Process Book for Improving Continuous Regional Analgesia Administration

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Improving Continuous Regional Analgesia Administration

Executive Summary

The Ultrasound-guided Transverse Abdominal Plane (TAP) block procedure is a continuous anesthetic for lower abdominal surgeries and post-operation pain relief. It has gained traction due to the increased number of abdominal surgeries such as gastrectomies and appendectomies, but also due to the benefits of not having to use opioids post-operation.

The procedure requires the anesthesiologist to use of an ultrasound to find the administration point, insert a cannula to the administration point, and then thread a catheter through the cannula. According to Dr. Joshua Oliver, an anesthesiologist at Beth Israel Hospital in New York, the major issue with this is that the certified registered nurse anesthesiologist (CRNA) must help thread the catheter since the anesthesiologist holds the cannula and ultrasound. This puts the patient at risk since the CRNA can't perform their primary job of taking care of the patient.

In order to increase the anesthesiologist mobility so he/she can perform the procedure themselves, a new cannula was created that has a scrolling mechanism that pushes the catheter through the needle, all in one hand so the CRNA isn't needed. The same gauge needle and catheter is used so that there isn't any change in anesthetic flow rate or force to pierce the skin.

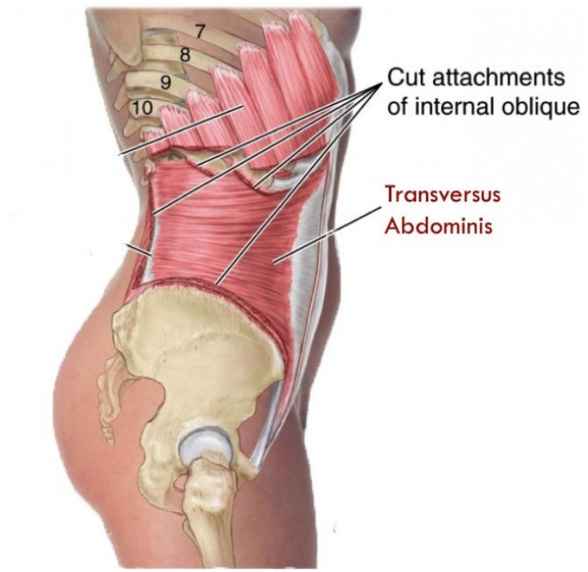
Overall the project was a success. Dr. Oliver loved the idea and thinks that it can simplify a complicated procedure. The device works well and is comfortable and ergonomic.

Table of Contents

Aksal Vashi, Arjun Patel, Sana Pournaghshband, Sean Monaghan

Improving Continuous Regional Analgesia Administration

A typical cannula and catheter used for the procedure.



An image showing the injection site, the Transversus Abdominis.

The TAP Block procedure is used for continuous anesthesia during surgeries or postoperative pain relief.

1. Background

The ultrasound-guided TAP block procedure is used to provide a source of postoperative pain relief for abdominal surgeries and in some cases, to provide regional anesthesia for day surgeries. Any condition that would necessitate surgery in the abdominal region (gastrectomies, appendectomies etc.) provides a situation in which this procedure could be used. The market for this procedure is growing. Gastrectomies are the fastest growing surgical procedure in the US at an average annual increase of 10% over the past 15 years. Appendectomies, as well, are the 11th most common surgical procedure in the US.

The TAP block procedure is conducted by an anesthesiologist and delivers a regional anesthetic to the entire abdominal region, and does so at relatively low risk, which makes it preferable to many of the existing alternatives. The TAP block will allow for certain minor surgeries to be performed with little to no discomfort to the patient, and will relieve other postoperative patients of pain in this region following more significant surgical procedure.

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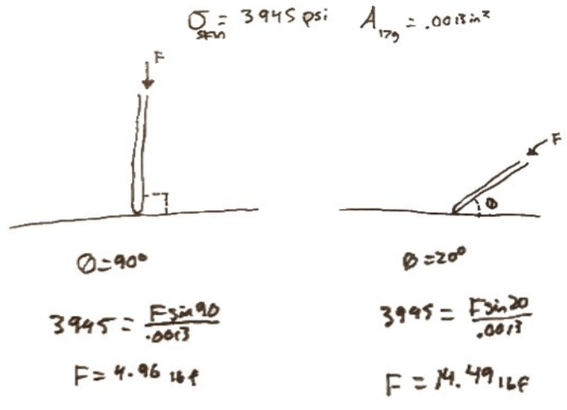
Improving Continuous Regional Analgesia Administration

Continuous anesthetic flow (via catheter)

- Constant flow rate of ~5mL per hour
- Steady-state scenario: $Q_{in} = Q_{out}$
- Even distribution of anesthetic along the distal end of the catheter due to 15 micro perforations.



Force to pierce the skin with a 17 gauge needle

- 4.96_{lbf} at a 90° to the skin (normal to skin).
- 14.49_{lbf} at a 20° to the skin (minimum degree allowed in order to see the cannula on the ultrasound).

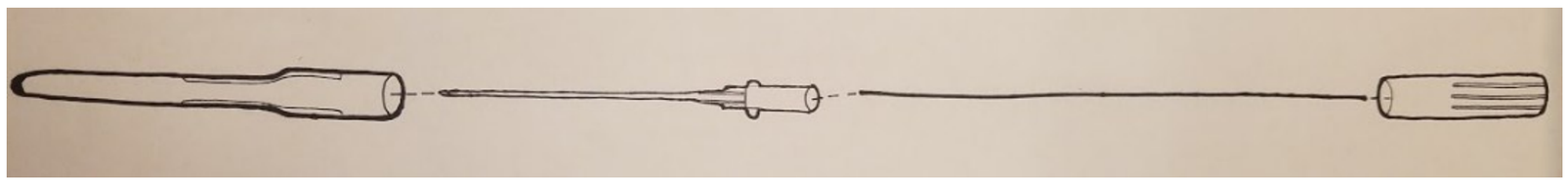
2. Analysis

Engineering analysis consisted of looking at the steady state flow rate of the catheter system and determining the force to pierce the skin with a 17 gauge needle.

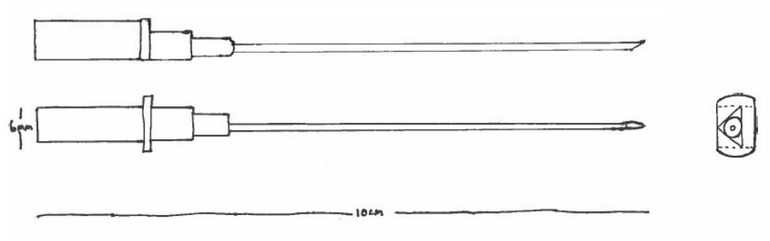
Determining the force to pierce the skin was essential because if future concepts change the needle gauge, the new force to pierce the skin must be within the standard calculated range so that anesthesiologists don't have to adapt.

The force to pierce the patient's skin is somewhere between pinching your thumb and pinky, to your thumb and index finger.

Exploded View of Cannula and Catheter with packaging.



Orthographic drawing of the cannula.



Aksal Vashi, Arjun Patel, Sana Pournaghshband, Sean Monaghan

Improving Continuous Regional Analgesia Administration

3. Project Framing

Objectives for the project included increasing the anesthesiologists mobility, decreasing number of steps in the procedure, decreasing analgesia administration side effects, and making the procedure more viable for geriatric, pediatric, and bariatric patients. Using metrics such as patient safety and anesthesiologist's ease adaptability, the most important objective and problem statement was defined as, "A procedure that increases the mobility of anesthesiologists delivering analgesia."

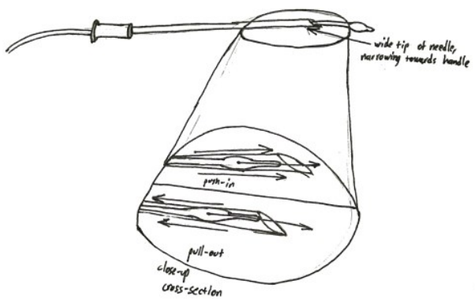
The procedure requires multiple hands to use the ultra sound, cannula and catheter.

User Profile Anesthesiologists:

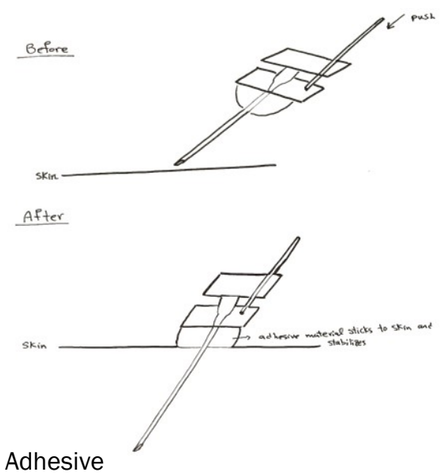
- Highly skilled and educated.
- Very specialized in certain procedures.
- High error risk due to complexity of procedures and significance of their job (sued often).

Aksal Vashi, Arjun Patel, Sana Pournaghshband, Sean Monaghan

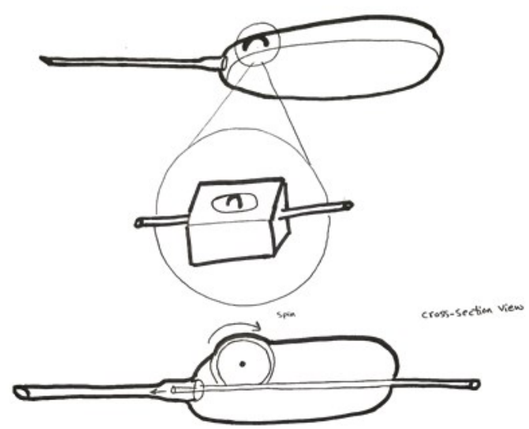
Improving Continuous Regional Analgesia Administration



Two in one



Adhesive



Scroller

4. Concepts

Key concepts included:

- Scrolling mechanism to push the catheter through the cannula
- Adhesive to stabilize the cannula so it can be left in place
- Two in one that allows for the catheter to be inserted with the cannula and then retracted.

Moving forward, the scroller was selected due to user feedback from Dr. Oliver. He mentioned that it seemed most reliable and it would require anesthesiologists to adapt the least.

Aksal Vashi, Arjun Patel, Sana Pournaghshband, Sean Monaghan

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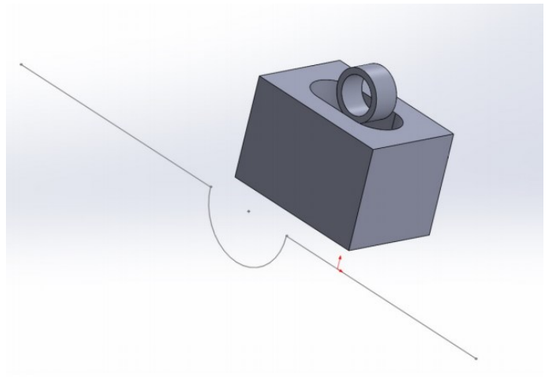
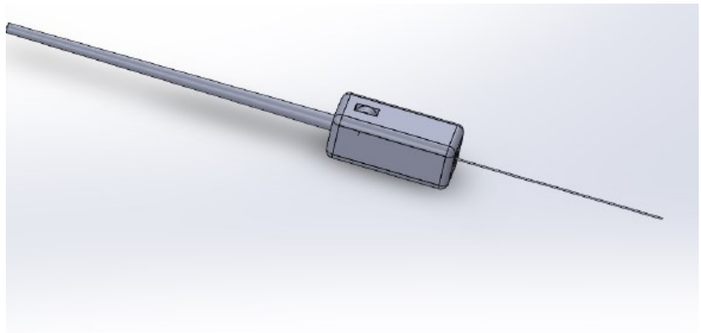
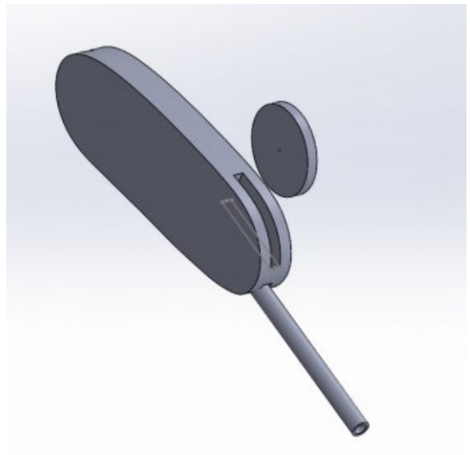


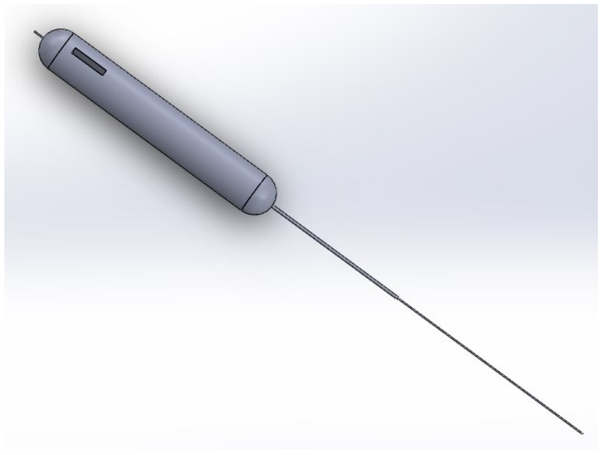
Turning a concept prototype into a device



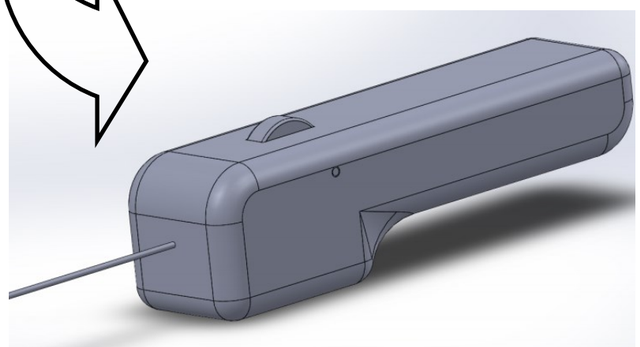
Dr. Oliver was worried about comfort and size.



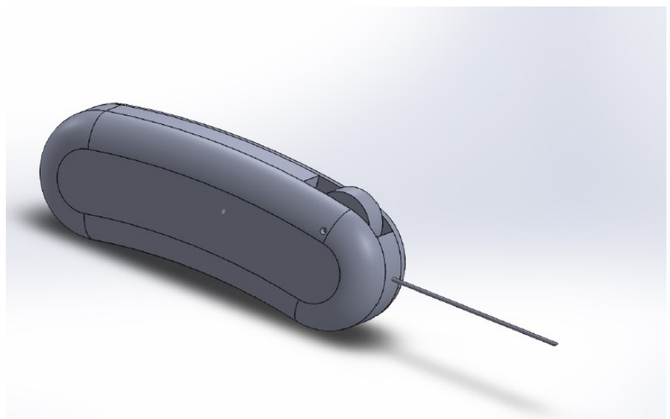
Scrolling mechanism seemed forced and wasn't comfortable.



Having the scroller on the distal end limited maneuverability



Catheter had to bend, decreasing functionality. Hard to manufacture.



5. Prototyping

When rapid prototyping, foam and foam cutters were used along with SolidWorks for CAD rendering. Wood sheets and laser cutting was used to assemble the final prototypes. Wood was used rather than 3D printing since it couldn't print a small enough hole for the catheter.

Dr. Oliver stressed user comfort and functionality of the catheter throughout the prototyping phase. Every iteration was sent to him for feedback and direction towards the final prototype.

Anthropometric data of hands were necessary in determining final size and shape.

Final assembly was ergonomic and efficient at moving the catheter through the device. Device is about 3.5 in. long.

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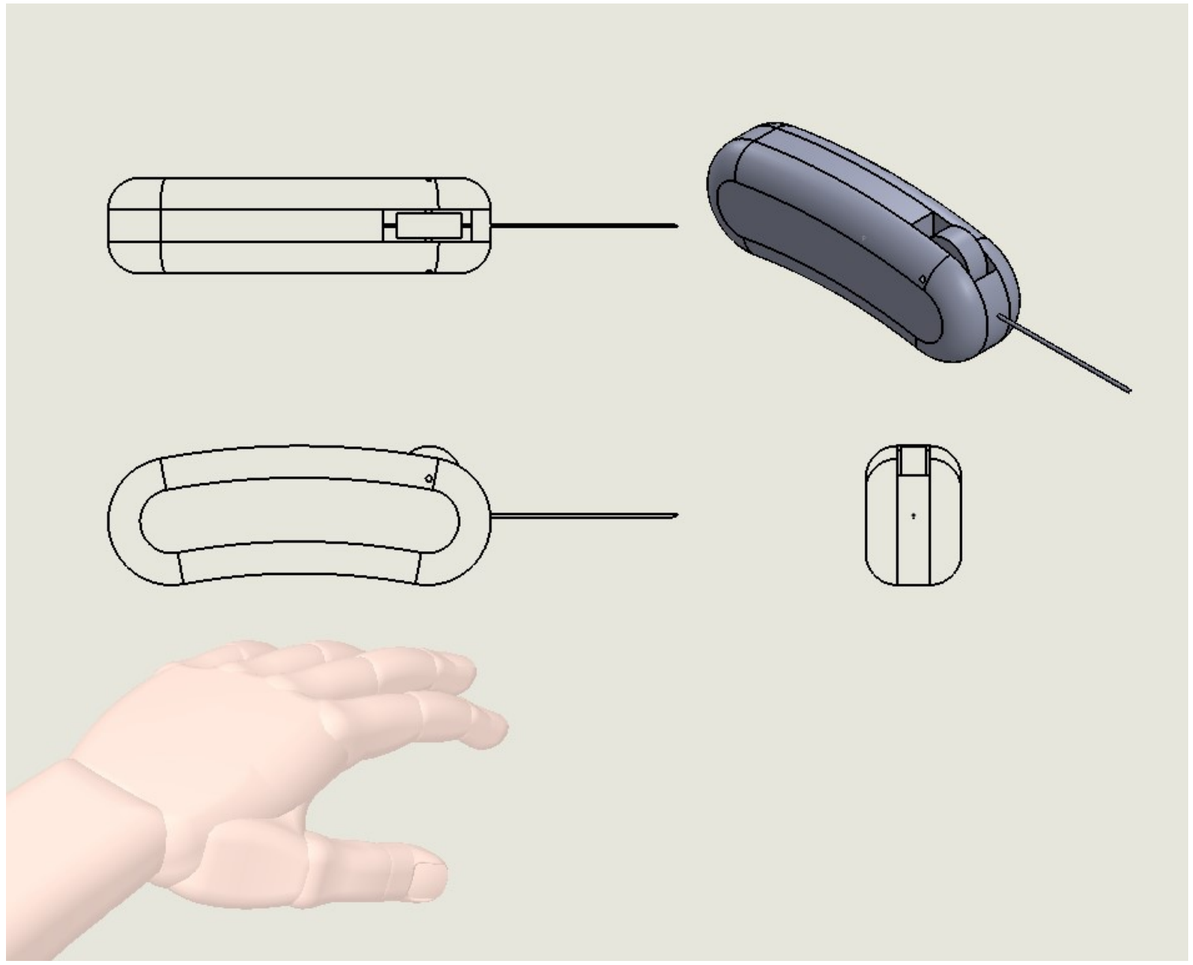
Improving Continuous Regional Analgesia Administration

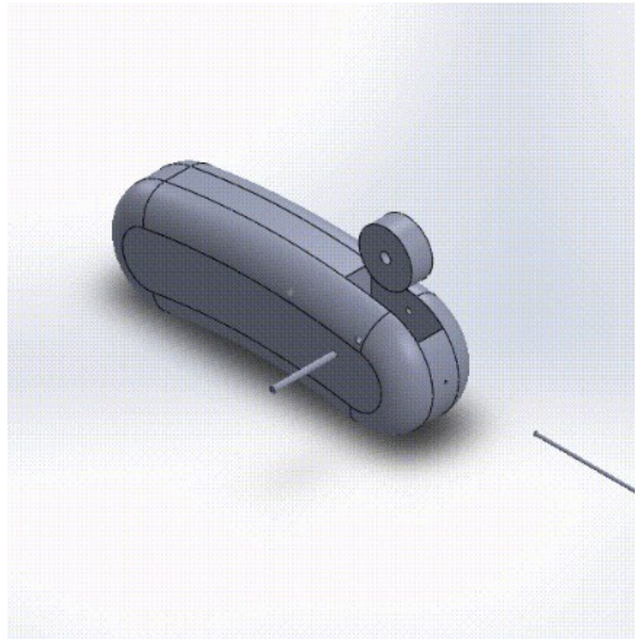


An orthographic drawing of the final device with a hand to show the size of the device.

6. Final Solution

Key Advantages and Novel Aspects:

- Allows the anesthesiologist to perform the procedure themselves
- Ergonomic for the 5th to 95th percentile
- No other product in the market that simplifies this procedure
- Maintains the same anesthetic flow rate and force to pierce the skin as the original procedure
- Can be reusable (polycarbonate and stainless steel) where the needle is attachable and pre-sterilized, or it can be cheap and disposable (injection molding and polyethylene).



An exploded view of the device showing the 4 parts, the axle, the wheel, the needle, and the body.