

# Knot too Tight - Knot too Lose

#### PRELIMINARY REPORT

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## **Abstract**

Proper suture tension is critical for achieving wound closure integrity and preventing tissue damage or knot failure. However, current veterinary training methods rely on subjective evaluation and repeated practice, with no qualitative system to teach students how to achieve optimal suture strength. Existing training tools either lack real-time feedback, are not commercially available, or only measure tension in the first knot throw, leaving a gap in effective suture training devices. To address this, two preliminary prototypes will be fabricated and evaluated prior to creating a final design. The first, a visual knot characteristic system, will use an overhead camera and machine learning model to analyze suture knots visually and provide real-time feedback on knot security, automating the assessment traditionally performed by instructors. The second, a force-sensing glove system, will integrate force-sensitive resistors (FSRs) into a wearable glove and wrist-mounted unit to measure suture tension and provide real-time visual feedback with minimal interference during training. The first design concept was prioritized for its alignment with traditional instructor evaluation methods, minimal interference with suturing technique, and adaptability. However, both this visual system and the glove-based force-sensing system will be fabricated and evaluated, with the glove serving as a practical, cost-effective alternative. To ensure both prototypes provide meaningful feedback, suture material properties will first be characterized through tensile testing. The visual knot identification system and force-sensing glove will then be evaluated for accuracy, usability, and effectiveness in guiding trainees toward proper knot tension.

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# Introduction

## **Motivation & Impact**

There is currently no device on the market or in the veterinary skills lab that teaches students how to tie a suture knot to achieve optimal strength. Suture knot tying is a skill that is purely learned through "feel" and extensive practice. For a knot to be secure, the suture material must plastically deform. However, students often struggle with either tying the knot too tightly and causing material failure, or too loosely, allowing the knot to unravel after they release the suture material. This is seen in Figure 1.

Students' suture knots are evaluated by a professor using a magnifying glass to determine whether the knot was tied correctly. There is no quantitative force value that defines an optimally secure suture knot, as this value depends on the suture material, thread size, pulling speed, and knot style. In the literature, only values of the ultimate tensile strength of some suture materials have been evaluated, with little to no data available on the tension in the final throw of the knot [1, 2, 3].

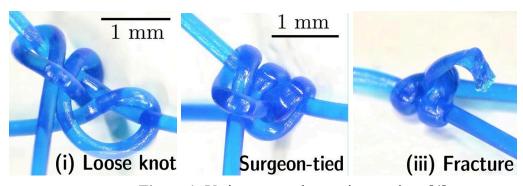


Figure 1: Various suture knot-tying tensions [4].

This project aims to quantify the optimal tension value and provide real-time feedback to teach students more efficiently and with fewer repetitions. This reduces costs, as each suture is about \$1.73 - \$1.83 per stitch [5], and helps minimize medical waste. Improper suture tension can cause tissue damage if excessive pressure is applied to the tissue. Additionally, if the suture material does not plastically deform, the knot may unravel, or wound dehiscence may occur [6]. In practice, a suture procedure can cost anywhere from \$50 to \$1,000 [7], consuming time, money, and resources for both the patient and hospital if re-suturing is required due to improper technique.

### **Existing Suture Training Designs**

The ForceTRAP visual force feedback system (Figure 2) is a device referenced in research articles, although limited information is available about the product. The device contains a microcontroller that converts a sensor's output from the model tissue into a calculated reaction force. This force is then translated into LED feedback for the user, where green indicates an in-range force (0.5 N - 1 N), orange indicates a slightly high force (1N - 2N), and red indicates an out-of-range force (>2 N) [8]. It provides feedback on needle insertion, knot-tying force, and alignment of the two tensioned suture threads.



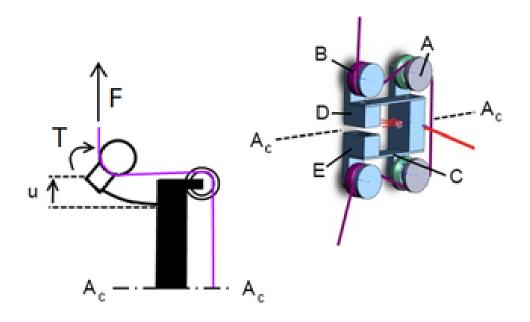
Figure 2: ForceTrap Training Device [8].



Figure 3: ForceTRAP Training System [9].

There is a standalone ForceTRAP (Figure 3) manufactured by Medishield. However, very limited information is available about this device, as the manufacturer's website no longer exists. Therefore, this device is currently not on the market. Additionally, it only measures the force in the suture thread of the first throw of the knot, which is independent of final suture knot tightness, as the last two to three throws determine a suture knot's tension.

Another measurement system used to measure force in surgical sutures is the Hook In Force (HIF) sensor. It utilizes a sensor and a magnet to measure the displacement of the thread once it is fed into the system. The purple line in Figure 4 represents the thread within the HIF sensor. This system can measure displacement in the range of 1 mm to 3 mm, converting measured displacement into a corresponding force output. The HIF sensor is referenced only in research articles and is not currently available on the market. Additionally, it is also not integrated into a system to measure the displacement of the final throw of a suture knot [10].



**Figure 4:** Hook in Force (HIF) Sensor [10].

Lastly, the wheel sensor (Figure 5) uses a Hall sensor that detects magnetic field changes as a magnet moves when the thread is pulled through the system. A greater displacement of the magnet corresponds to a greater pulling force. The Hall sensor outputs a voltage signal, which is then processed by a microcontroller that converts it into pulling force values and translates these into LED feedback. A green LED indicates a safe working range for the pulling force, while a red LED is a warning that the pulling force is too high. The wheel sensor is only found in research literature and is not currently on the market. It is also not integrated into a training system for students to use.

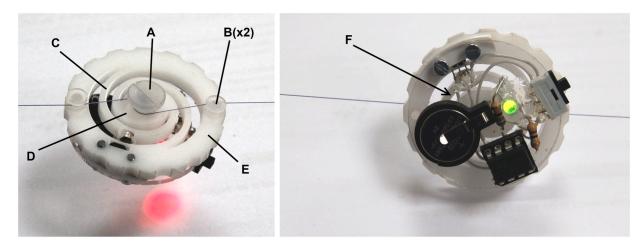


Figure 5: Wheel Sensor [11].

#### **Problem Statement**

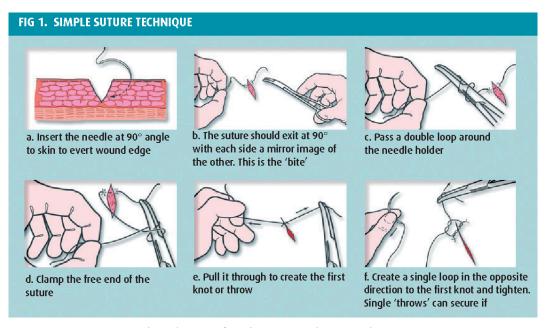
In veterinary training, mastering the skill of applying appropriate suture tension is essential for successful wound closure and patient recovery. However, novice practitioners often struggle to judge the correct amount of force needed, leading to either insufficient tension or excessive tension, which can cause plastic deformation of the suture material or tissue damage. Currently, the evaluation of suture technique relies heavily upon subjective instructor feedback, lacking objective, real-time metrics to guide learners. This gap hinders consistent skill development and increases the risk of procedural errors. There is a critical need for a real-time suture tension measurement and feedback system to help students learn to apply optimal tension, prevent material or tissue compromise, and improve surgical outcomes through data-driven training.

# **Background**

## Variability in Suturing

The team is tasked with creating a real-time suture tension measurement and feedback system to teach students proper suture knot strength. A knot is secure when the suture material plastically deforms. Many variables affect knot security, including suture material, knot type, and material size.

A "throw" is the term used to describe the action of crossing the ends of the suture to form a loop and then wrapping one end of the suture around the other [12]. See Figure 6 for the first throw of a suture knot. The client requested that the team focus on square knots (Figure 6) when developing the measurement system, with plans to expand the measurement system to accommodate additional suture knot types.



**Figure 6:** First throw of an interrupted square knot suture [12].

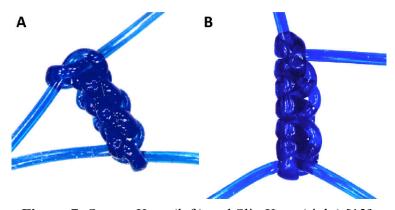
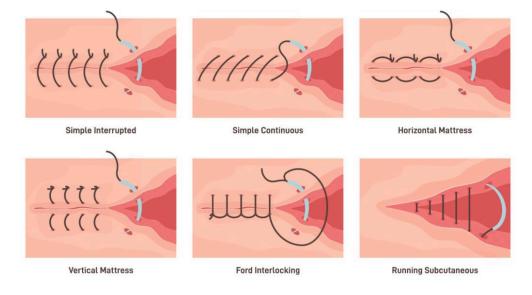


Figure 7: Square Knot (left) and Slip Knot (right) [13].

Surgeons learn numerous suture patterns. The client demonstrated simple interrupted and simple continuous suture techniques (Figure 8). To simplify the task of designing this system, for the preliminary design, the team will focus on measuring tension in simple interrupted sutures.



**Figure 8:** Basic Suture Patterns [14].

The client primarily uses Maxon, Biosyn, and PDS for their sutures. Maxon is an absorbable monofilament made from polyglyconate (glycolide and trimethylene carbonate) [15]. Biosyn is another absorbable monofilament made from Glycomer 631 [16]. Polydioxanone or PDS is a synthetic absorbable monofilament homopolymer of poly(p-dioxanone) [17]. PDS generally exhibits higher maximum tensile strength and lower stiffness [3]. Biosyn absorbs much more quickly and has better flexibility. Maxon has similar material properties of absorption and strength to PDS, but Maxon exhibits greater memory [18]. Since these sutures all have different material properties, the tension required for a secure knot will vary by material. Therefore, only one of these suture materials will be selected in our preliminary design, and the team will work to expand to multiple material types in future prototypes.

Lastly, there are various suture thread diameters standardized by the United States Pharmacopeia (USP) scale (Figure 9) [19]. Larger numbers followed by a zero indicate thinner suture material, while larger numbers without zeros indicate thicker sutures. Suture size affects knot security, as thicker suture sizes are more difficult to plastically deform, while thinner sutures are more prone to material failure during tightening. During the preliminary design phase, the team will pursue 2-0, 3-0, and 4-0 sizes and later expand the range of compatible suture sizes. In the future, this system will be further developed to accommodate additional suture patterns, materials, and thread diameters.

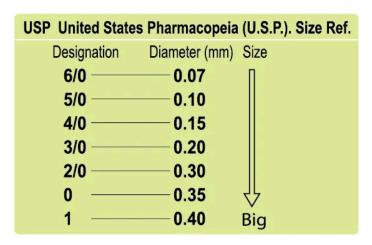


Figure 9: Example Suture Sizes [20].

### **Client Information**

The client, Dr. Margene Anderson, from the Veterinary School of Medicine, oversees educational advancement and faculty development. Dr. Anderson serves as the primary point of contact for the project. Dr. Paul Merkatoris, a large animal surgeon, and Dr. Sara Colopy, a small animal general surgeon, also support this project. They teach veterinary students and provide the team with clinical insight into the suturing process. Together, they provide feedback throughout the design process to ensure that the device is feasible, functional, and meets the project's needs. Additionally, the clients have taught the team proper suture techniques to deepen the team's understanding of the project needs and strengthen design ideas.

## **Product Design Specifications**

This system shall be designed to provide objective, real-time feedback on suture knot tension with a feedback latency of less than or equal to 3 seconds. If a quantitative measuring system is used, the tensioning device must withstand forces up to 30 N, with a working range of 0-20 N and accuracy of  $\pm 0.5$  N [19, 21]. The feedback must be immediate and intuitive to the user through a visual or sound indication. The training system must be durable and withstand repeated use by students learning in the skills lab. It must survive over 500 training cycles without mechanical or electrical failure. Any electrical components shall be well below shock hazard thresholds per IEC 62368, and compliance with IEC 61010-1 to ensure electrical safety of the device [22, 23].

The device shall not interfere with the user's ability to perform a suture technique. To ensure seamless integration into suturing workflow, the system shall not increase suturing time by more than 15 seconds. The device must be compatible with different suture sizes, including 2-0, 3-0, and 4-0 diameters, through a calibration process. Lastly, the total device cost shall remain within the client's budget of \$250, with a potential for an increase in funding for this project. Additional details on the Product Design Specifications can be found in Appendix A.

# **Preliminary Designs**

#### Visual Knot Characterization

Currently, trainees' knots are evaluated visually by an instructor to determine whether the suture has achieved sufficient tension to induce plastic deformation and ensure the final throw is adequately secured. During this evaluation, instructors look for gaps between the final throw and the base of the knot, as well as signs of unraveling; both of which indicate insufficient tightening.

The proposed solution aims to automate this assessment using an overhead camera combined with a machine learning model to analyze the knot directly. Rather than relying on instructors to provide feedback after the procedure, this system would optically detect loosening in real time, enabling students to immediately recognize whether they have applied proper tension. This reduces the delay between performance and feedback, making it easier for trainees to associate knot security with the technique and force they applied.

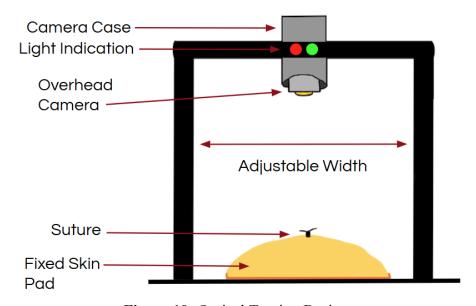
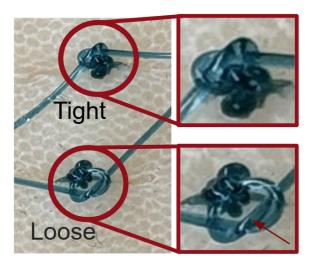


Figure 10: Optical Tension Design.

The proposed design is shown above in Figure 10. The training module would consist of a sturdy frame with adjustable width to accommodate different users, and a fixed, interchangeable skin pad to maintain consistent imaging conditions. An overhead camera is housed in a removable case attached to the frame and is connected to a red/green light for real-time feedback.

This design concept does not utilize direct measurement of the tension in the suture, but rather would be trained to evaluate knots the same way instructors do currently. Machine learning (ML) is a subset of artificial intelligence (AI) that is focused on enabling machines to learn from provided data to improve their performance without being explicitly programmed. For this design concept, a machine learning model could be trained on a large dataset of knot images,

such as the one pictured in Figure 11, to learn visual features that distinguish secure knots from insecure ones. The process would involve extensive image training and exploration of the most effective methods for visual recognition. Potential features include pixel coloration differences within the gap between the final throw and the base of the knot (as shown with the red arrow in the bottom right corner of Figure 11), variations in knot diameter between tight and loose knots, or other extractable characteristics relevant to assessing knot quality.



**Figure 11:** Comparison of square knots: the top knot demonstrates correction tension, while the bottom knot illustrates insufficient tightening.

## Displacement as an Indicator of Plastic Deformation

Another method that can be used to determine when a suture knot is sufficiently tightened is to use displacement values as an indirect indicator of plastic deformation in the suture material. Displacement values are dependent on both the suture's material properties and diameter, and would first need to be characterized and validated through controlled mechanical testing. The proposed design concept, illustrated in Figure 12, incorporates a location sensor that tracks the position of the user's hands in a defined coordinate system before and after the knot of the final throw is pulled tight. This allows the system to calculate the total displacement and provide real-time feedback to the user with a visual indicator (e.g., a green light) when the target displacement is reached. Compared to force-based measurement, displacement is a simpler and more accessible parameter to monitor; however, challenges such as grip slippage during knot tying may result in inaccurate readings.

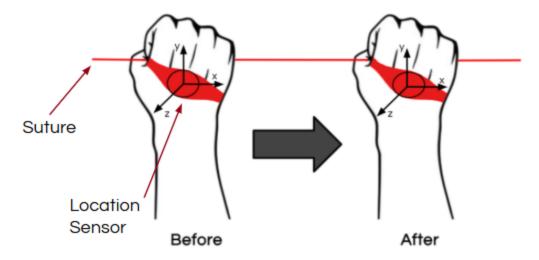


Figure 12: Location Sensor Design to Measure Displacement.

#### Tension or Force as an Indicator of Plastic Deformation

Force is the intensity of the push or pull of an object. Measuring the force of the trainee's pulling, pinching, or tightening motions are all methods of capturing and quantifying the suturing process and provides insight into their technique, precision, and control. Using force offers a means of assessing suturing proficiency in a measurable and repeatable way.

One simple way to determine the force of pinching or pushing on the suture is with the use of force sensor resistors (FSR). These sensors detect the force applied to them and respond by changing their resistance value. Some FSRs are commercially available with calibration charts that directly correlate specific resistance values with force values. Others, however, require manual calibration using standardized weights and a system to map resistance to force. This system would be incorporated into a wearable glove and wrist-mounted design that allows for minimal interference of the procedure, shown in Figure 13. In this concept, the force sensors would be sewn into the glove at critical contact points. Wires embedded in the glove would connect these sensors to a compact digital processing unit housed on the wrist. This unit would interpret sensor data in real time and provide immediate feedback to the user via visual indicators, such as LED lights. Testing and iteration would be necessary to determine the optimal placement of the FSRs on the glove, ensuring minimal interference with the trainee's hand movements and maximum accuracy in force capture.

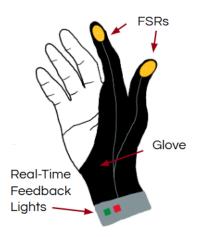


Figure 13: Wearable FSR Design.

A second critical aspect of evaluating suturing technique is the tension applied to the suture thread during the final knot-tightening phase. Excessive tension may damage the suture, while insufficient tension will cause the knot to slip. To measure this, a tensiometer can be incorporated into the training process as a temporary attachment to the suture.

One option is a three-pronged tensiometer, shown in Figure 14. This device can be clipped to the free end of the suture just before the knot is tightened. As the trainee pulls the thread, the downward movement of the bottom prong reflects the tension applied. An internal sensor measures the displacement and correlates it to a tension value.



Figure 14: Three-Pronged Tensiometer Design.

Alternatively, a spring-loaded tensiometer offers a more dynamic approach. In this design, see Figure 15, the trainee loops the suture through the hook or pulley mechanism connected to a calibrated spring. As they pull the suture to tighten the knot, the spring stretches. The distance of spring displacement corresponds to the force exerted, which can then be converted to tension values using pre-established calibration data.

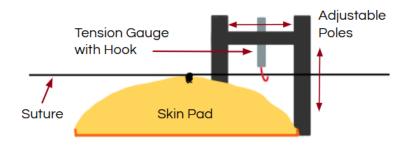


Figure 15: Spring-Loaded Tensiometer Design.

Both of the tensiometer designs require integration with a digital feedback system, ideally providing real-time feedback through visual cues, including LED lights or haptic feedback (like vibration). This would allow trainees to immediately understand if they are applying too much or too little tension during knot tying.

The integration of FSRs and tensiometers in surgical training tools offers a quantifiable data-driven approach to assessing and improving suturing skills. Future iterations could incorporate Bluetooth or Wifi modules for data logging and remote evaluation. By combining wearable sensor technology with intuitive feedback mechanisms, this system has the potential to significantly enhance training outcomes, promote muscle memory, and reduce variable performance across trainees.

# **Preliminary Design Evaluation**

Table 1 presents the design matrix used to evaluate each of the design concepts against the criteria outlined in the product design specifications (PDS) in Appendix A. The highest-weighted criterion is functionality, defined as the device's ability to provide objective, real-time feedback on suture tension. The tool must provide feedback during the suturing process so that students can learn to recognize when proper tension has been achieved.

The second most important criterion is integration with the suturing workflow that students are currently taught. The device should simulate natural suture technique while providing feedback; if it interferes with existing methods or introduces non-standard movements movements, it risks reinforcing improper technique post-training

Durability is also a key consideration as the training tool will undergo repeated use by trainees. Additionally, because sutures vary in diameter and material, the design must be adaptable or able to be calibrated to accommodate these differences.

Finally, feasibility and affordability are included to ensure the selected design can be realistically developed within the team's available resources, time, and budget over the course of the school year.

	Visual Knot Characterization		Force Sensing Glove		<b>Location Sensor Design</b>	
	Unweighted	Weighted	Unweighted	Weighted	Unweighted	Weighted
Functionality (25)	3	15	5	25	3	15
Workflow Integration (20)	5	20	2	8	3	12
Durability (15)	4	12	1	3	4	12
Adaptability (15)	4	12	4	12	2	6
Feasibility (15)	3	9	5	15	5	15
Affordability (10)	2	4	4	8	4	8
Total (100)		72		71		68

**Table 1**: Design Matrix for evaluation of measurement methods.

#### Evaluation: Visual Knot Characterization

The visual method of knot characterization scored highly for workflow integration because it relies only on an overhead camera, introducing no physical obstacles and preserving natural suturing technique. Its durability is ranked highly, as the design is not subject to direct mechanical loads. The design's adaptability benefits from consistent visual characteristics of secure versus insecure knots across different suture types, unlike mechanically based designs that require calibration. However, this concept scored lower in functionality because providing real-time feedback is more complex than in other designs; the system must analyze multiple frames per second with a machine learning algorithm and translate the results into usable feedback. Feasibility and affordability were also ranked lower due to the need for an expensive, high-definition camera and extensive image training to support machine learning, an area the team currently has limited experience in.

#### Evaluation: Force Sensing Glove

The force sensing glove received varied scores across multiple categories, showing its strengths and weaknesses in comparison to the other designs. The glove scored highest in functionality and feasibility because it has strong practical utility in capturing force data during use and offers a technically achievable and implementable design. This design also scored low in workflow integration and durability, two categories that are codependent. With integration of the glove, this option causes the most disruptions to the suturing process. Consequently, because it is constantly under a mechanical load, it might not withstand repeated or prolonged use without

degradation and sensor impact. Lastly, the glove received a relatively high score in both adaptability and affordability. This indicates the design can be used across different suture sizes and materials. Additionally, the components to create the design are inexpensive and widely available.

#### **Evaluation: Location Sensor Design**

The location sensor design scored highly in the feasibility category due to its use of displacement as a measurement parameter, which is comparatively simple and accessible to implement. It also received strong scores in affordability and durability because the location sensor and visual feedback circuitry are generally low-cost and expected to remain reliable under normal operating conditions. However, functionality was rated lower because grip slippage during knot tying could lead to inaccurate displacement measurements. In terms of workflow integration, potential issues may arise from the sensor's placement on the user's hand, which could interfere with natural hand movements. Additionally, the adaptability of this design is more limited than other options, since displacement thresholds must be predetermined through mechanical testing for each specific suture material and size.

## Final Proposed Design

The visual knot characteristics design has been selected as the primary proposed solution. It was chosen due to its close alignment with current analysis techniques, minimal interference with suturing techniques, and advantageous adaptability and durability compared to other designs. Conceptually, it is the most promising option. However, the complexity of training a machine learning model and the significant coding required make it less feasible at this stage. To balance promise with practicality, the team has decided to split efforts: half of the members will focus on building a database for image training and beginning preliminary work on the knot characteristics design to ensure its viability before committing full resources, while the other half will develop a prototype of the force-sensing glove. The glove design is more affordable, simpler to fabricate, and ranks highly in terms of functionality because of its ability to provide real-time feedback using a force-sensitive resistor.

## **Fabrication**

#### Materials

Visual Knot Characterization Materials

A majority of the work this semester to create the knot characterization design will focus on building a large database of suture knot images and training a machine learning model to recognize the characteristics that differentiate a tight knot from a loose one. To accomplish this, the team will need to obtain both knot-tying materials and imaging equipment.

The client has provided various sizes of surgical sutures, a suture practice pad, and surgical instruments, including: forceps, scissors, and thumb forceps. For consistency, the initial database will be built using 3-0 sutures, as this size is commonly used for closure of thick skin, fascia, muscle, and tendon repair, and was recommended by the client [24].

The team has evaluated camera options to ensure sufficient resolution for capturing clear images of knots. A standard iPhone camera or a digital camera will be used for preliminary data collection to validate an approach before committing a large portion of the budget to specialized equipment. For higher-quality imaging, the team has identified the DinoLite Digital Microscope as a potential option. This is a handheld microscope composite camera (AV/Video RCA output) that is compatible with Windows and offers features such as measurement, calibration, geotagging, and edge detection [25]. This camera provides a magnification of 20x-50x, 200x with a resolution of  $640 \times 480$  pixels and is pictured below in Figure 16 [25].



Figure 16: Dino-Lite Handheld Microscope Camera.

To create a machine learning model, we will need a Python environment with ML Libraries, such as TensorFlow or PyTorch. PyTorch is an open-source machine learning library developed by Meta AI, and it is optimized for unstructured data like images, where deep learning can automatically extract features [26]. This platform will be used for initial prototyping, and adjustments will be made as needed.

In addition to the visual characterization component, a frame will need to be fabricated to hold the camera in a consistent position, as shown in Figure 10. The team has considered fabricating the frame with 3D-printed PETG filament due to its resistance to water, UV light, and temperature. However, there is concern that the available 3D printers may not be large enough to produce a frame of the desired size. Because the frame is not required until the machine learning model has been developed, this is a lower priority and will likely be addressed next semester, assuming the design concept remains unchanged.

### Force Sensing Glove Materials

To fabricate the force sensing glove, the team will utilize textile and structural materials, sensors and electronic components, and calibration tools. The glove will be composed of a tight-fitted material, like neoprene or spandex. For sewing the sensors onto the glove wall, thread or conductive thread will be used. Velcro or elastic bands will be used to secure the wrist-mounted processing unit.

To create a functional electronic circuit, two to three FSRs are required with a microcontroller to process the data and control feedback. An analog-to-digital converter (ADC) will be used to convert the FSR's analog signal to digital values for processing. Resistors are needed for the voltage divider circuit and LED indicators, green and red, will depict the system output to the user. Long wires or connection cables will be used to connect the sensors to the processing unit, and a battery is required to power the system.

Standardized calibration weights will be used to model the force-resistance curve for the sensor used. A 3D printed wrist housing model will be created using PLA or Carbonfiber.

#### Methods

## Visual Knot Characterization Methodology

The initial phase of the prototyping process will involve building a dataset of square knot suture images preprocessed and classified as pass or fail. All images will need to be validated by the client to ensure correct labeling. OpenCV will be used to preprocess the images, including cropping, resizing, and reducing background noise to ensure consistency and to prepare them for training. The preprocessed images will be divided into three datasets: a training set for model learning, a validation set for tuning hyperparameters, and a testing set to evaluate the model's performance, each containing 100 images. Each image in the training set will be labeled as 'tight' or 'loose' based on client validation.

To expand the dataset and improve model robustness, data augmentation techniques, like rotation, flipping, and brightness adjustments will be applied to generate additional variations of existing images. The processed images will then be used to train a convolutional neural network (CNN) in PyTorch, a type deep learning model well-suited for image classification tasks .

During training, the model will iteratively make predictions of the output, calculate the error, create derivatives of the error with respect to its parameters, and update those parameters using gradient descent. Key hyperparameters, including batch size, number of epochs, and learning rate, will be defined to guide this optimization process. Each epoch will include a training loop for model learning and a validation loop to monitor performance improvements. Through repeated optimization, the model parameters will be adjusted to minimize error with each training step. Once the model achieves sufficient accuracy, fabrication on the main frame and camera housing unit will commence.

### Force Sensing Glove Fabrication Outline

The fabrication of the force-sensing glove system will ensure functionality, accuracy, and user comfort. A form fitting glove will serve as the base for sensor integration, prioritizing flexibility and minimal interference with hand movements. FSRs will be sewn into the critical contact points on the glove, likely the thumb, index finger, or palm. This will be done with fabric glue, adhesive pads, or non-conductive thread. Care will be taken to ensure the sensors are flush with the glove surface and do not shift during finger movement. The FSRs are integrated into a voltage divider circuit, shown in Figure 17, using resistors matched to the FSR's range. This circuit is necessary to convert varying resistance into measurable voltage signals. Wires are routed along the surface on the inside lining of the glove, securely linking the sensors to a small microcontroller on the wrist. The enclosure housing the sensor will be 3D modeled and printed to hold a rechargeable battery and voltage regulator.

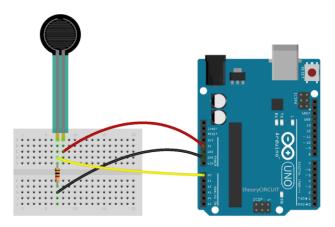


Figure 17. Voltage Divider FSR Circuit.

Once the hardware is assembled, the system will undergo calibration using standardized weights to apply known force values to the sensor. The data will be used to generate a calibration curve to convert sensor readings into actual force measurements.

The microcontroller is programmed using the Arduino IDE to continuously read the analog voltage from each FSR, convert it into force using the calibration data, and output feedback. Real time feedback is implemented via external LEDs that change color or intensity based on the level of force applied. This will provide immediate visual cue to the trainee.

# **Testing and Results**

## Suture Tensile Strength Testing

To define the material properties of different suture sizes and brands, the team will perform tensile strength testing using a MTS Criterion Model C42.104 and a TW elite data

acquisition program. For each suture type, a knot-pull test will be conducted to replicate the mechanical conditions experienced during the final throw in a square knot. The test set-up is represented clearly in Figure 18 below. For each test, approximately 3-5 square knots will be tied and positioned in the center of the load cells to ensure symmetrical loading [27].

The samples will be tested at a strain rate of 50 mm/min using a low capacity load cell (≤100 N) to ensure an accurate measurement at low tensions typical for suture materials. Multiple samples will be tested to gather mechanical data on a wide range of suture sizes, materials and manufacturers.

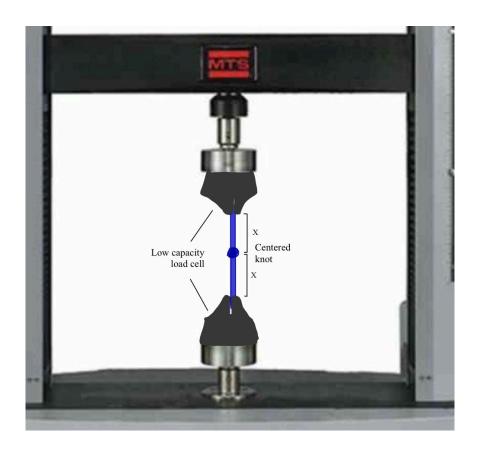


Figure 18: MTS Tensile Strength Test Set-Up [28].

After data collection, the raw force-displacement data will be exported in text file format for post-processing in MATLAB. With this data, stress-strain graphs will be generated to identify key mechanical parameters, including the plastic and elastic deformation ranges, yield strength, and ultimate tensile (fracture) strength. The plastic deformation tension range derived from mechanical testing will be used to construct and calibrate the team's force censoring glove prototype.

## **Prototype Testing**

The two fabricated prototypes, which use visual knot identification using AI and a force sensor glove will be tested to evaluate specific design requirements.

## Visual Knot Identification using AI

Once the team's machine learning model has completed training, accuracy and reliability will be assessed during the validation and testing phases.

If the team develops the model using Python, we will use the K-Fold cross validation method to help the model generalize beyond the training data and improve the robustness while minimizing bias. This method involves splitting the data into 10 smaller subsets (folds) containing 10 images each of secure and loose knots. For each of the 10 experiments, K-1 folds will be used to train the model and the remaining 1 fold to test the model. The test fold will rotate each time, ensuring that all 100 knot images are ultimately evaluated [29].

To assess performance beyond the raw accuracy, the team will perform testing reliability using a F1- score and error analysis during the training phase. The F1 score will provide insight into the model's precision and recall using the equation shown in Figure 19. A baseline F1-score of 0.8 will be used to determine whether the AI model meets the desired performance threshold. The error analysis will further investigate mistakes in the model to determine if they are random or concentrate around certain cases.

Precision 
$$\frac{tp}{tp+fp}$$
 Recall (Sensitivity) 
$$\frac{tp}{tp+fn}$$
 F1-score 
$$\frac{2*precision*recall}{precision+recall}$$

**Figure 19:** Equations to calculate precision, recall and F1-Score. Variables include true positives (tp), false positives (fp), and false negatives (fn) [30].

If the team finalizes use of the Pytorch development platform, we will utilize the program's provided validation and testing methods to evaluate model performance. Additional testing will be conducted on the fully assembled prototype once the AI model can accurately and reliably identify a secure square knot.

### Force Sensing Glove

Testing of the force sensing glove will focus on two primary objectives: evaluate the prototype's impact on suturing technique and usability, and assess the accuracy and consistency of the sensor in detecting the applied force that corresponds to the optimal knot tightness. Once the prototype is fully assembled and functional, the team will test the accuracy of the calibration to confirm that the force reading corresponds accurately to known tension values. Any discrepancies between the glove's reading and the reference measurements will be corrected through recalibration.

Following calibration, user testing will be conducted to evaluate the device's performance during realistic learning suturing conditions. A large sample size of participants will be recruited to account for variability in hand size, grip strength, and knot-tying technique. Each participant will be asked to tie a series of knots with and without the force sensor glove. The data will be used to evaluate whether the glove accurately and consistently detects the force range associated with a properly tightened knot and measure suturing times to determine whether the device interferes with natural technique or speed. Participant feedback will also be collected regarding comfort, flexibility, and ease of use. Results from this testing phase will guide further refinements to the initial force-sensing glove prototype.

## **Discussion**

## **Ergonomics**

The device chosen should accommodate for bias and inclusivity within its design. Namely, trainees' hand sizes, grip strength, and dexterity may affect how users interact with the device. The knot characteristics AI model will accommodate this due to limited human interaction with the device. The force sensor glove would need to be one size fits all or be commercially available in different sizes. Additionally, the sensor placements will need to vary depending on the size of the glove to address variabilities in the suture procedure due to hand size and dexterity. Another key consideration of the design will be novice versus advanced trainees. The designs need to be intuitive and not reliant upon expected force or speed values that are expressed by experienced surgeons. Next, the design must accommodate a multitude of training contexts. While the School of Veterinary Medicine at the University of Wisconsin -Madison hosts training in a clean, large, and resourceful room, to address widespread suture applications, the design should be adaptable to varying training environments. This involves utilizing low-cost materials, having offline functionality, and modular components for use in developing areas. Lastly, the interface should accompany a culturally neutral system that provides consistent feedback. It needs to avoid idiomatic language, confusing graphics, and assumptions about prior knowledge.

#### Ethical Considerations

Although the device will not be incorporated into patient healthcare settings, ethical concerns can arise in how the device is marketed, adopted, and relied upon in training environments. Firstly, if the device gives inaccurate feedback, it can reinforce poor technique. The training tool must undergo rigorous validation and calibration. To increase device accessibility and equity, the system should maintain a low-cost structure, low maintenance, open-source software, and proper licensing. To reduce the probability of trainees' dependence upon the device for feedback, the solution should build judgment and encourage reflective practices, not just mechanical repetition.

## Sources of Error

While the knot characteristics and FSR circuit designs presented earlier are proper indicators of tension and the suturing procedure, both have multiple sources of error that could pose testing and efficacy concerns. In the knot characteristics system, lighting and imaging conditions (including shadows, glare, and ambient light changes) are crucial to the AI models' ability to recognize and identify knot features. Variability in suture material and color will also affect pixel values used in training prediction and lead to misclassification of secure and loose knots if the model is not trained on diverse data. Variations in knot configuration and technique (including hand dominance, technique, and angle of pull) can result in visually correct knots that differ from those in the training set. This can cause incorrect diagnoses of tight knots like false negatives and false positives. Another large concern for the AI training process is overfitting and underfitting. Overfitting occurs when the model becomes too tailored to the training model, causing it to perform poorly in general use. Underfitting will not allow the model to capture nuanced differences between secure and insecure knots. Lastly, for the knot characteristics approach, latency in providing feedback could confuse trainees and provide incorrect associations between their actions and feedback received.

In the FSR glove, most of the sources of error revolve around the sensor itself. For example, the FSR sensor requires precise calibration. Without this, the force readings will be inaccurate and calibration can drift over time, reducing reliability. Additionally, sensor placement will greatly vary the force output results. Incorrect sensor placement can fail to capture key pinch or pull forces or falsely record pressure from non-relevant movements. Optimal sensor placement may vary between users, hand size, and technique. Lastly, movement artifacts from unrelated hand movements can introduce noise or unintended pressure in dynamic suturing tasks. Glove material might affect adjacent readings.

## **Conclusion**

In conclusion, the proposed suturing training device addresses a critical gap in veterinary education by providing real-time, objective feedback on suture tension. This skill is essential for surgical success but difficult for novices to master. By utilizing optical analysis through a

machine learning model or force-sensing wearable technology, the proposed designs offer versatile approaches to skill development that mirror instructor assessments while reducing subjectivity and feedback delays. These innovations have the potential to improve learning efficiency, reduce material waste, and promote animal welfare by ensuring students develop proper technique before operating on live patients. While technical and logistical challenges remain, continued development and validation of these initiatives could significantly enhance the quality and consistency of surgical training in veterinary programs.

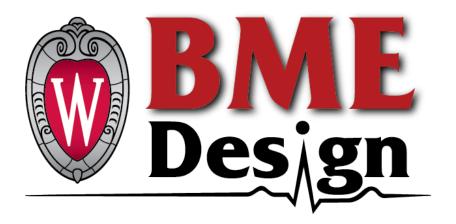
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# **Appendices**

# Appendix A: Product Design Specifications



Knot too Tight - Not too Loose

PRODUCT DESIGN SPECIFICATIONS (PDS)

**BME 400** 

#### **Team Name:**

The Knotorius Five

### **Team Members:**

Madison Michels (Team Leader)

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Kate Hiller (BSAC)

Sadie Rowe (BPAG)

Presley Hansen (BWIG)

#### **Client:**

Dr. Margene Anderson

#### Advisor:

Professor Walter Block; University of Wisconsin - Biomedical Engineering Department September 18th, 2025

#### **Function/Problem Statement:**

In veterinary training, mastering the skill of applying appropriate suture tension is essential for successful wound closure and patient recovery, However, novice practitioners often struggle to judge the correct amount of force needed, leading to either insufficient tension or excessive tension, which can cause failure of the suture material or tissue damage. Currently, the evaluation of suture technique relies heavily upon subjective instructor feedback, lacking objective, real-time metrics to guide learners. This gap hinders consistent skill development and increases the risk of procedural errors. There is a critical need for a real-time suture tension measurement and feedback system to help students learn to apply optimal tension, prevent material or tissue compromise, and improve surgical outcomes through data-driven training.

#### **Client requirements:**

- Provide real-time feedback.
- Give veterinary students an indication when suture is pulled with correct tension and speed.
- Prefers the device to be minimally disruptive to the suturing process.
- Measure tension during the final throws of the square knots.

#### **Design requirements:**

- 1. Physical and Operational Characteristics
  - a. Performance Requirements
    - i. The sensor must correctly measure the speed and tension of a suture.
    - ii. The device must contain a display that identifies a range of force and speed required to plastically deform a suture in order to secure a square knot.
    - iii. Sutures vary in both material and width to accommodate the different force required to close wounds on animals of various sizes, therefore, each suture type demands a unique force and speed to secure a square knot [1]. The device should allow for calibration to different sutures, allowing it to be used across multiple suture types.

### b. Safety

- i. The device shall not interfere with the ability of the user to perform a suture technique. Interference can pose a safety risk as the user is handling many surgical tools, including sharp objects such as the suture needle.
- ii. The device shall be made with a material that is smooth, disinfectant-resistant, and easy to clean. Ensure compliance with ISO10993 if in contact with live tissue.
- iii. There shall be electrical safety in the device:
  - 1. Voltage and current values shall be well below shock hazard thresholds per IEC 62368 [2] [3].
  - 2. All exposed wire (if any) shall be insulated.
  - 3. There shall be a current limiter to prevent device overheating.
  - 4. Compliance to IEC 61010-1. This international standard outlines safety requirements for electrical equipment used in measurement, control, and laboratory applications [4].
  - 5. If the device requires a charging component, the charger shall be compliant to IEC 62368-1 international safety standard for ICT and AV equipment [2].
- iv. There shall be mechanical safety in the device:
  - 1. There shall be a maximum force limit, the load applied shall not exceed safe values.
  - 2. The device shall be stable to prevent tipping or moving unexpectedly during use. The electrical components shall be secured in or on the device.
  - 3. The moving parts of the device shall be enclosed or guarded to ensure user safety.

#### c. Accuracy and Reliability

- i. The tensioning device must withstand forces up to 30 N, with a working range of 0–20 N [5].
- ii. The force sensor must have an accuracy of  $\pm 0.5$  N to ensure measurements are close to the actual force within the working range [5], [6].
- iii. The force sensor must have a sensitivity of 0.1 N to reliably detect small changes in tension, giving users realistic feedback for training purposes [6].

#### d. Shelf Life

- i. The device will be used each semester in a training environment. During storage over break periods, it must maintain full functionality when returned to normal operating temperature and humidity conditions.
- ii. Shelf life is not a priority constraint for this device.

#### e. Life in Service

- i. The sensing element should withstand repeated use during training sessions. Additional discussions with the client will be conducted to determine the required number of tensioning cycles the device must endure without performance degradation, where each cycle consists of one application and release of tension in the suture.
- ii. The device must withstand cleaning after each training session involving biological material, including a thorough wipe-down with a disinfectant solution, without loss of functionality.

## f. Operating Environment

- i. Non-electronic components must tolerate disinfectant wipes and incidental contact with biological material without structural or functional degradation.
- ii. The device must maintain functionality under normal operating temperatures and humidity.

## g. Ergonomics:

- Users should be able to tie knots with their hands close to the practice pad, mimicking real surgical technique. The device must not cause awkward reaches or unnatural hand angles.
- ii. The device should not noticeably alter the resistance or feel of knot tying.
- iii. Real-time feedback should be intuitive and immediate, delivered through vibration, LED, or audio cues.
- iv. The device should integrate smoothly with existing training methods so users do not have to adjust their typical working posture.

#### h. Size:

i. The sensing element should remain compact to ensure users can practice in a realistic, unobstructed space.

ii. If used in future surgical use, the device must maintain a low-profile form that does not obstruct access to the wound site. The device should not be larger than a table-top device to maintain these requirements.

### i. Weight

- i. The device should be lightweight to avoid fatigue or unreasonable movement during suturing practice.
- ii. The device should feel unobtrusive in use, so users focus on knot tension rather than compensating for added weight.

#### i. Materials

- i. The device should be made of lightweight, rigid materials to maintain low weight and structural integrity.
- ii. Internal electronics should be housed in a compact, lightweight, and protective enclosure to prevent damage.
- iii. If used for future clinical applications, materials should be biocompatible and sterilizable.

### k. Aesthetics, Appearance, and Finish

- i. The device should have a clean and professional appearance appropriate for training and potential clinical environments.
- No specific color, style, or finish is required, but finishes should support durability and user comfort.
- iii. All surfaces should be smooth and free of sharp edges to ensure safe handling during practice or surgical use.
- iv. Visual indicators, such as LEDs or labels, should be clearly visible without distracting from the suturing task.

#### 2. Production Characteristics

#### a. Quantity

i. According to the client, one device is required for teaching purposes. After fabrication, testing, and approval from the client more devices could be created to upscale the number of students that can learn at a time during a lab section.

Additionally, this product could be applied to industries aside from veterinary applications, so more could be replicated for teaching in human applications.

#### b. Target Product Cost

 The client has provided \$250 for the project budget with room for negotiation and increases as necessary. This cost, however, will include testing materials, sutures, and the design itself.

#### 3. Miscellaneous

# a. Standards and Specifications

- i. This device shall comply with FDA standards as it is, by definition, a medical device as it is "intended to affect the structure or any function of the body or other animals..." [7] The device is utilized in conjunction with the user to complete suture knot tying, which affects the structure of the body.
- ii. ISO 14971:2019 Risk Management [6]
  - 1. Risk analysis through Failure Modes and Effects Analysis (FMEA) should be completed to identify potential risks for the patient, operator, and property. This includes gathering data and reviewing literature about the risks of similar medical devices. This standard states that the concept of risk involves the probability of the occurrence of harm and the severity of its consequences.
- iii. Code of Federal Regulations, Title 21, Chapter 1, Part 803 [9]
  - Manufacturers and facilities that use the device must report deaths and serious injuries that the device has caused or contributed to through a Medical Device Report (MDR).
- iv. IEC 61010-1:2010 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use [10]
  - 1. Surface temperature limits for protection against burns
  - 2. Protection against electrical shock
  - 3. Resistance to mechanical stress
  - 4. Protection against the spread of fire
  - 5. Protection against hazards from fluids

- v. ISO 12100:2021 Safety of machinery General principles for design Risk assessment and risk reduction [11]
  - This standard establishes a strategy for risk assessment, identifying hazards, and risk reduction in machinery design. If the device incorporates any mechanical or machinery components, compliance with the standard is required.
- vi. ASTM F2458-05:2024 Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants [12]
  - This test method shall be used to evaluate the force values of a suture, allowing for the assessment of material properties and failure of the suture material. This test method is for comparing bonding processes for susceptibility to fatigue, mode of failure, and environmental changes.
- vii. ISO 10993-1:2018 Biological Evaluation of Medical Devices [13]
  - 1. The device shall be biocompatible as the device is in contact with live tissue (user and potentially patient).
  - 2. Further biocompatibility testing shall be completed if the device is to be used during surgical procedures to ensure hemocompatibility.
- viii. IEC 60601:2015 General requirements for medical electrical equipment [4]
  - 1. This standard outlines the basic safety and essential performance of medical electrical equipment.
  - 2. This standard includes identifying and testing the operating temperature of the device.

#### b. Customer

i. The initial device is intended for students at the University of Wisconsin-Madison School of Veterinary Medicine. The device will primarily be used in the curriculum of the first and second year students, as it is intended for beginners in suture techniques. However, the device has the potential to benefit students across broader areas of medicine, including medical schools, dental schools, and other healthcare training institutions.

#### c. Patient-Related Concerns

- i. If the device were to display inappropriate feedback for the correct tension or speed while securing a knot, students would learn incorrect suturing techniques that could translate to the quality of suture on live animals later in the student's career. This puts animals at risk for wound dehiscence after surgery if the square knots are not secured correctly.
- ii. Surgical wound dehiscence can lead to infection, excessive scarring, and necrosis on the wound site [14], all of which compromise the welfare of animals.
- iii. Additionally, poorly thrown sutures on cadavers limit their future use for training and increase the demand of additional animal cadavers in academic settings.

## d. Economic Impact

- The cost of the suture varies depending on suture material, but the average cost of an individual monofilament absorbable suture is \$1.75 - \$1.83 per stitch [15].
   Real-time feedback on tension and speed can decrease learning time and ultimately lower the amount of suture material needed for practice.
- ii. If improper tension is applied to sutures, stitches have a higher chance of breaking or unraveling. Depending on the size of the open wound, additional procedures might be necessary. Suture procedures cost can range from \$50 \$1,000 to cover expenses for personnel, medicine, and surgical instruments during an operation [16].

#### e. Competition

The use of real-time force analysis in surgical settings is scarce, but drawing recent attention due to its effectiveness in reducing heal time and improving aesthetics after incision. One notable research study conducted by T. Horseman et. al. developed three force sensor recording techniques that highlight unique approaches to installation, force detection, and functionality [6].

- i. Hook in Force (HIF) Sensor
  - 1. Shown in Figure 1, this sensor is a U-shaped device composed of two spring blades (feature C) and four plastic discs (feature A) that guide the suture material through the machine. Two discs are lined with silicone

(feature B) to prevent damage of the thread material. A magnet (feature E) and sensor (feature D) work in conjunction to measure the displacement of the device once the string is fed into the system. The design allows for a maximum detectable displacement of 3 millimeters (mm) and a minimum detectable displacement of 1 mm.

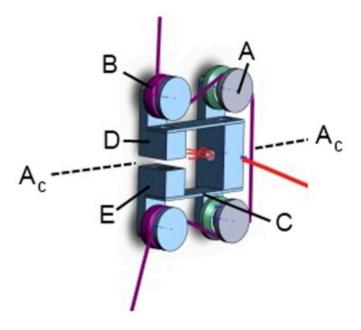


Figure 1. HIF sensor labeled diagram.

The free body diagram shown in Figure 2 displays the pulling nature of the system once a suture is threaded through. The spring blade counteracts the movement of the suture being pulled, leaving a displacement for the sensor and magnetic to measure.

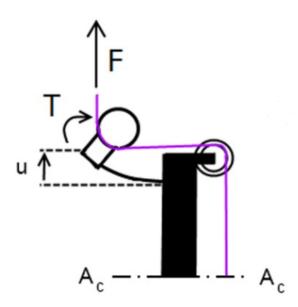


Figure 2. HIF Sensor Free Body Diagram.

## ii. Stitch Force (SF) Sensor

1. The SF sensor measures the forces required to close the tissue around a wound. It is in continuous contact with the skin and requires 2.5 mm of the incision to be positioned. Shown in Figure 3, the SF sensor includes a housing (feature A), spring blades oriented in a circle (feature B), a fissure tip (feature C), and a hall sensor and magnet (features E, G, and D). Once inserted, the thread creates a torque in the tip and relies upon the hall sensor and magnet to read the displacement of the spring blades. The resulting force is output in volts (V) [6].

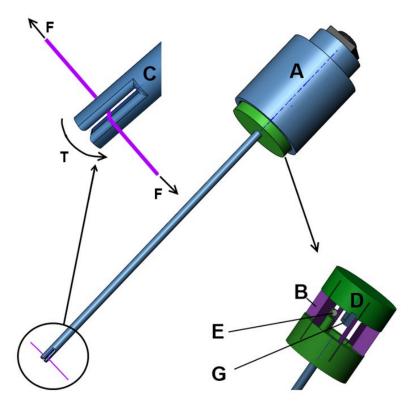


Figure 3. SF sensor labeled diagram and free body diagram.

#### iii. Wheel Sensor

1. The wheel sensor was designed to address training needs for students and practitioners. The system is designed to be simple, small, lightweight, and cheap. The wheel was laser cut with medical grade plastic, and three metal pins were placed in through holes along the edge. The wheel supports itself between two tensioned threads. The pulling force can be related to the output signal of the hall sensor after calibration. An ATtiny85 micro controller controls the system and operates at 100 hz. The entire design weighs 11.3 grams (g), but can be reduced to 8 g if a custom circuit board is used. Two LED lights guide the accuracy of the trainee, green symbolizing a safe working range for the pulling force and red depicting that the surgeon has exceeded a predefined threshold [6].

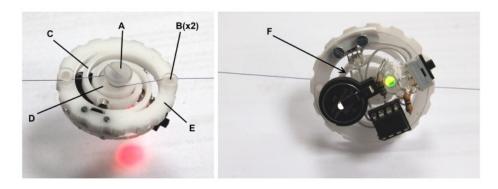


Figure 4. Wheel Sensor Diagram. A - inner pin, B - external pins, C - spiral-shaped bar, D - inner ring, E - external ring, F - embedded electronics for force feedback [6].

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