that any force applied to the shaft would result in an equal and measurable force on the sensor. To measure the required pull wire tension before deflection would occur, the side wall of the catheter tip was placed in contact with the sensor shaft. A tension was then applied to the pull wire which caused the tip to bend against the sensor, and the resulting force of the tip against the sensor was measured.

4.4.3 Range of motion

The side-to-side range of motion of the catheter tip was measured by placing the catheter joint against a marked template with markings corresponding to the degree of catheter bending from -90 to 90 degrees, with a minimum resolution of 5 degrees. In a first experiment, sufficient tension was applied to the pull wires to achieve the maximum range of motion from side to side. In a second experiment, minimal load conditions, where minimal tension was applied to each pull wire to achieve bending, were applied to measure the range of motion before resistance to motion occurred. Resistance to motion occurs when the catheter sheath or the joint itself interferes with additional bending. Minimal load conditions are important for the design of catheter actuation systems which apply tension to the pull wires to achieve a desired bend angle as well as the development of manual control systems. Within this angle, equal tension is provided to both pull wires and the angle of the joint is controlled by either extending or retracting each pull wire. Beyond this angle, additional tension must be provided to the pull wire on either the left or right side of the catheter to achieve further bending.

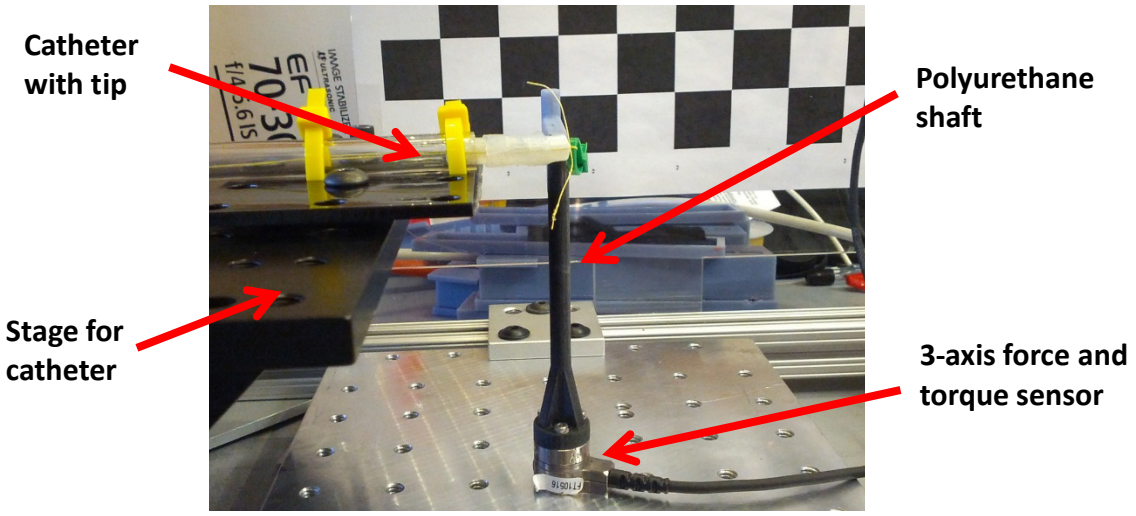

Figure 30. Force testing setup, with components highlighted

4.4.4 Actuation speed

To determine the maximum speed the catheter joint's bend angle could be adjusted before physical limits such as joint failure or high resistance would occur, tension was applied alternately to each pull wire and the time to sweep through a certain angle measured. For this experiment, the pull wires were actuated manually. Speeds significantly greater than which can be achieved through manual actuation were ignored since the target speed for actuation is slow (90 degrees per second).

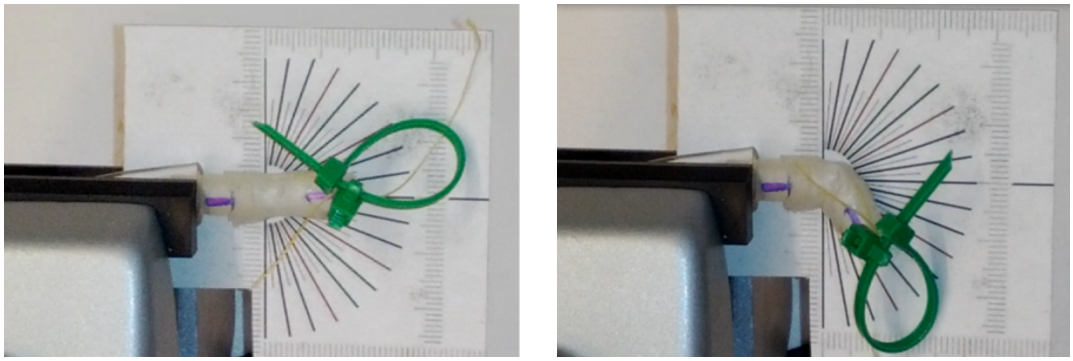

Figure 31. Range of motion testing

CHAPTER 5. RESULTS

5.1 Testing

5.1.1 Axial force

The catheter joint prototype withstood 4-fold higher axial forces during testing than designed for, demonstrating that the joint has a high factor of safety, which is critical in high-risk environments such as the heart where failure of the catheter could be dangerous and even fatal. The 2:1 scale prototype withstood 4-fold higher force than the design specification of 2 N before mechanical failure occured, as shown in the figure and data table below. Interestingly, axial strength increased by at least three times as the joint was bent from 0 to 90 degrees. This result is due to the design of the pin joint, where the mode of failure changes depending on the bend angle. At low bend angles, forces on the joint cause deflections

similar to beam bending as force is applied to the opposite end of the anchoring points to the outer and inner segments of the joint. This deflection occurs due to tensile and compressive forces on the inner and outer segments of the joint and is dominated by the Young's modulus of the material. At high bend angles near 90 degrees, however, the primary mode of failure is due to shear as force is applied to the side of the inner and outer segments which presents a much thicker moment of inertia.

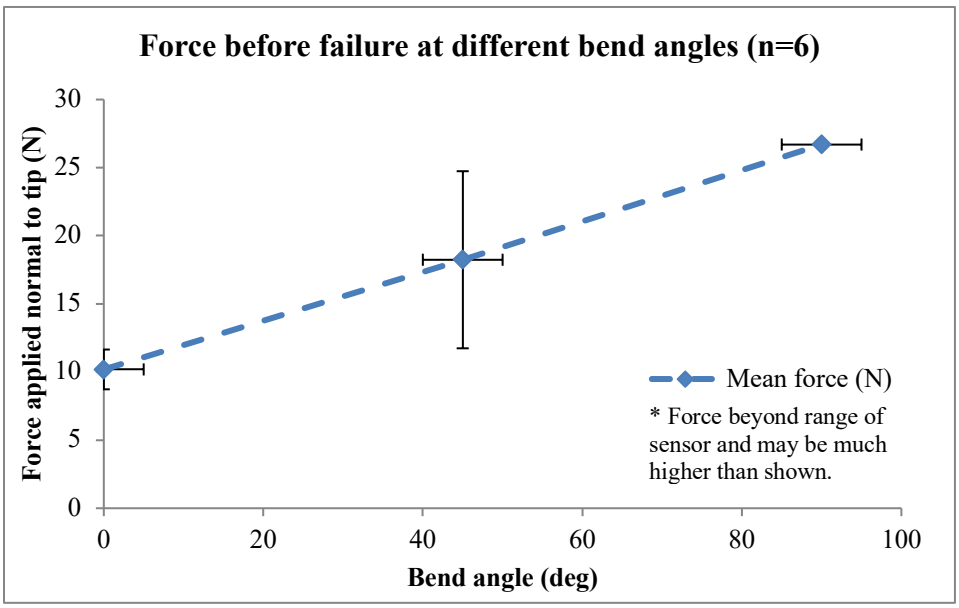

Figure 32. Force before failure at different bend angles

Angle (deg.)	Mean force (N)	SE (N)
0	10.19	1.46
45	18.24	6.5
90	≥26.7	N/A

Table 4. Force before failure at different bend angles

5.1.2 Lateral force

Furthermore, the prototype was also resilient to lateral forces and lateral deflection, exceeding the design specifications on tolerance before failure and accuracy of the tip position. As shown in the figure and table below, the catheter joint is resistant to lateral deflection, as a tension on the pull wire is much smaller than the lateral force applied to the

tip can prevent deflection from occurring. The actual mechanical advantage of 4.81 shown by the slope of the linear regression model is within the standard error of the expected mechanical advantage of 4.57 for the joint.

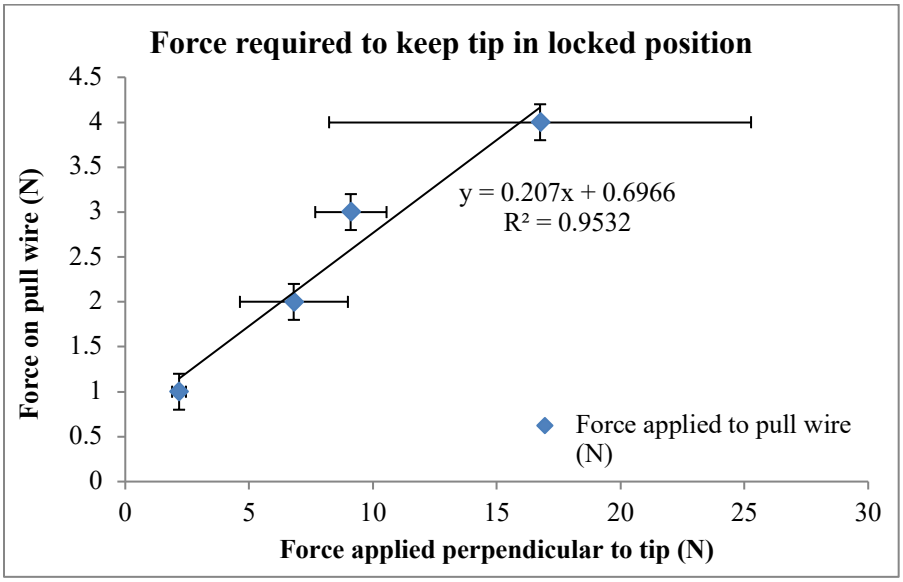

Figure 33. Force required to keep tip in locked position

5.1.3 Range of motion

The range of motion of the catheter tip was close to the desired design specifications, as shown by the bar chart below which shows mean values of joint bending at maximum tension (red) and minimal tension (green). Differences between left and right were due to inconsistencies with prototype manufacturing, since the catheter joint is symmetrical. The joint bent from -85 to +80.7 degrees, or a total angle of 165.7 degrees (n=7, SD: 6.05 degrees). This is within 8% of the target design specifications and within the standard error of the measurement itself.

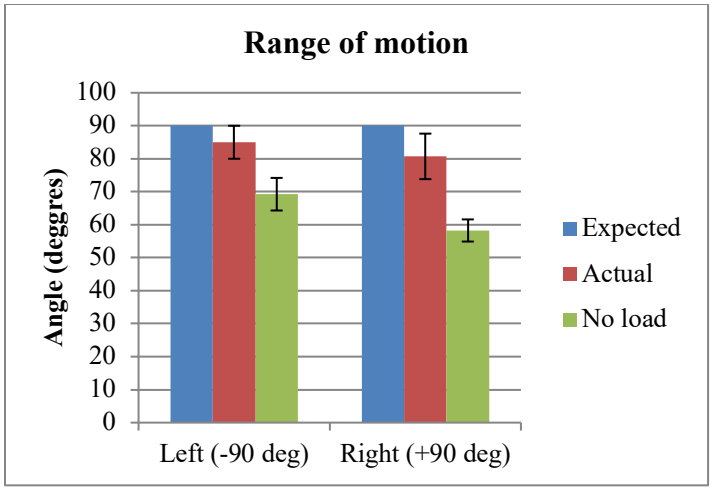

Figure 34. Pin joint range of motion

Under minimal load conditions, the joint bent from -69.25 to +58.25 degrees or a total angle of 127.5 degrees (n=20, SD: 4.22). The minimal load range represents 76.9% of the total range of motion of the catheter joint.

The measured actuation speed was more than 10 times higher than the design goal of 90 degrees per second, even despite manual actuation. The catheter traversed its entire range of motion in 0.173 seconds (n=37, SD: 0.03), or 960 degrees / second. Furthermore, each traversal from left to right was within 4.2 degrees of the entire range of motion, which is well within the 10 degrees of accuracy defined by the design goal.

CHAPTER 6. DISCUSSION

Overall, the results of the 2:1 scale prototype testing meets or exceeds most of the design goals set at the onset of the project summarized in the table below, with only a few limitations. First, a 1:1 scale prototype was not tested. This is because the manufacturing of the joint using methods such as standard milling, wire electron deposition molding, or press molding is not a trivial problem, and would be prohibitively expensive and time consuming given the timeline for the project. Second, features such as the pin and overlapping segments of the 2:1 scale prototype were poorly resolved by the 3D printer used in manufacturing, as those features were as small as or smaller than the minimum feature resolution that the printer is capable of creating. Finally, the prototype was made of polyurethane instead of AISI 302 stainless steel, which greatly reduced the strength of the joint.

	Goal	**Actual**
Diameter	3 mm	6 mm (2:1 model)
To manipulate end effectors	Inner channel	Inner channel
Range of motion	-90 to +90, <1 cm bend radius	-85 to +80.7°, 6 mm bend radius
Flexion speed	90° / sec	960° / sec
Axial force	> 2 N	10 N
Lateral force	> 1 N	27 N
Flexion accuracy	10°	4.2°
Flexion resolution	5°	N/A

Table 5. Performance specifications as they relate to the design goals

CHAPTER 7. EXPENSES

7.1 Budget

My budget for the ES100hf project is given in the table below. Many of the materials and sensors which I need for prototyping, testing, and my final design were already available at Harvard, either in the Undergraduate Teaching Labs and available to all students or at 60 Oxford St. 3D printing costs for the final prototype were billed to the Howe lab but were minimal due to the small volume of material. Because of this, more than $400 is remaining in the project budget.

Item	Source	Price
Final 2:1 scale prototype		
10 mm O.D. vinyl tubing	Dickson's Hardware	$4.95
Clear heat-shrink tubing	Design Lab	$0
High-strength Kevlar thread	McMaster-Carr	$27.67
3D printing	60 Oxford St.	$10 (est.)
Ecoflex 0010A silicone rubber	Pierce G6b	$0
Zip ties	Pierce G7a	$0
Testing		
1/8'' Black acrylic sheet	Pierce G11	$0
0.062'' Aluminum 6061 sheet	Pierce G7a	$0
ATI F/T 10517 3-axis force and torque sensor	Harvard Biodesign Lab	$0
Prototyping		
3D printing	Pierce Hall	$0
InstaMorph plastic	Instamorph.com	$16.99
Coffee grounds	Already owned	$0
Table salt	Already owned	$0
Foam pipe insulation	Dickson's Hardware	$1.39
5/16'' Hose clamps (x4)	Dickson's Hardware	$6.45
1'' vinyl tubing	Design Lab	$0
1/8'' misc. plastic tubing	Design Lab	$0
Braided galvanized wire	Dickson's Hardware	$8.21
34 AWG ceramic-insulated wire	Design Lab	$0
Temperature sensor	Design Lab	$0
	TOTAL	**$75.66**
	Budget remaining	**+$424.34**

Table 6. ES100hf Project Budget

7.2 Mass production cost estimate

The proposed manufacturing steps in producing the catheter joint draws upon many similarities to existing manufacturing techniques for cardiac catheters in use, allowing a reliable cost estimate to be derived. For instance, cardiac biopsy forceps catheters are press molded from surgical stainless steel at a 2.3 mm outer diameter. Like the catheter joint, they also are actuated using steel pull wires to control the opening and closing of the forceps. The forceps have a small pin joint which allows it to open and close. A catheter lumen joins the end effector to a handle which is used for pull wire control.

Figure 35. Biopsy forceps catheter[30]

The wholesale manufacturing cost for 500 disposable 2.3 mm O.D. biopsy forceps catheters is set between $3.75 and $4.75 per piece.[31] We would expect that the catheter joint, should it be put into production, would cost around the same amount to manufacture.

Cardiac biopsy forceps catheters retail between $50 and $200, depending on the brand name of the company producing it[32]. This serves as a conservative estimate for the retail price of the catheter joint. Since the joint can be used universally with many types of end effectors and enables doctors to steer the tip of the catheter, it is speculated that increased demand may drive this price higher.

CONCLUSION

This project demonstrates that a feasible cardiac catheter wrist is not only realizable, but also low-cost and highly functional. Furthermore, the current design was the best of nearly twenty potential candidates covering the majority of the field. Although this project focused on creating a prototype catheter joint that could be adaptable to current catheters in use, it is the hope of the author that in the future this catheter joint will be integrated upstream in a variety of multi-degree of freedom steerable catheters. This will enable doctors to more accurately target heart tissue in cardiac procedures, perform a larger variety of complex procedures non-invasively, and most importantly save precious time and frustration during heart surgery.

To achieve this end, a more permanent at-scale prototype made from stainless steel must be manufactured, tested to catheter engineering standards, and approved for use in cardiac procedures via both animal and human clinical trials. Furthermore, additional functionality, such as integration into a robotic catheter control system similar to that which is being developed by the Harvard Biorobotics Lab, would also need to be designed and tested. This will likely require significant capital investment to form a company and time which can take charge of these ‘heavy-lifting’ steps; however, these should not be out of reach depending on the circumstances.

ACKNOWLEDGEMENTS

The author would like to thank Prof. Robert D. Howe PhD, Paul Loschak, Jordan Stephens, Frank Hammond, Leif Jentott, Panagiotis Polygerinos, Samuel Kesner, Dr. Pedro del Nido MD, Dr. John Triedman MD, Dr. Diego Porras MD, Prof. Daniella Faas, Prof. Gu Yeon-Wei, Prof. Robert Wood, and all of the Harvard Engineering Seniors for their inspiration, advice, and guidance throughout this project who truly helped make this project successful.

SUPPLEMENTARY INFORMATION

A.1 Patent Search

ENDOSCOPE SHAFT WITH SLOTTED TUBE
US 6,749,560 B1
Issue Date: Jun 15, 2004
First Named Inventor: Gregory S. Konstorum

This patent describes a one-piece hollow tube made with alternating patterns of slots made of a superelastic alloy, like SMAs, that allow the tube to bend without deforming along the slots of the device. This design also provides stiffness and resistance to torsion along the length of the tube. This is very similar to my idea of a square wave tube and is similar to what is currently in use in endoscopes today. The invention is actuated by pull wires as well. The patent also claims an endoscope imaging device which makes use of the flexible slotted tube.

STEERABLE CATHETER WITH ADJUSTABLE BEND LOCATION AND METHOD
US 5,533,967
Issue Date: Jul 9, 1996
Inventor: Mir A. Imran

This is a steerable catheter with a control handle that allows bending in one DOF but also an inner shaft which determines the bend location of the catheter by changing in length. This allows the catheter, as claimed by the inventor, the ability to move in a second degree of freedom, as a larger catheter tip size should change the distance the catheter tip is away from different features in the heart. The inventor claims that the adjustable bend device should retain stiffness.

ARTICULATED TUBE STRUCTURE FOR USE IN AN ENDOSCOPE
US 4,432,349
Issue Date: Feb 21, 1984
Inventor: Susumo Oshiro

This is a multi-segment endoscope tube which consists of jointed segments that are spaced by the joints and can freely rotate in one degree of freedom around sets of joints at the interface between one segment and the next. These segments compose the outer sheath of the endoscope or catheter, and are actuated by pull wires. Furthermore, an inner coil spring maintains the structure of the catheter sheath unless bent. The inventor claims that this device can run the length of the endoscope or simply be present at the tip.

A.2 Detailed Drawings (all units in mm)

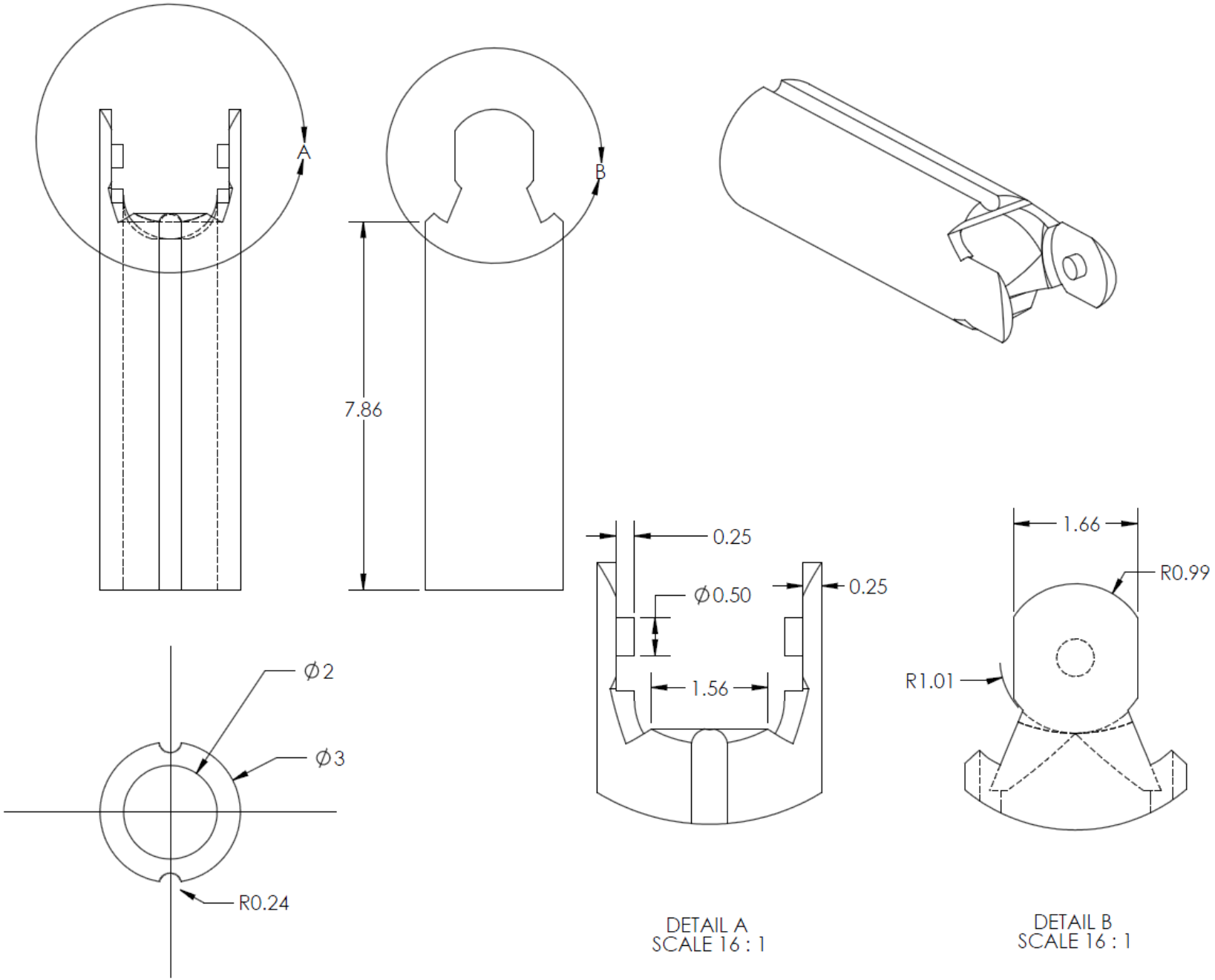

Figure 36. Bottom part of pin joint

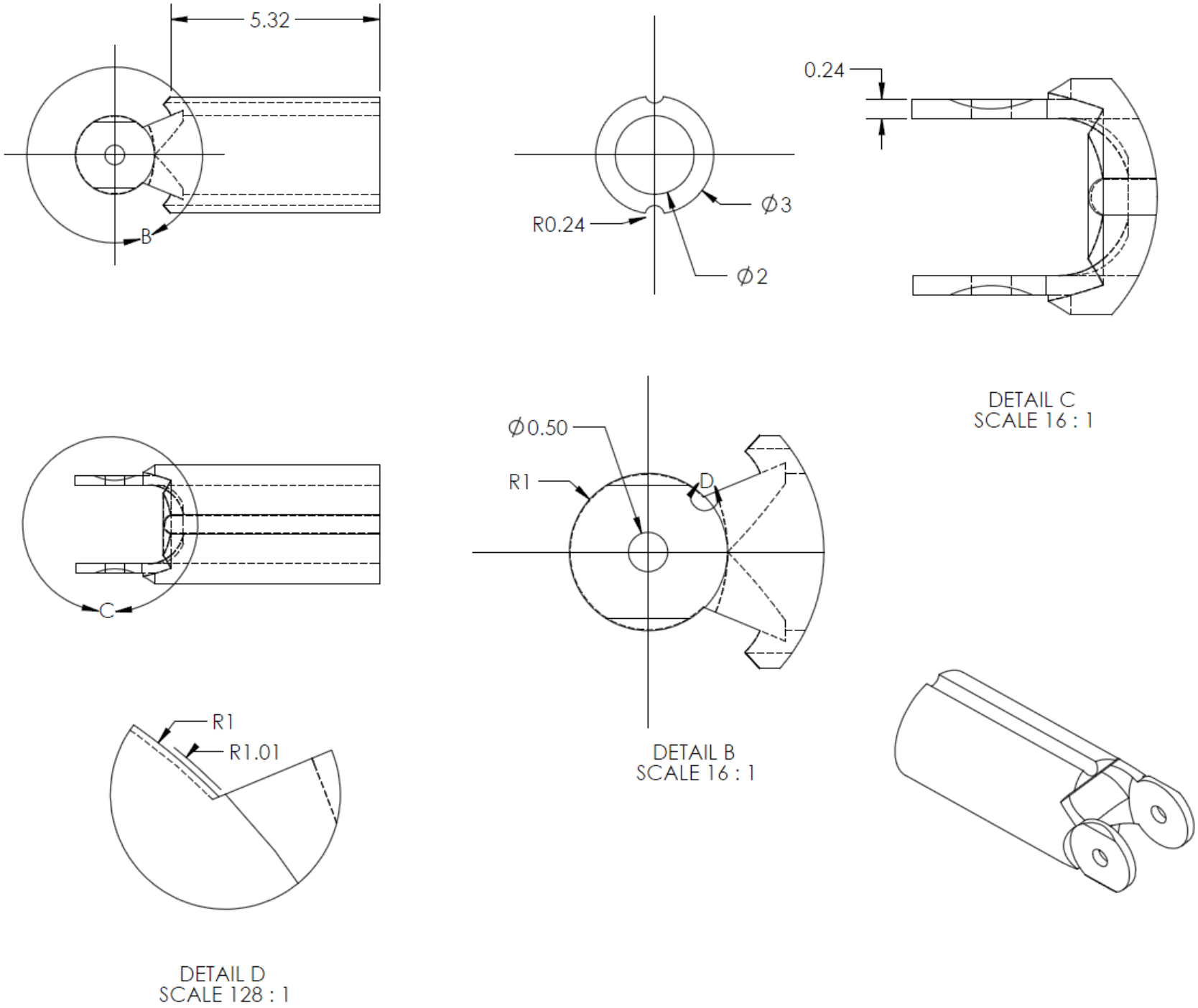

Figure 37. Top part of pin joint

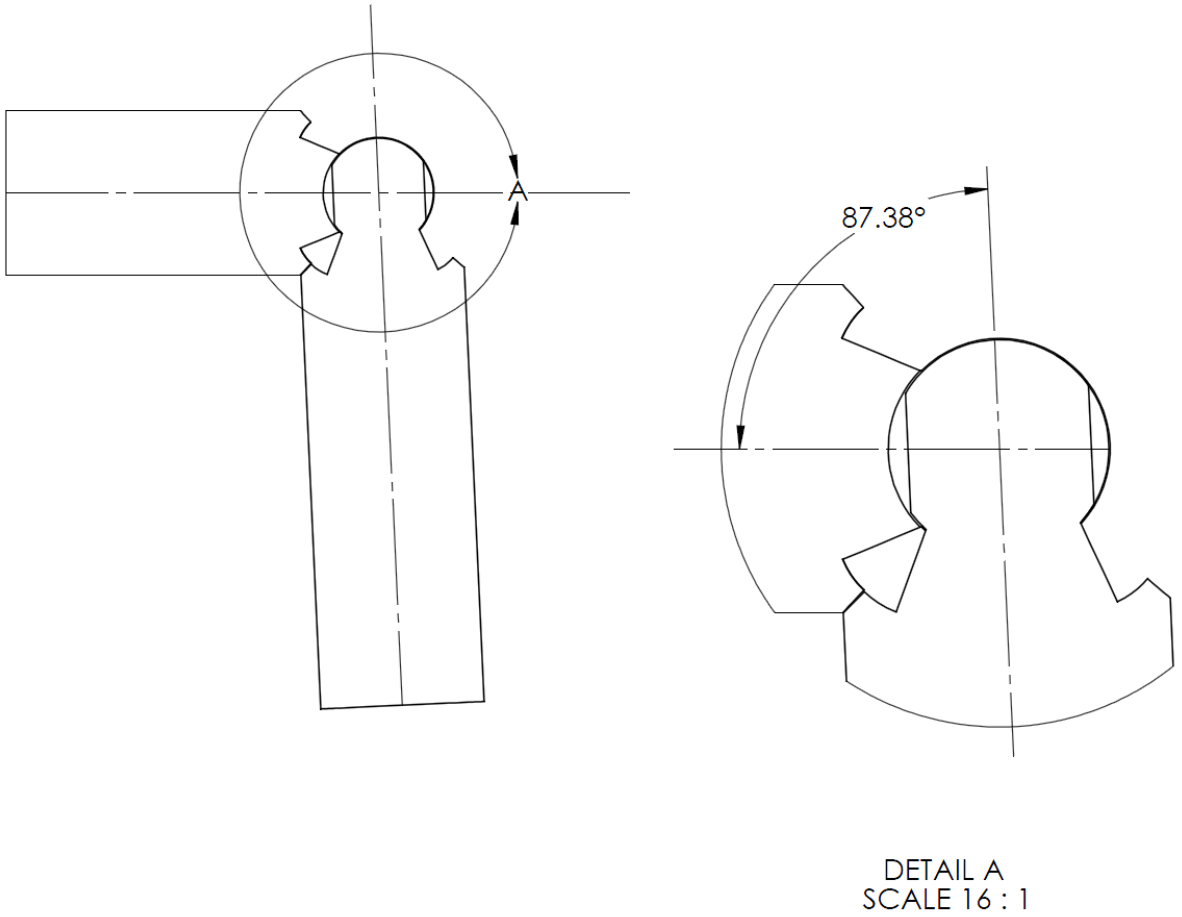

Figure 38. Pin joint assembly

A.3 Testing Videos

Link: https://www.dropbox.com/sh/gvtun5pri5erb69/nNLdl_R4Ld

A.4 CAD Files

Link: https://www.dropbox.com/sh/7uslsk1ktnf88xv/EtbQM4Fo8E

A.5 Additional Images

Testing: https://www.dropbox.com/sh/18kfbjd4qre66r4/NRuBbmX1aN

Prototypes: https://www.dropbox.com/sh/l7tkdiq1opakgla/vaCuDQO96Q

CAD simulation: https://www.dropbox.com/sh/pfyw3zael401vpj/Umv7YnXtcg

A.5 ISO and ASTM Test Standards for Catheters

ASTM F623 - Standard Performance Specification for Foley Catheter

BS EN 1618 - Catheters other than intravascular catheters. Test methods for common properties

DIN EN 13868 - Test methods for kinking of single lumen catheters and medical tubing

ISO 594-1 - Conical fittings with 6% (Luer) taper - Part 1: General Requirements

ISO 594-2 - Conical fittings with 6% (Luer) taper - Part 2: Lock Fittings

ISO 10555 - Sterile, single-use intravascular catheters

A.6 Units used throughout the paper

2.2.2.1 Durometers (D)

2.2.2.2 French (Fr)

- 1 French = Diameter (mm) × 3 ≈ circumference of catheter
- Driving dimension is the diameter, not the circumference
- Uniform steps in increments of ⅓ mm
- No upper limit
- Easy to calculate since not based on pi

2.2.2.3 Gauge (awg)

2.2.2.4 Needle-gauge (“gauge”, based off of bwg)

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