

## **SINGLE ENTRY TUNNELER [SET] FOR HEMODIALYSIS GRAFT PROCEDURES**

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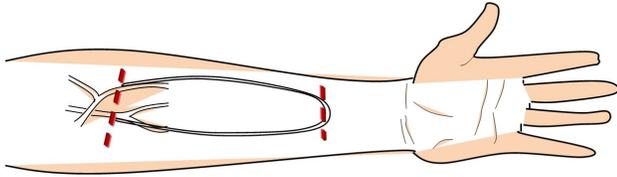
### **ABSTRACT**

*This paper describes the design of the single entry tunneler (SET), devised to create a loop-shaped path in forearm subcutaneous tissue prior to placement of a vascular graft for hemodialysis access. Existing tunnelers are almost universally rigid and require high forces and multiple incisions to complete even the most simple path geometries. Furthermore, they are guided from the handle with limited tip-location feedback. This paper presents a three-stage tunneler design consisting of concentric nested tubes. The first stage is a straight stainless steel tube; the second is a smaller pre-curved nitinol tube and the third is a straight inner nitinol tube. By deploying the stages in this order, SET is able to produce an approximately 180° looped path in tissue. A tip that is illuminated via a fiber optic cable provides visual feedback of the tip location. The SET outer diameter is limited to ensure that the pre-curved nitinol will not exceed its yield strain and not require an excessive force to be deployed from the straight outer stage. Therefore, a custom dilator was designed to increase the size of the tunnel to one suitable for the intended graft. A prototype of the SET tunneler and dilator system was manufactured. The device was shown to achieve the desired path in ballistics gel and was capable of at least 100 repeated-use cycles. By reducing the number of required incisions and improving ease of use during graft insertion procedures, the SET has the potential to greatly reduce the risk of infection and degree of unnecessary tissue trauma while increasing tunneling accuracy.*

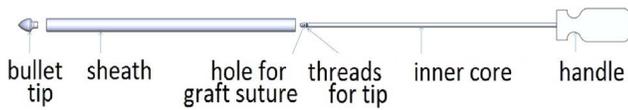
### **1 Introduction**

Many medical operations such as peripheral vascular and hemodialysis access procedures require subcutaneous graft placement for the purpose of non-anatomic circulation of blood. Medical devices called vascular tunnelers bore through subcutaneous tissue, creating a path in which to place the graft. Grafts can be harvested from the patient's own vasculature or manufactured artificially. These tunneling procedures often require complex geometries that defy the abilities of straight rigid tools. For long-term hemodialysis or hemofiltration, the forearm of the patient is usually fitted with a long access graft anastomosed between the brachial artery and a vein near the elbow, and extending in a loop towards the wrist, Figure 1. The long profile provides a range of easily accessible sites over the length of the forearm from which blood can be drawn, filtered and returned to the body.

Most current tunnelers consist of a long rigid shaft attached to a sturdy handle. The outer shaft protects an inner rod, which is attached to the handle at one end and screwed into a bullet tip at the other, Figure 2. After making the proximal and distal incisions, the shaft is inserted into an incision and advanced through tissue to the opposite incision. When a satisfactory tunnel has been created, the bullet tip is unscrewed from the rod end protruding from the incision. A graft is sutured to holes in the rod end and pulled through the outer shaft. Once the graft is pulled through, the outer sheath is slid out of the tunnel and the graft can be anastomosed to the relevant artery and vein. For com-



**FIGURE 1.** Current tunnelers require two incisions to place a graft along a 180° loop path (incisions denoted with broken lines)



**FIGURE 2.** Components of a traditional tunneler

plex paths, like the 180° bend described above, it is impossible to complete the required geometry in one step. These paths necessitate a separate incision and tunnel to form a complete loop.

## 2 Prior Art

A detailed search of previous patents and peer-reviewed literature was conducted to investigate prior art related to vascular tunneling and other steerable medical instruments.

### 2.1 Existing Devices

All vascular tunnelers used in the operating room today are variations on large diameter, rigid tubes with a fixed curvature, Figure 3. As described above, most tunnelers have a handle, inner rod, rigid sheath, and bullet tip, sized to the diameter of the tunnel required [1]. Some manufacturers offer a low profile version with a flexible sheath [2] or no sheath at all [3]. These variations can only be used with artificial vascular prostheses as natural grafts cannot withstand the trauma of being pulled through bare or lightly shielded tissue. A few patents illustrate tunnelers with flexible shafts [4], however these models still require multiple incisions to produce the dialysis loop geometry. All models available make use of primarily stainless steel and aluminum materials with the exception of the flexible sheath design which utilizes plastic.

### 2.2 Related Technologies

A review of the medical and academic literature reveals several devices whose purpose is to provide steering capabilities. Catheters and endoscopes have similar steering goals with the



**FIGURE 3.** Gore tissue tunneler set [1]

exception that they usually operate in a less restricted environment and do not have to forcibly cut or bore their way through tissue [5] [6]. Tunnelers for cosmetic surgery use ultrasonic energy produced at the tip to dissolve fat tissue and create a tunnel, but destroy the surrounding tissue in the process [7]. Two commercially available, passive needles for spinal procedures, such as vertebroplasty, deploy a superelastic pre-curved stylet from a stiffer concentric outer cannula [8] [9]. When inside the cannula, the stylet is substantially straightened and upon deployment of the stylet from the cannula's distal tip, the stylet will then take its preformed shape. This approach has been extended to thin steerable medical instruments made from multiple, overlapping pre-curved concentric tubes. To truly navigate through the body, six degrees of freedom have to be controlled and recent work has focused on actively controlling a needle's curvature through overlapping pre-curved cannulas [10] and steering around obstacles in the body [11] [12]. In addition, puncture resistance needles take advantage of blunt tip geometries to reduce the risk of skin puncture during suturing procedures [13]. While steerable and puncture resistant needles provide helpful insight, they operate at a much smaller scale than the average tunneler and therefore care needs to be taken in scaling up the analyses.

## 3 Device Design

### 3.1 Design Requirements

Before conceptualizing the device it was necessary to fully understand the vascular tunneling procedure and the inadequacies of the current tunnelers. Consultations were held with practicing vascular surgeons and two vascular tunneling procedures were observed. The following requirements were extracted from these encounters, in approximate order of importance:

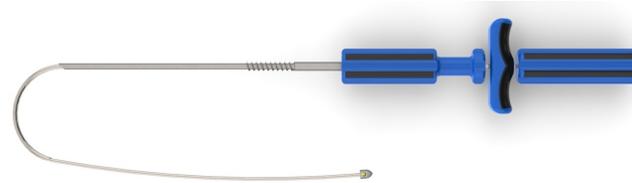
1. *Path geometry* – The device must quickly traverse the required geometry. In dialysis procedures this path often requires a 180° loop in around 5 minutes.
2. *Tunnel diameter* – The tunnel must be of a large enough diameter to fit the required graft. The work space was narrowed to accommodate tunnels between 4mm-8mm.

3. *Graft integrity*—The graft must not kink or otherwise become damaged during the procedure.
4. *Tip bluntness*—The device’s tip must be constructed so there is minimal risk of skin puncture.
5. *Ergonomics*—The current procedure requires a large force to bore through tissue. Ideally the device would be comfortable and easy to use well within the surgeon’s physical capacity.
6. *Operator feedback*—The device must provide feedback by which the surgeon can detect where and how deep the device is tunneling. The current devices provide only limited tactile feedback at the handle.
7. *Number of incisions*—Internal tissues exposed to open air risk infection, increase healing time, and incur operative expense. The device must reduce the size and number of incisions to the extent possible.
8. *Design for manufacture/assembly*—The device should be designed with the principles of ease of manufacture and assembly, keeping in mind that the device must be disassembled quickly for sterilization.
9. *Sterilization*—All materials used in the device must be compatible with common sterilization techniques or cheap enough to be disposable.
10. *Cost*—A current tunneler set costs around \$1000 and lasts for around 35 procedures. Hospitals will only evaluate new devices that provide significant advantages at reasonable cost.

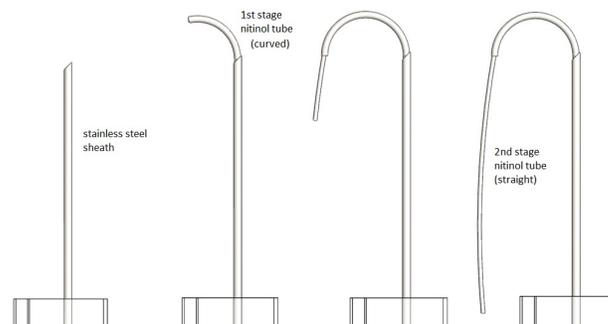
The defined functional requirements focused the design process on three critical problems with current devices. One, current rigid tunnelers require at least two incisions to accomplish this rather common procedure. The design space was narrowed down to of a tunneler that could create a loop tunnel in the forearm via a single incision. Secondly, traditional tunnelers require an uncomfortably large input force to bore through tissue making them unnecessarily inaccurate. They are typically equipped with a significantly blunted tip so as to reduce the risk of accidental skin or organ puncture and provide only limited haptic feedback. The proposed tunneler design incorporates strategies to reduce the input force required to advance through tissue and provides direct distal tip location feedback. Once a desired path has been accurately tunneled, a vascular graft must be installed. As current graft installation methods require a large tunnel size, a custom device was designed to dilate the tunneled path.

### 3.2 Solution Overview

The device design is shown in Figure 4. It is organized into three modules: a tunneling module, a feedback module, and a dilator module. The three-stage tunneling module creates the forearm loop tunnel with a comfortable input force using a set of concentrically stacked tubes. The feedback module integrates a distal tip illumination mechanism during the tunneling procedure. Lastly, the dilator module enlarges the tunnel to a size suitable for a vascular graft. Once the tip returns to the initial in-



**FIGURE 4.** SET Tunneler Design, including handle, tunneler, and feedback modules



**FIGURE 5.** Deployment stages of nested nitinol tubing

cision, the dilator is slid over the whole tunneler starting from the end with the lighted tip and moving towards the handles. Finally, the tunneler module is removed and the graft is inserted into the dilator along the tunneled path.

### 3.3 Tunneling Module

A number of potential strategies were explored for satisfying the functional requirement of achieving a 180° loop bend. An ideal solution combines both tunnel creation and steering in the same module. Vibrating or rotating devices were explored as methods of improving a device’s ability to bore through tissue. However these methods result in significant tissue trauma and provide little advantage in the necessary size regime. Restricting path creation to a small tunneler diameter allows a surgeon to bore a tunnel by applying less force. However, as cutting through tissue becomes easier, skin puncture becomes more probable. Therefore, it became crucial to explore how to alter tip geometry such that the accuracy gained from reducing the force required to cut through subcutaneous tissue balances out the increased skin puncture risk.

The selected concept consists of a multi-stage tunneler design with three nested tubes as illustrated in Figure 5. The first stage is an outer straight stainless steel tube; the second is a pre-curved nitinol tube; and the third stage is an inner nitinol tube. Each tube is rigidly attached to a separate handle at the proximal

end. At the beginning of the procedure the sheaths are nested inside the outer sheath and flush with its distal end. After the initial incision is made, the outer sheath is inserted into the tissue of the forearm. Next, the second and third stages are deployed, one at a time, paying careful attention to the tunneler tip position. Nitinol, a hybrid alloy made from nickel and titanium, was chosen for the second and third stages because of its ability to withstand very high strains (typically 3 – 6%) [14] without plastically deforming. Advancing nested curved tubes in straight tubes of higher stiffness provides a mechanism for creating a curved path from a single entry incision.

According to consultations with vascular surgeons, 95% of patients have forearms widths within 6-9 cm.

The minimum radius of curvature is dependent on the strain limit the material can withstand and the geometry (thickness) of the pre-curved nitinol tube, Figure 6. When a curved tube of length  $L$  is straightened, the outermost arc of the curved tube strains in compression and the innermost arc strains in tension. A curved tube of length  $L$  (measured along the tube midline), cross-sectional outer radius  $r$ , and bend radius  $R$  has an inner arc length  $L_0$ . From geometric relations [15], we can derive the equation:

$$L_0 = L \left(1 - \frac{r}{R}\right) \quad (1)$$

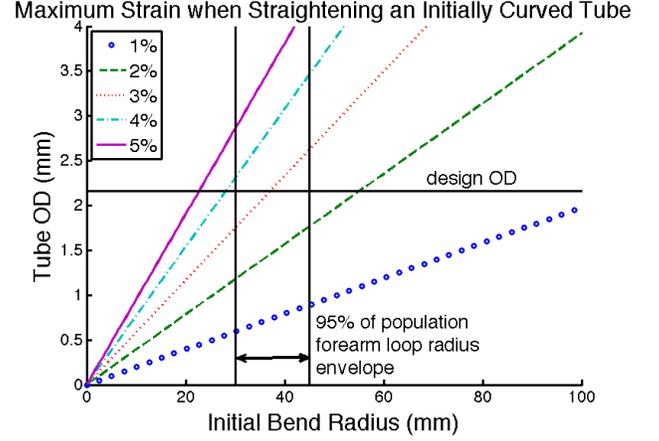
When a curved tube is straightened, the maximum longitudinal strain occurs at the innermost portion, which stretches from  $L_0$  to  $L$ . This results in a maximum strain,  $s_{max}$ ,

$$s_{max} = \frac{r}{R - r} \quad (2)$$

The middle nitinol tube was sized to have outer and inner diameters of  $2.16\text{mm}$  and  $1.65\text{mm}$ , respectively. Setting a minimum bend radius of  $30\text{mm}$ , the tube profile falls within the forearm width of 95% of the population without the material plastically deforming. Under these conditions the material will experience a strain of 3.73%, less than its yield strain.

Inserting a straight nitinol tube into a larger pre-curved tube will result in a combined curve of larger radius than the pre-curved tube alone. Additionally, the bend angle (or angular span) of the curved section decreases by the same ratio that the bend radius increases by. Assuming that the tubes act in pure bending, the ratio of the radius of the pre-curved tube alone to the radius of the combination of the two tubes or angle ratio,  $AR$ , can be calculated directly from the tube geometries:

$$AR = \frac{R_{precurved}}{R_{combined}} = \frac{Span_{combined}}{Span_{precurved}} = \frac{IR}{IR + 1} \quad (3)$$



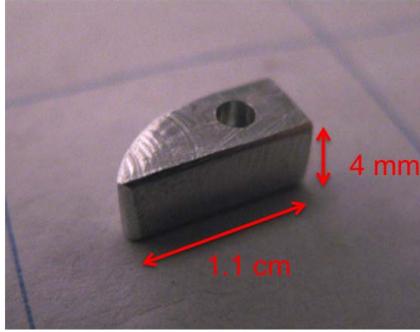
**FIGURE 6.** The tube outer diameter is limited by the maximum bend radius allowed by human forearm geometry and the maximum yield strain defined by material properties. The design assumed a conservative nitinol max strain of 5%.

where,

$$IR = \frac{I_{curved}}{I_{straight}}, \text{ and } I = \frac{\pi}{4}(r_{outer}^4 - r_{inner}^4) \quad (4)$$

The dimensions of the smallest nitinol tube ( $1.37\text{mm}$  OD x  $0.965\text{mm}$  ID) were chosen to balance axial stiffness with radial flexibility. Increasing smallest tube's axial stiffness improves the device's ability to bore through tissue while increasing the smallest tube's radial stiffness will increase the bend radius of the middle curved tube when the device is assembled. The angle ratio,  $AR$ , of the designed selection is 84%. Therefore, inserting the straight tube into the curved tube of  $30\text{mm}$  bend radius increases the bend radius of the combination to  $35.7\text{mm}$ , which is still within the bend radius functional requirement of  $30 - 45\text{mm}$ .

**3.3.1 Tip Design** Much previous literature is devoted to the design of blunted needles to reduce skin and glove puncture when suturing [16] [17] [18] [13]. However, both analytical and experimental force models do not scale well as the modes of tissue failure differ when using a needle vs. a tunneler. Tests were conducted on a series of different tip geometries in pork shoulder to determine empirically what shape best satisfied the functional requirements. The final tip design, as seen in Figure 7, displays a curved profile on one side which helps guide the tunneling module along the curved path, while remaining blunt enough to prevent accidental skin puncture.



**FIGURE 7.** The tip's curved profile guides the tunneler along the looped path

### 3.4 Feedback Module

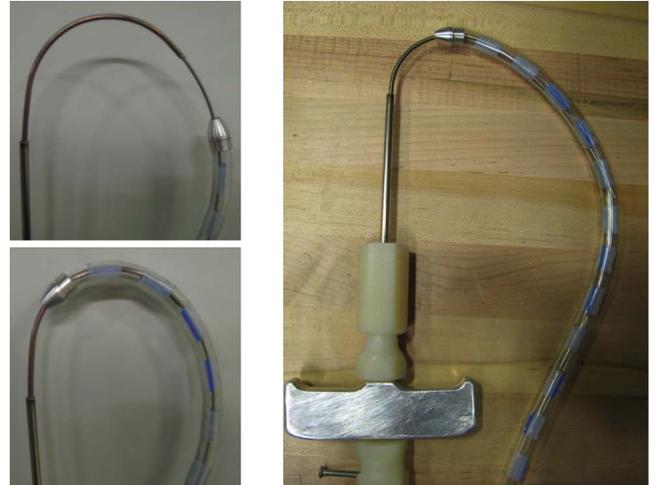
Traditional tunnelers provide no direct feedback of the distal tip location. Currently, surgeons either feel the tip through the skin, which requires removing a hand from the tool, or rely on haptic force feedback at the handle. The latter gives some indication about the type of tissue the tunneler is passing through. The SET's small profile reduces already limited tactile location feedback, therefore it requires an additional feedback mechanism.

Other feedback mechanisms, including force feedback, vibration and noise, were deemed unsuitable for the surgical environment as they are expensive to implement, break the surgeon's concentration from the operating site, and can be easily ignored in a busy operating environment. Due to these concerns, visual feedback in the form of an illuminated tip was chosen as the feedback mechanism. A successful visual feedback system should provide depth information (up to 20mm beneath skin surface) and directional information of the distal tip, have a small form factor such that it can be easily integrated into the tunneler module, and be sufficiently bright for viewing in an operating room environment.

### 3.5 Dilator Module

Based on an evaluation of the current methods, a graft installation procedure was designed that integrates with the proposed single-entry loop tunneler. The path in the tissue made by the tunneling module is significantly smaller than the path needed for graft insertion due to the tunneler's small profile. This created the need for a dilator capable of expanding the original path created by the tunneler. In addition, the graft has to be drawn through the tunnel without kinking, twisting, or cutting into the surrounding tissue. The dilator had to enlarge the tunnel to the proper diameter for a graft (4 – 8mm in diameter) and follow a radial path of radius 3 – 4.5cm created by the tunneler.

The vast majority of commercially available dilators are made to follow relatively straight paths and enlarge existing body cavities such as the urethra. They are inadequate for actively tun-



**FIGURE 8.** Dilator module sliding over the tunneler module. The dilators alternating stiff and non-stiff sections help it slide over the tunneler module's looped profile smoothly.

neling through tissue while following a curved path of relatively small curvature. Pulling the graft directly through the tunnel is suboptimal as bench-level experiments demonstrated that it resulted in the graft chafing against and cutting into the tissue while being pulled around the curve, increasing the risk of infection.

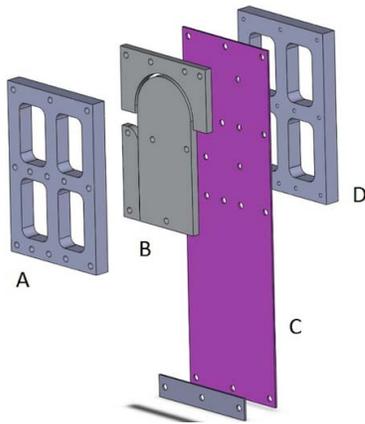
A dilator, Figure 8, was developed to expand the path from the original tunnel size to the proper graft diameter, flexible enough to follow a 6 – 8cm diameter path, and yet still stiff enough to be pushed through the tissue from the proximal end. In addition, the dilator was designed to be hollow so as to allow for a graft to be passed through after removal of the tunneler module. Following dilation, the graft will then be sutured to the distal tip of the tunneler and drawn through the dilator by retracting the nested nitinol tubes. After the graft has successfully passed through the tunnel, the dilator is removed and the graft is sutured to the appropriate blood vessels.

## 4 Prototype Construction

### 4.1 Tunneling Module

Straight ground nitinol tubes of varying diameters were obtained from the Nitinol Development Corporation. The nested tubes were thermoset in an iron and aluminum stencil, Figure 9, at 525°C for 30 minutes. After annealing, the tubes were immediately quenched in a cold water bath to maintain the desired austenitic phase [14]. The tips of each tube were ground at a 45° angle to ease the sliding of inner tubes within outer tubes.

The handles on the first and second sheaths are pressed together to deploy the middle tube in a syringe-like actuation. The middle handle is a horizontal bar perpendicular to the nitinol



**FIGURE 9.** Stencils used to thermoset nitinol tubing. Stencils were perforated in order to decrease the quenching time. Components: A - upper picture frame, B - lower picture frame, C - stencil, D - stabilizing sheet

tube.

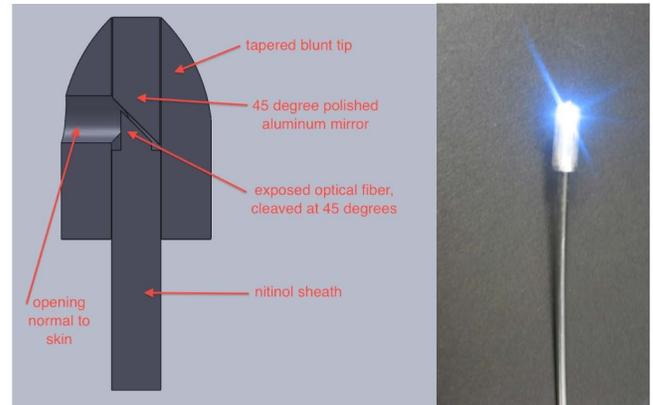
#### 4.2 Feedback Module

The tunneler tip is illuminated via a light source in the handle which passes through an optical fiber to the tunneler tip. The smallest nitinol sheath's inner diameter,  $0.965\text{mm}$ , sets the upper bound for the fiber diameter. The fiber needs to be significantly less stiff than the nitinol sheaths and also be able to complete the  $3\text{cm}$  minimum bend radius of the tunneler. The Thor Labs Silica Multimode end-glow fiber was selected because it is readily available and met all of the above criteria. It has an outer diameter of  $0.730\text{mm}$ , a minimum bend radius of  $20\text{mm}$ , and a high light transmission efficiency.

A coupling mechanism was machined to attach the LED to the end of the fiber. When situated in the subcutaneous tissue, oriented perpendicular to the skin, this tip creates a visible light circle on the skin surface in a well-lit room. Bench level experiments revealed that it was difficult to observe a visible light circle when the fiber's angle of incidence was not sufficiently perpendicular to the skin. Various means were explored for redirecting the light. One method was to cleave the fiber at a  $45^\circ$  angle. The fiber was first scored with a diamond scribe and then strained to propagate the resulting crack across the fiber. Achieving a clean  $45^\circ$  angle was difficult in practice due to limited access to cleaving tools. Thus, an angled mirror design, seen in Figure 10, was chosen that reflects light at  $90^\circ$  towards the skin surface.

#### 4.3 Dilator Module

The single-entry tunneler dilator consists of alternating  $1.5\text{-}2\text{cm}$  segments of stiff polytetrafluoroethylene (PTFE/Teflon) tub-



**FIGURE 10.** [LEFT] Tip light design with fiber cut at  $45^\circ$  angle. [RIGHT] Tip prototype

ing and more flexible Tygon PVC (S-50-HL formulation) tubing capped at the distal end with a tapered stainless steel tip. The alternating segments provide the dilator with axial stiffness to push forwards along the required trajectory, while keeping the radial stiffness to a minimum allowing the dilator to bend around the tight curve. A  $4.76\text{mm}$  hole through the center of the dilator tip allows the dilator to be passed over the tip of the tunneler module and follow it around the pre-tunneled curve. Due to low material costs, this module can be easily disposable and manufactured in a variety of diameters to accommodate grafts of different sizes.

#### 4.4 Assembly

The tunneler is assembled by sliding each successively smaller sheath into the handle end of the larger sheath. The handles are attached to the two nitinol sheaths with set screws. The outer steel sheath is press fit into its handle. The fiber optic cable and tip are slid in from the the distal end and attached to the flashlight coupling in the outer handle. Disassembly is achieved by reversing this process. The tunneler is designed to be easily disassembled to allow for the cleaning and sterilization of each piece separately.

### 5 Testing and Validation

Each module was tested separately to make sure that it met all functional requirements in conditions similar to the actual operating environment. Then, the full prototype was assembled and tested.

#### 5.1 Tunneling Module

Initially, the tunneling module was tested in air by clamping the outer sheath and pushing out the subsequent stages in order. Starting from a retracted position, first, the middle sheath and

then the inner sheath were deployed from the stainless steel tube. Although calculations predict a radius of curvature of 30mm should be achievable by a larger nitinol tube, in a testing environment, larger tubes exhibited plastic deformation and spring-back. Furthermore, it was noticed that the middle nitinol sheath noticeably straightened upon insertion of the inner, straight, nitinol stage. Due to these observations, the fabrication conditions were altered such that the curved middle sheath was thermoset to 210° and a bend radius of 38.1mm. Upon insertion of the inner nitinol stage, the curvature of the two combined sheaths extended to 180° at a bend radius of 44.5mm. While the result was within the given range of arm geometries, the device would only meet the specifications of a few patients. Therefore, in a third iteration, the inner nitinol sheath was thermoset in a circle shape by clamping it in a closed loop with a radius of 6cm. When deployed after retracting both sheaths into the stainless steel tube, there was no noticeable plastic deformation or straightening of the middle nitinol sheath.

### 5.2 Feedback Module

The final feedback module prototype was tested in the subcutaneous fat layer of a pork shoulder. A 1W LED flashlight was coupled to the fiber-optic cable which was connected to the aluminum tip. The thickness of the fatty tissue was varied and the resulting diameter of light on the skin surface was measured. Figure 11 shows the diameter of the light circle on the skin surface correlating well with the thickness of the fatty tissue. The final prototype exceeded this module’s functional requirements. The light was visible at greater than 20mm depth. Moreover, the diameter and intensity of the visible light circle properly displayed feedback for both the tip position and depth. Finally, as the tip was rotated, the light circle became more oblong providing some data on tip rotation. However, this information was not precise and further tip modifications would have to be made to effectively communicate this information to the surgeon.

### 5.3 Dilator Module

The dilator module was successfully tested in both raw pork shoulder tissue and ballistics gelatin. In the raw pork shoulder, a curved metal rod with dimensions and a radius of curvature similar to that of the SET was inserted in the subcutaneous tissue. The dilator was then pushed over the metal rod in the tissue by applying sufficient force to the dilator from the proximal end. In the ballistic gelatin, the SET was used to create a curved path and the dilator was then passed over the tip of the SET creating a larger tunnel. An artificial graft was successfully passed through the resulting tunnel. While dilating a tunnel in a confined space is lightly to cause additional trauma, the act of dilating a pilot tunnel should cause equal or less trauma than that caused during a traditional procedure without a pilot hole. Additional testing is necessary to verify this claim.

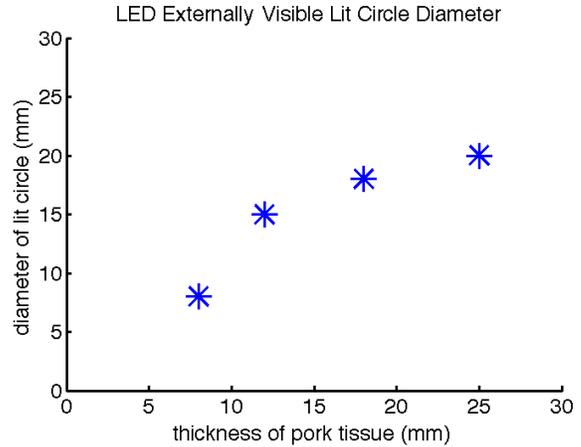


FIGURE 11. Light diameter versus tissue thickness for the final prototype

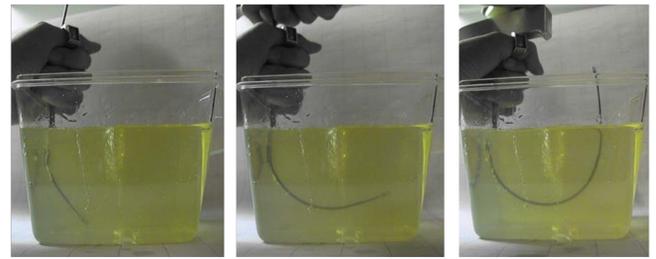


FIGURE 12. Prototype test in ballistics gel. The device moves cleanly through the gel in the proper trajectory.

### 5.4 Prototype Assessment

The modules were assembled as outlined previously and the prototype was tested both in air and in warm ballistics gel, Figure 12, to simulate physiological temperatures. In gel the prototype was capable of creating a looped path with a radius of curvature of 38.1mm. The gel was cleanly cut and exhibited no excess tearing in unwanted directions. The device was cycle-tested in air by repeatedly inserting and retracting each nitinol stage as would be done during normal use. After 100 cycles, the prototype was able to complete the same path with no measurable plastic deformation of the nitinol stages.

## 6 Future Work

Current vascular tunnelers for hemodialysis access cause excess trauma, provide limited location feedback, and require multiple incisions. The device presented in this paper can complete a 180° loop in the human forearm in a single incision while providing the surgeon sufficient feedback to make critical guiding decisions. As over 350,000 patients are currently on dialysis,



**FIGURE 13.** Final prototype

it is essential to reduce risk of infection and limit excess tissue trauma to the extent possible.

While this paper takes initial steps towards realizing a single-entry tunneler product, there are a few pending challenges that need to be considered. By further characterizing nitinol strain behavior, one can make headway in decreasing the allowable radius of curvature of the loop-path. A radius of curvature reduction would make the device plausible for patients with smaller forearms. Secondly, the device may benefit from the improved controllability of a tube advancement mechanism such as a ratcheting handle. An attachment like this would allow the surgeon to advance each stage along known discrete increments. This would also provide the surgeon with a free hand to stabilize the device in tissue. An alternative would be to design anchoring features such as tissue threads incorporated into the first stage that would grab tissue at the incision and hold the device in place.

While this device has been tested for one critical path geometry, there are many other tunneling paths which could be optimized by the use of stacked tubes of various curvatures and stiffnesses. Furthermore, the lighted tip could be implemented in both single-entry and traditional tunnelers to improve surgeon feedback. It is the authors' hope that this design will provide insight for procedures beyond its designated functional setting.

## ACKNOWLEDGMENT

This device was designed and fabricated for a term project in MIT 2.75 Precision Machine Design Course and was supported by the Center for Integration of Medicine and Innovative Technology [www.cimit.org](http://www.cimit.org) under U.S. Army Medical Research Acquisition Activity Cooperative Agreement W81XWH-09-2-0001. The information contained herein does not necessarily reflect the position or policy of the Government, and no official endorsement should be inferred. Special thanks are due to Alex Slocum, Nevan Hanumara, and Dave Custer for providing a wonderful class environment from which our project spawned.

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