Knot too Tight - Not too Loose

PRODUCT DESIGN SPECIFICATIONS (PDS)

Team Name:

The Knotorius Five

Team Members:

Madison Michels (Team Leader)

Lucy Hockerman (Communicator)

Kate Hiller (BSAC)

Sadie Rowe (BPAG)

Presley Hansen (BWIG)

Client:

Dr. Margene Anderson

Advisor:

Professor Walter Block; University of Wisconsin - Biomedical Engineering Department

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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:

The client requests that the device provides real-time feedback, giving veterinary students an indication when a suture is pulled with the correct tension and speed to appropriately secure a square knot during both continuous and interrupted sutures. Additionally, the client prefers the device to be minimally disruptive to the suturing process and only requires the device to measure during the final throws of the square knots. This avoids tightening the suture closer to the skin while still ensuring the knot is secure.

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 ±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:
    i. 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.

j. 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.
    ii. 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
    i. 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]
            1. 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]
    1. 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]
    1. 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
    i. 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.

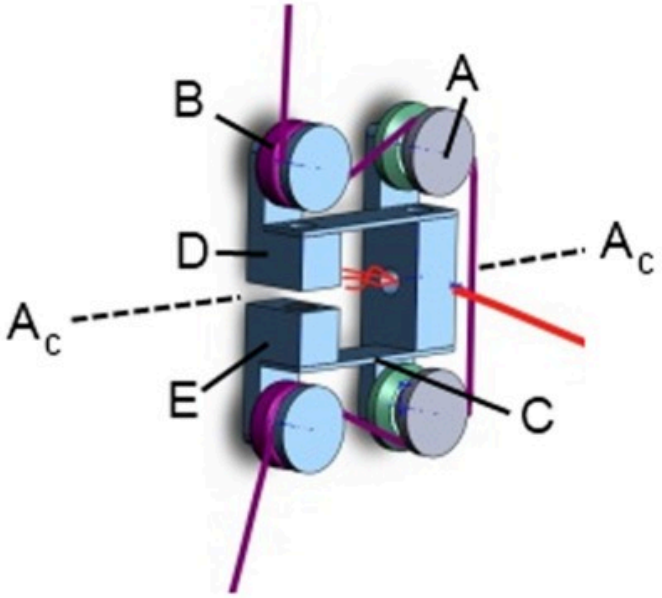

Figure 1. HIF sensor labeled diagram.

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.

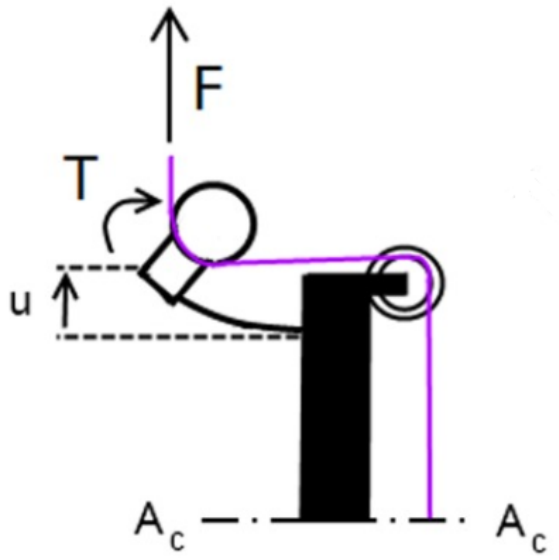

Figure 2. HIF Sensor Free Body Diagram.

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].

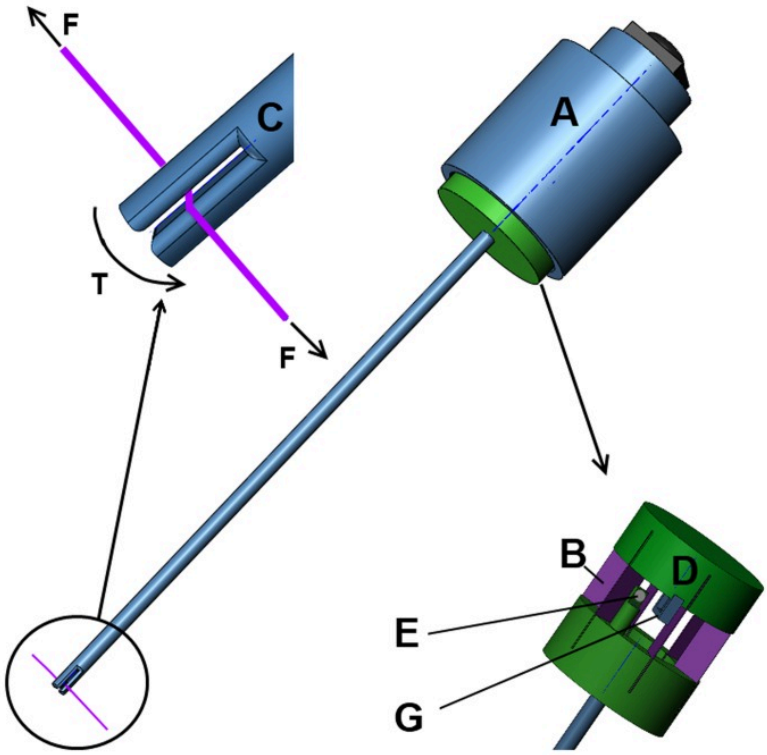

Figure 3. SF sensor labeled diagram and free body diagram.

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].

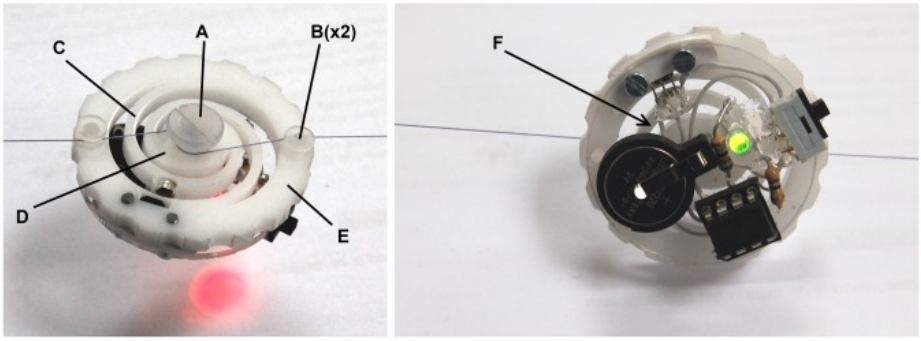

Figure 4. Wheel Sensor Diagram. A - inner pin, B - external pins, C - spiral-shaped bar, D - inner ring, E - external ring, F - embedded electronics for force feedback [6].

Resources

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