

Design and Development of an Epidural Needle Puncture and Retraction Device

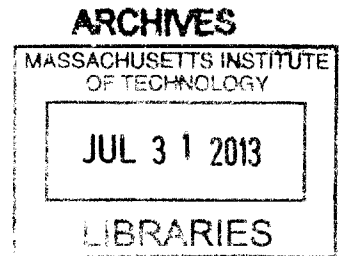
by
Alan K. Xu

Submitted to the Department of Mechanical Engineering in
Partial Fulfillment of the Requirements for the Degree of

Bachelor of Science in Mechanical Engineering
at the
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Abstract

Over 2 million epidural procedures are performed every year in the United States, but many result in complications caused by over puncture, where the needle punctures farther than the epidural space. A usable model of a previously developed flexure-based solution was made and utilized in designing a new epidural device which may reduce the risk of over-puncture. A clinical background of epidurals is presented, along with the usable model and new design. Prototypes were manufactured and tested to validate the model and fabrication method. Potential improvements and future steps are outlined. The proposed device has the potential to minimize epidural complications and the model may also be used to expand the number of applications of this flexure-based solution to over puncturing.

Acknowledgements

I would like to thank Nikolai Begg who guided me through this project and whose prior work made this project possible. I would like to thank Prof. Alex Slocum who has also been invaluable ever since he was my freshmen advisor, the IDC who graciously let me use their prototyping facilities, and of course the friends and colleagues with whom I've travelled along the way.

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Technical Background

Epidural anesthesia is a part of a larger class of procedures where some area underneath tissue needs to be accessed. In these cases, it is often impractical, counterproductive or detrimental to remove the tissue covering the target anatomy, so a puncture device that does minimal damage to the tissue above the area of interest is commonly used. These devices are long, slender, and significantly more rigid than the tissue in order to minimize the size of the hole created, and to reasonably puncture the tissue when a force is applied on the device. Because the tissue has a natural strength and elasticity, the tissue will balance the loaded force until the tissue's yield load is reached. Ideally, the user would then immediately stop applying a force on the device, but there is a short delay between the user recognizing the tissue has yielded, and then compensating for the force previously applied [1]. In the interim, the unbalanced force on the device will cause it to accelerate deeper into the patient, potentially damaging delicate underlying tissue and/or organs. Over puncturing therefore can then result in serious complications while performing puncture access procedures.

One way device makers have attempted to solve this problem is by minimizing the force needed to puncture tissue by using a tip geometry that results in a higher stress concentration at the tip. When less force has been applied at the moment when the tissue yields, the resulting acceleration at puncture is less and the device will travel a shorter distance by the time the user is able to compensate[1]. Another attempt at reducing complications caused by over puncture is by making the device tip much blunter so that the tip is less damaging if and when it comes into contact with the underlying features. Several other efforts to reduce needle damage to the tissue layers have centered around needle design[2]. However, the underlying problem of sudden acceleration upon puncture before the user is able to compensate is not addressed.

A potential solution that has not yet been commercially developed is flexure-based and reacts instantaneously to the loss in resistance at the moment of puncture. A diagram of the mechanism is presented in Figure 1. The flexure operates by converting the force on the tip during the puncture procedure into a friction force greater than a restorative spring force [1]. When the tissue fails, there is no longer a tip force, reducing the friction force to less than that of the restorative spring force. The spring immediately withdraws the tip and the flexure to which it is coupled. The goal is to use a sharp tip to minimize the required penetration force, but also use a blunt sheath for the tip so that when the device and user inevitably accelerate, the mechanism will actively oppose the forward acceleration and there is less risk of tissue damage.

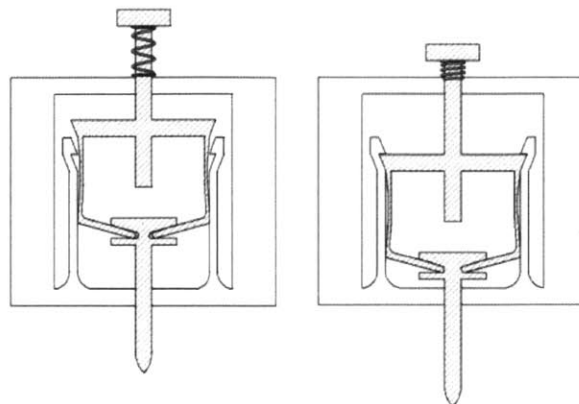


Figure 1. Schematic of flexure-based puncture device [3]. (Left) Unloaded, tip withdrawn configuration (Right) Preloaded and being loaded at the tip configuration.

Clinical Background: Epidural Technique

Over 2 million epidural procedures are performed every year in the US, often used to administer an anesthetic or steroids to reduce the sensation of pain or inflammation[4]. The procedure works by the medication coating the nerve endings in the epidural space surrounding the needle tip. In certain procedures, patients treated with spinal-epidural anesthesia had a shorter time to home readiness and reported better satisfaction and lower pain than those treated with general anesthesia[5]. Some procedures involve a single dosage, while in others a catheter is left behind after the needle is removed to allow continuous drug administration. A not-to-scale illustration of a needle puncturing an interspinous ligament, a comparatively tough tissue, to reach the epidural space is shown in Figure 2.

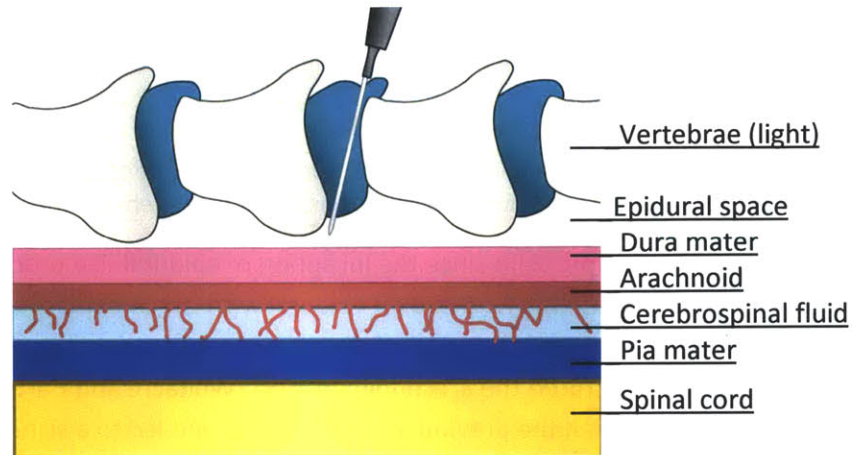


Figure 2. A not-to-scale diagram of the epidural needle in the epidural space with the surrounding tissue layers [6].

The Loss of Resistance (LOR) technique is one of the ways the practitioner can sense the needle has entered the epidural space. However, the procedure can be difficult because there is tough tissue next to delicate tissue, meaning a higher force is needed to penetrate the tough tissue, but the chances of tissue damage are greater for the delicate tissue[2]. It can be confusing during the needle insertion because there are also multiple, smaller LORs before reaching the epidural space as seen in Figure 3. The final drop after reaching 8N represents entry into the epidural space. In the same study, the average maximum force before LOR in humans was 6.0 ± 3.0 N [7]. Note that in Figure 3, the force increases again after entering the epidural space, indicating the needle is now over puncturing into the dura mater.

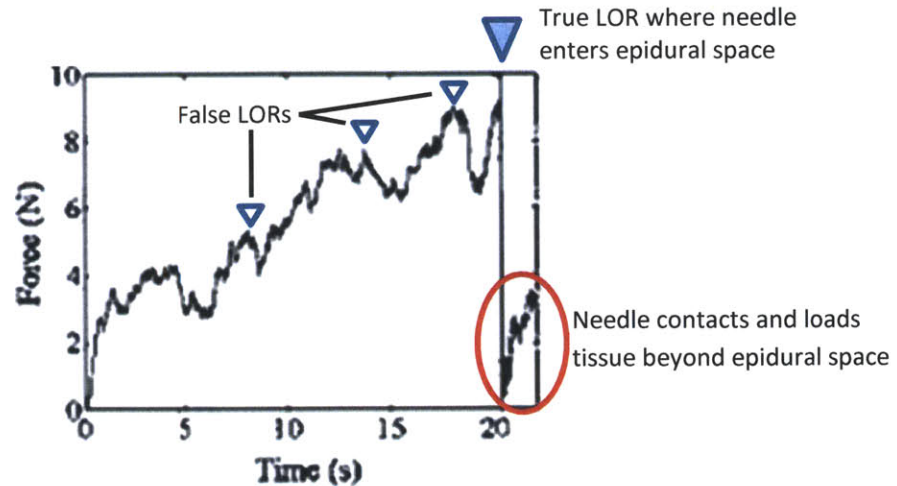


Figure 3. A sample force profile of a human epidural procedure [7]. Note there are several LORs before ultimately reaching the epidural space and how the force begins to increase even after penetrating the epidural space.

Over puncturing has been a problem since the inception of epidural-like procedures. By the early twentieth century, half of patients who had an epidural with large needles had complications, normally headaches, which has been linked to CSF loss [2]. CSF loss implies that the needle has exceeded the epidural space and has punctured the arachnoid. In 1951, Whitacre and Hart developed a pencil-point needle which was smaller than the previously used needles and led to a significant reduction in the reported cases of complications. A reduction in needle size most likely reduced the damage to the dura and arachnoid, reducing the CSF loss. Subsequent commercialized needle designs that attempt to address this problem involve thinner diameters, or different tip geometries as illustrated in Figure 4.

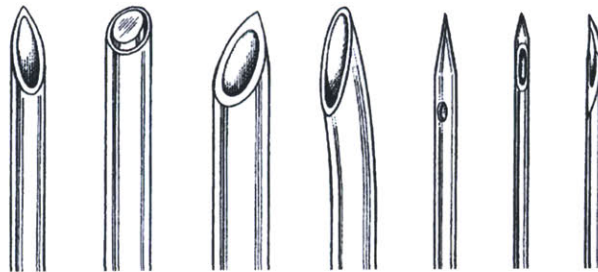


Figure 4. Schematic of different epidural tip types and needle sizes.[2]

A modern solution is using imaging to help track the needle in epidural procedures, but does not address the inevitable needle acceleration upon puncture. For example, fluoroscopes, as shown in Figure 5, and computed tomography can help verify that the needle is correctly placed, or is still outside the epidural space. Some needles also have depth markings, as shown Figure 6, so the practitioner can know not to exceed a certain distance based on the patients physical characteristics[8].

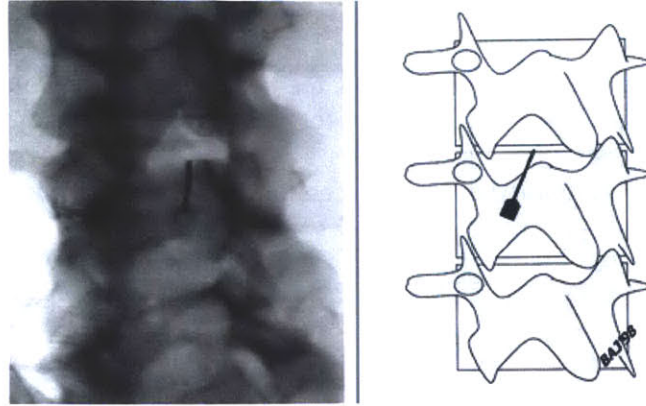


Figure 5. Epidural needle after have been guided into the epidural space with corresponding schematic view[9]



Figure 6. B. Braun Perican® epidural needle with 1cm length markings [10]

Problem Statement

Current, commercial epidural needle designs attempt to minimize the damage caused to the patient during the procedure by improving the practitioner's ability to sense when the needle has entered the epidural space, and/or minimize the damage the needle tip may do to the underlying tissue structure. These devices do not address the fundamental problem of the practitioner temporarily accelerating forward upon puncture. A design currently in development offers a flexure-based solution, however has not been specifically adapted for epidurals.

If a flexure-based solution could be adapted to work with the forces and constraints of epidural needle insertion so that the sharp needle tip is withdrawn into a blunt enclosure the moment the tissue has yielded, the frequency of over puncture may be reduced while increasing patient safety and comfort.

Design Process

In order to adapt the existing flexure-based solution, the flexure mechanism must be first better understood. Figure 7 illustrates a demonstration prototype with a schematic of the flexure design. Using the existing equations which described its mechanics, a computer model was created and developed to predict whether a given configuration would be successful for an epidural procedure.

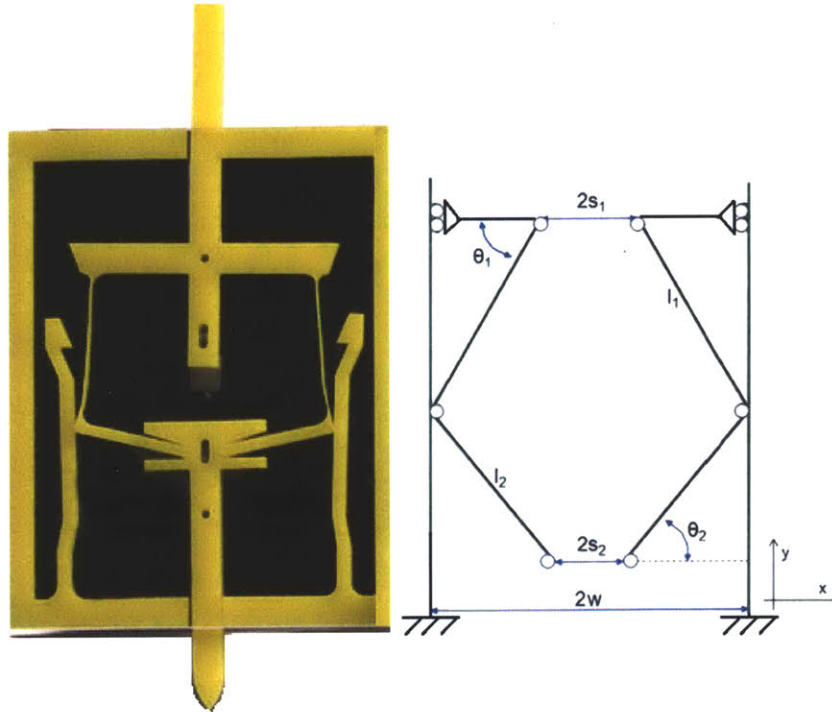


Figure 7. Flexure mechanism prototype and schematic [1].

Design Principals

Due to previous machining issues in the development of the flexure, rapid iteration was used to converge on potential epidural solutions[1]. The functional requirements in Table 1 were then used to guide the iteration. The initial configuration was based on an existing flexure known to engage the sidewalls and then release when unloaded.

Table 1. A list of functional requirements to guide device design

Functional Requirement	Description
Maintain intended function of epidural procedure	Allow epidural needle to enter and stay within the epidural space to administer medication, or allow a catheter to remain for constant administration
Reduce risk to the patient	Reduce complications by minimizing the over puncturing and associated damage
Reduce discomfort in the patient	Reduce CSF leakage and other damage to the tissue surrounding the epidural space
Reliability	Device must work repeatability and consistently
Cost effective	Device should be cost effective for institutions given its ability to be reused or to be disposed. This may require cost effective parts and/or simple assembly

In order to match the computer model's iteration, a fabrication method that allows for rapid iteration was also used. Several methods were considered, including laser cutting, waterjet, wire electrical

discharge machining, and 3D printing. Rapid iteration would require low cost, quick turnaround time, and relatively easy access. Laser cutting was chosen because of the presented options, it satisfies the requirements the best. Laser cutting works with plastic, which would be a strong option in the future if injection molding was used for mass production. In this case, 3mm acrylic was chosen as the main material from which pieces were made because it works well with laser cutters, and is readily available.

Given that any device would not be significantly larger than current epidural needles used, the amount of additional hardware, such as bushings, were minimized by using passive techniques like Saint-Venant’s principal for interconnecting parts[11]. For a laser cutter, the pieces must also be designed to be layered and preferably with minimal third axis machining required. Maintaining the same part thickness would also minimize interruptions and loading times. Small features such as threads should also be avoided due to the additional precision needed and higher chance of accidental material failure; press fitting can be utilized instead.

Mechanism Analysis

In the existing flexure device design, there are three primary stages describing the device’s function: the preload, the tip being loaded, and then puncture[3]. The preload allows the user to expose the tip without applying additional force to the device. This reduces the risk that the user may prevent the retraction of the flexure and tip. Each stage has a corresponding force condition that must be satisfied in order for the mechanism to work as intended:

1. Preload requires a friction force greater than the restorative spring force
2. The tip force cannot exceed the friction between the flexure and the preload force
3. The preload force must disengage when the tip force has come within a certain percent of the puncture force

Manually entering values into the mechanics equations that described these requirements would have been prohibitively time consuming so a more usable computer model was created. The equations were entered into an Excel spreadsheet that allowed the user to keep track of dimensions, material properties, and expected puncture forces from epidural procedures. When one input was updated, the computed forces would update automatically, indicating whether the three above conditions were satisfied or not. The equations used are discussed in greater detail in Appendix I. An example summary of the forces is shown in Figure 8.

Check Force Conditions		
<u>Pre Load can Engage, $F_s < F_l$</u>	Ok1	
	F_s	2.398 N
Resultant friction force due to F_c at zero tip load		3.676 N
effective safety factor		1.533
<u>Device Steady during Insertion (Sum Friction, $F_f + F_l > F_s + F_t$)</u>	Ok2	
	$F_f + F_l$	22.311 N
	$F_s + F_t$	12.398 N
	F_f	18.997 N
	F_l	3.314 N
	F_s	2.398 N
	F_t	10.000 N
If not enough friction, slips at this tip load:		19.914
effective safety factor		1.800
<u>Before puncture, Cantilever force < Spring force</u>	Too much friction	
	F_s	2.398 N
	F_l	3.314 N
effective safety factor		0.723

Figure 8. An example output summary of the Excel model

Beyond calculating whether the force conditions would be satisfied, the model was then refined to check mechanical robustness. Additional equations were added to check whether there was risk of buckling or excessive bending within the device given the loading forces and a safety factor. The kinematic properties of the device were also included in order to quantify the cantilever performance and device acceleration.

Most importantly, the model allows the user to see the model tolerances. By varying certain flexure parameters, the expected performance of the device can be seen to vary greatly while others do not. The robustness of the model also indicates what level of inherent variation is within the device. For example, if the walls of the device are too thin, they will bow when the flexure presses on them; the lower than expected friction force between the flexure and the wall may result in a different friction force, which may prevent the conditions of a working device from being satisfied.

Alpha Prototype Development

Alignment is a large issue when working with a relatively small device. By Saint Venant's principal, the contact length of the outer mated piece was over three times the width of the inner piece to minimize their binding. There were also significant improvements in alignment when using shoulder bolt screws compared to regular machine screws. This was addressed with a custom feeler gauge and Saint Venant's principal. For the gauge, a slot of known width (0.125in in Solidworks) was created and then several four-prong gauge pieces, each prong having a different thickness, were sequentially inserted into the slot. When an appropriate press fit and clearance fit could be felt, the corresponding dimension difference between the prong and the slot would be used. A sample gauge piece and reference slot can be seen in Figure 9. For 3mm acrylic cut on the Epilog lasercutter used for this project, the ideal CAD should be oversized by 0.01in per surface for a clearance fit (based on a 0.125in gap and a 0.145in gauge piece). For an intermediate press fit, dimensions should be oversized by 0.011in per surface (based on a 0.125in gap and a 0.147in gauge piece).

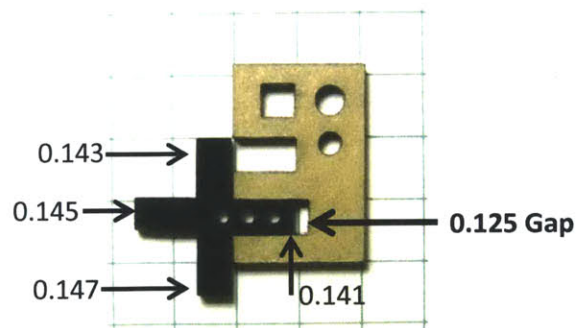


Figure 9. Custom feeler gauge made to find optimum gap for press fit and clearance fit. Dimensions are in inches.

To decide a set of flexure dimensions that worked, the computer model was initially seeded with the dimensions of a previous flexure used in [1]. The values were then modified until a set of values satisfied the flexure conditions. While one set of values may work, there is a large envelope of flexure dimensions that can satisfy the flexure conditions, and even more so if other materials are considered.

Without Cantilever Preload

In order to confirm the model with a simpler case, a version without the cantilever preload was created. This version operated as expected where the tip is loaded in order to “preload” and then it tolerates subsequent loading. Once the tip force is lost, the flexure appropriately loses friction force and it is withdrawn as expected.



Figure 10. A working flexure version without the cantilever.

With Cantilever Preload

Optimizing the cantilever design is one of the most challenging aspects of this project. The cantilever shape underwent several iterations as seen in Figure 11 in order to improve preload and flexure friction. While the first cantilever was a simple, rectangular beam, additional features were later added. For example, areas that came into contact with the flexure gained a 4.5 degree slant in order to compensate for a similar bend in the cantilever when the cantilever tip is displaced for the preload. The cantilever surface would “appear” flat instead of introducing a vertical reactionary force component. Hybrid cantilevers were also tested, as shown in Figure 12, where the beneficial qualities of one shape of cantilever were paired with that of another in an effort to reduce laser cutting time. Figure 12 also shows some sample assembled flexures with cantilevers.

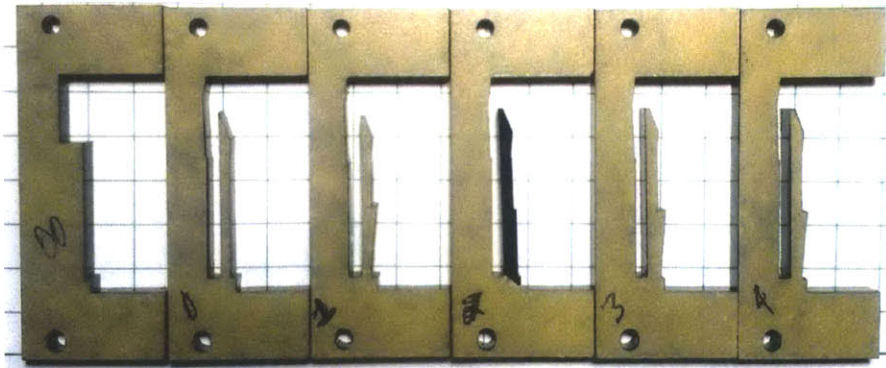


Figure 11. Several iterations of the cantilever design in an effort to optimize the preload and tip loading forces

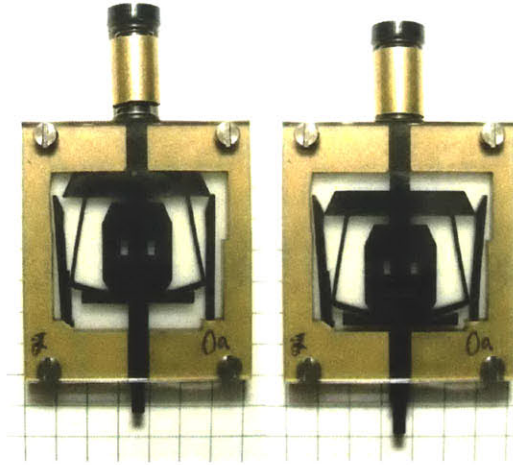


Figure 12. Device with hybrid cantilever walls, showing unloaded and preloaded state.

In order to improve the flexure's alignment with the cantilevers as it is being moved forward, the flexure is lightly preloaded even in the unloaded case. Because the required cantilever displacement for a sufficient preload approached the thickness of the cantilever, this initial nominal loading helps ensure the flexure stays centered between the cantilevers as it translates.

Based on the design requirements and experience gained in working with the flexures, Figure 13 **Error! Reference source not found.** illustrates a potential flexure-based epidural solution.

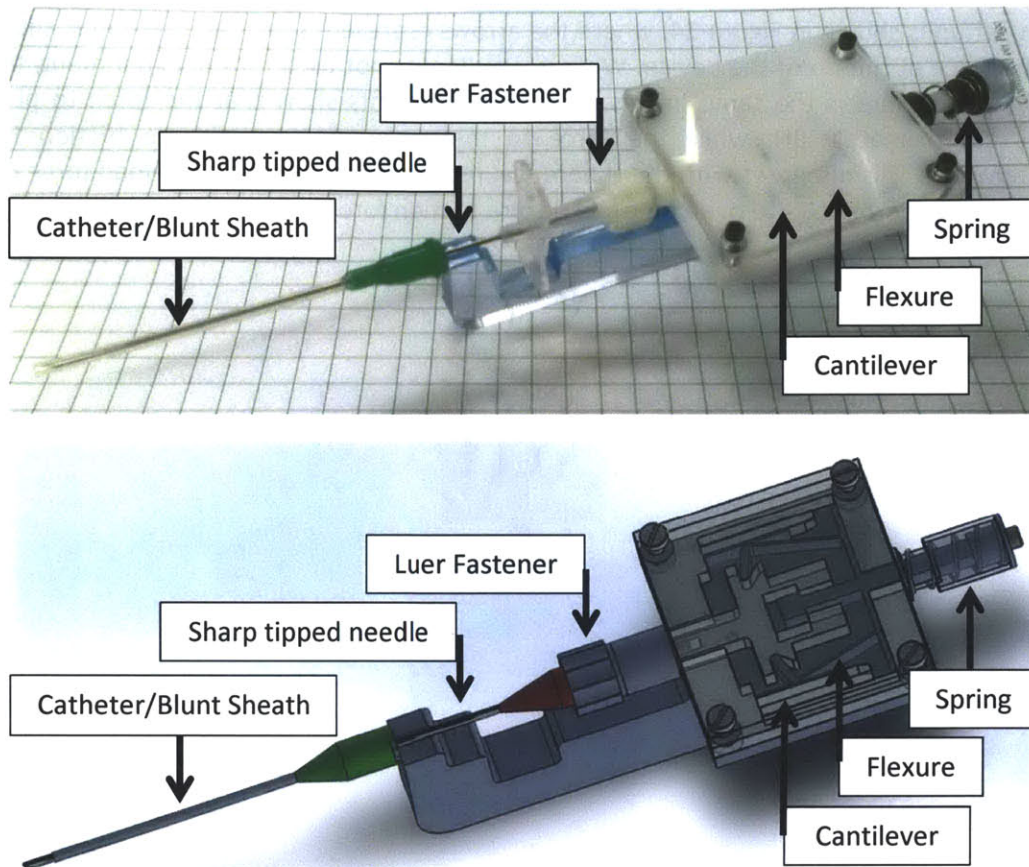


Figure 13. A comparison of the prototype iteration with a schematic CAD.

Because a catheter may need to be left in contact with the epidural space, a catheter serves as the blunt sheath for the sharp tip. A simple handle was added to the flexure design so that the catheter is limited by the end of the handle. When the flexure and needle are retracted, the handle will prevent the sheath from moving backwards at the same time.

The device is designed so that catheter allows only the sharp tip of the needle, which is approximately 2mm, to be exposed while puncturing tissue. When the tip retracts, the distal tip of the device is then as close as possible to where the needle tip originally was. In commercial needle sets, a catheter can come packaged with the needle, so when loading the catheter and needle in the device, the catheter simply needs to be extended forward, over the end of the handle, instead of being fully removed and repositioned onto the needle. Minimal preparation with the needle minimizes the risk of the user being injured by the needle tip. A luer lock is used to minimize effort and maximize a secure fitting between the needle and the device.

Tests and Observations

The device was tested with a force scale in order to validate the theoretical model. A model of the experiment set up is shown in Figure 14, where the arrows represent force the user input and the scale indicates the force at the tip of the device. While a needle was not used for the experiment, the overall force felt by the flexure is the same in this case. Measurements show that the force to preload the device was approximately 9N, while the force to then overcome the flexure friction force was approximately 20N. This disagrees with the theoretical model which suggests a preload force of approx. 2N to preload and approx. 16N to overcome the flexure friction force.

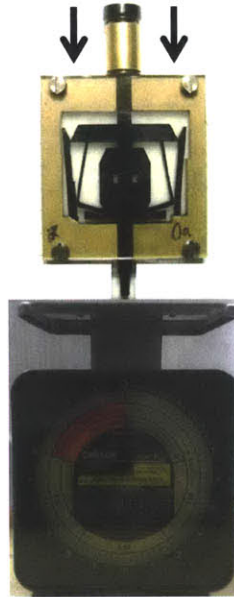


Figure 14. Diagram of force testing setup

One potential cause of the discrepancy between the forces the model predicts and the actual device experiences is due to an incorrect coefficient of friction in the model. The coefficient is one of the more sensitive components of the model and therefore inaccuracies would significantly change the expected and actual performance. For example, given a working coefficient of friction of 0.4, only a 7.5% increase was tolerable; any additional friction would prevent the flexure from withdrawing, and any less friction would prevent the flexure from being preloaded. The friction force used in the model was obtained by conducting a friction test between two sheets of acrylic. The coefficient found was 0.51 ± 0.03 , which is within the above tolerance range, but may not have accurately characterized the laser cut surface because uncut sheets were used for the test. The cut edges do have a minor taper on them, which would prevent a strong surface to surface contact in the actual device, and is not taken into consideration in the model.

The forced interference between parts in order to improve their alignment was also not taken into account and therefore be the reason why there is a discrepancy between the model and the prototype. The cantilever shape was modified in order to ensure contact with the flexure, which causes the prototype to deviate from the model. While adding slopes to compensate for beam curvature due to bending, as seen in Figure 15, should better match what the model anticipates, it may significantly change the beam bending mechanics.

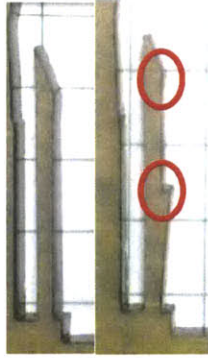


Figure 15. A close up of some cantilever modifications that deviate from a simple beam

A brief capability analysis of the first laser cutter used indicates that there can be up to 20% variation in intended dimension between the CAD model and the cut piece, as seen in Figure 16. A 20% variation in the bottom flexure bars exceeds the window for a working device, and affects fine features the most. This is most likely caused by the diameter of the laser head, and then the taper from an improperly focused or powered laser. This prompted the usage of the feeler gauges to have a stronger control loop regarding dimensions. Another problem that could have contributed to this inaccuracy include the acrylic warping due to thermal stress concentrations caused by the laser cutting process.

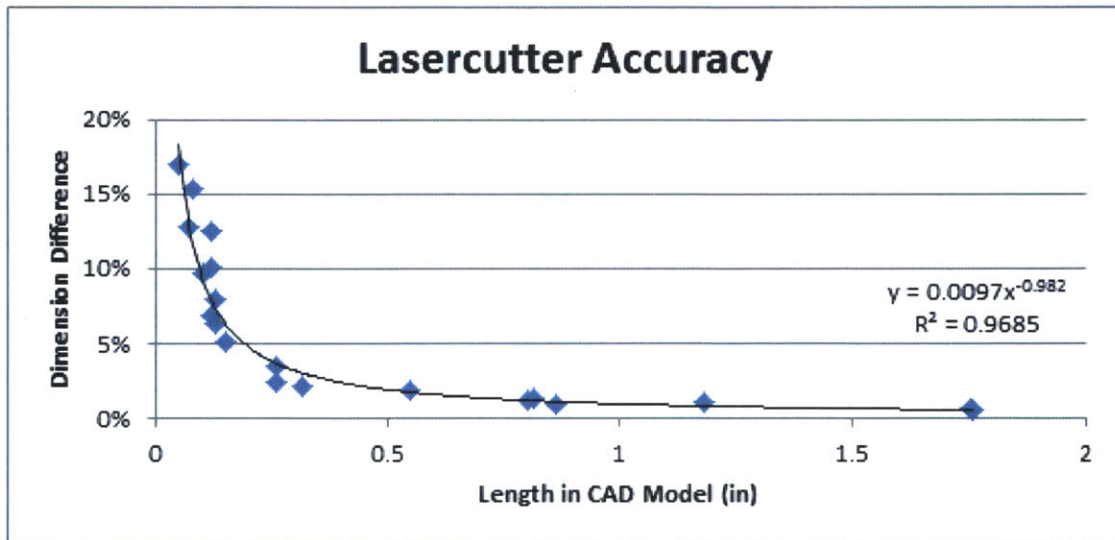


Figure 16. A graph showing how the laser cut dimensions deviate from the dimension used in CAD.

Future Work

In order to successfully commercialize this epidural device, the model (and subsequent prototypes) and the manufacturing process both need to be addressed. Improving the accuracy of the coefficient of friction used by the model is also critical. Because of the taper caused by the laser head, pieces do not contact as initially expected and needs to be better characterized. As prototypes were iterated to converge on a working solution involving the preload, the prototype design diverged with the model due to more complicated geometries, such as non-uniform cantilever beams, were used. Some kind of correction factor may be able to be deduced from correlation with sufficient testing.

An alternative to improving part contact is precisely attaching the complicated, smaller features to simpler, larger parts which would be aligned. The goal is that it will be easier to align the larger pieces since the gap difference can be significantly smaller than the piece size. A draw back would be that this increases the number of components, material, and assembly time, but would reduce the number of iterations needed to perfect the clearance fits.

Conversely, decreasing the thickness of the pieces used could improve the accuracy of the model. By reducing the thickness, the edge finish is more uniform. While this may require certain pieces to be thicker in order to compensate for the loss in stiffness, this actually then relatively minimizes the laser head width impact on the dimensions of the flexure. This also has some greater practical benefits, such as less energy to cut it using a laser cutter, and faster cooling times if being injected. Consequently, variation in material thickness will be a greater concern.

A sensitivity analysis should be performed because it may illustrate whether there is a different set of dimensions that can reduce the sensitivity of the model components, thereby improving the overall tolerance. Additionally, when moving to manufacturing, pieces that require high tolerances may be treated as such, while the pieces that don't can be made more cost effectively.

While the device could be made to operate with existing needles with a luer fitting, a revised needle that takes advantage of a sharp tip (low insertion force) with blunt sheath (low damage) should be made to further reduce the risk of over puncture. Experiments should also be done to see if perpetually having a blunt sheath in order to provide result in a blunt tip impedes certain epidural procedures.

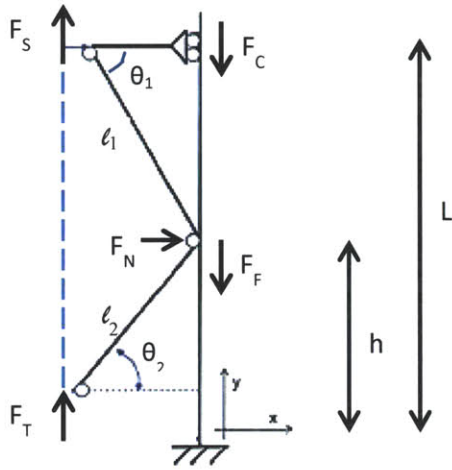
Conclusion

Epidurals constitute a significant portion of puncture access procedures. They also have a high incidence of complications, caused by over puncture. The flexure based needle retraction offers improvement to the fundamental problem of the needle continuing to accelerate after it has punctured into the epidural space. The alpha prototype demonstrates that this continues to be a difficult problem due to the precision needed to ensure all three conditions are met. Future work on making the model better at describing the performance of a physical prototype compared to that of a theoretical prototype, and improving the manufacturing process may make this solution a highly viable one. A generalized model can also expand the problems that the flexure-based solution can solve, ranging from medical devices to in-home repair because the flexure aspect can inherently be applied to many puncture problems.

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Appendix I



Mechanics equations describing the preload, loading, and puncture condition are presented below [12] Equal half of flexure and cantilever mechanism, denoted by dashed line.

F_S : force from spring
 F_T : force from tip of device being loaded
 F_N : normal force on cantilever from flexure
 F_F : friction force due to F_N
 F_C : force on flexure due to cantilever deflection
 F_L : friction force due to F_C
 L : cantilever length
 h : height of where flexure contacts cantilever

The flexure force is described as follows:

$$F_N = \frac{F_T}{2 \tan \theta_2} - \frac{F_S}{2 \tan \theta_1}$$

The friction forces caused by the flexure on the cantilever are then as follows, where μ is the friction coefficient between the flexure and the cantilever, and the factor of two to take into account that there are two cantilevers whose forces are cumulative:

$$F_F = 2\mu F_N \quad F_L = 2\mu F_C$$

In order for the device to preload, condition (1) must be satisfied, and then condition (2) must be satisfied in order for the flexure to not retract when using the tip in the epidural procedure.

$$(1) F_L > F_S; (2) F_F + F_L > F_S + F_T; (3) F_L^* < F_S$$

When the tissue has been punctured, F_T goes to zero, resulting in F_F to also go to zero. However, if the preload was still in place, the flexure would still be unable to retract. The current solution is viscoelasticity in the cantilevers. During loading, F_F increases the load on the cantilever, causing the tip to displace further from the flexure, which reduces F_L at the same time. When F_N goes to zero, the cantilever begins to return to its preload state, but due to viscoelasticity, the flexure will have a short period to retract if the effective F_L at the time is below F_S as in condition (3) where this temporary F_L is donated with an asterisk. The flexure then must withdraw so that subsequent cantilever contact is less than F_S allowing the flexure to finish withdrawing fully.

The displacement of the cantilever tip, $w(L)$, is more exhaustively described in the following equation, where E and I are the Young's modulus and bending moment of inertia of the material:

$$w(L) = \frac{-(h-L)^3 F_C}{3EI} + \frac{(h-L)^3 F_C^2 + L(LF_C + hF_N)^2}{2EI(F_C + F_N)} - \frac{(h-L)^3 F_N^3 + (LF_C + hF_N)^3}{6EI(F_C + F_N)^2}$$

This can be simplified for two cases: 1. When $F_C = 0$, F_N must have bent the cantilever enough to compensate for the preload, and 2. When $F_N = 0$, equation for w reduces to a simple cantilever with load F_C as shown below:

$$w(L, F_C = 0) = \frac{Lh^2 F_N}{2EI} - \frac{h^3 F_N}{6EI}; w(L, F_N = 0) = \frac{F_C}{3EI}$$