Tissue Pressure Monitoring for Anterior Cervical Retraction

Design of Biomedical Devices and Systems I

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Abstract

Anterior cervical spine conditions are commonly treated with anterior cervical discectomy and fusion (ACDF) surgery. During this surgery, the trachea, esophagus, muscles, and other surrounding tissues are retracted for the duration of the surgery. In some cases, this retraction leads to post-surgical complications, notably dysphonia and dysphagia. While no one cause has been established for these complications, some hypothesize that the issue arises from the mechanical force exerted on the tissue over an extended period of time during surgical retraction. There is a need for a method to monitor tissue-pressure during ACDF surgery to minimize soft-tissue injury and prevent post-surgical complications. Clinically used retractors are purely mechanical and offer no feedback on the amount of force applied to tissue. While work has been done to incorporate sensing elements into retractors for other types of surgeries, there is no commercial product that measures mechanical force on the retractors used for spinal surgery. The proposed design solution incorporates force transducers in two locations on the retractor. A replaceable strain gauge will be incorporated into the arm of the retractor to give a single measurement of the torque applied to the retractor as it holds back tissue. A network of force-sensitive pads will also be placed on the retractor blade to provide a spatial distribution of the forces exerted on the blade by retracted tissue. Together, this combination of force transducers provides a comprehensive summary of tissue pressure for real time monitoring intra-operatively. All components must be sterilizable and replaceable for our disposable business model. The design also must provide sensitive, real-time feedback and not interfere with normal surgical operation. Proposed future work includes fabrication of a physical prototype and testing of the prototype with bench and tissue testing. For bench testing, the sensors will be validated and calibrated by applying known forces. For tissue testing, the sensors will be applied to animal and human cadavers to assess the feasibility of using the device intra-operatively and to determine its success in measuring real tissue pressure values.

Introduction

Anterior cervical discectomy and fusion (ACDF) requires surgeons to retract the trachea, esophagus, and surrounding soft tissue to access the cervical spine. Excessive force or prolonged retraction can lead to complications such as dysphagia and dysphonia, which affect a significant number of patients and can delay recovery.[1] Despite this, current retractors provide no feedback about the pressure being applied or how long tissues have been under load.

Our project aims to address this unmet need by developing a retractor that monitors real-time tissue pressure and cumulative time-under-load. This solution has the potential to reduce preventable soft-tissue injury and improve outcomes for the large and growing population of ACDF patients. By giving surgeons actionable feedback during the procedure, our device supports safer surgical practice and enhances the standard of care.

Problem Statement

There is a need for a way to provide real-time monitoring of tissue pressure during anterior cervical spine surgery to minimize soft-tissue injury and postoperative complications from the surgery.

Disease State Fundamentals Summary

Anterior cervical spine disorders such as cervical radiculopathy and cervical myelopathy are common causes of neurologic impairment in adults. Cervical radiculopathy occurs when spinal nerve roots in the cervical region are compressed, most frequently due to disc herniation or degenerative changes like cervical spondylosis. This condition causes neck pain, radiating arm pain, numbness, and motor deficits, and affects approximately 85 per 100,000 people annually.[2] Cervical myelopathy involves compression of the spinal cord itself and is the most common cause of cervical spinal cord dysfunction in older adults.[3] Because the cervical spinal cord contains ascending sensory tracts, descending motor pathways, and neuronal cell bodies arranged in segmental organization, compression at different cervical levels produces distinct clinical deficits. Damage to the upper cervical cord may impair diaphragmatic function, while lower cervical lesions often lead to hand and wrist weakness.[4]

To treat these compressions, surgeons frequently perform anterior cervical discectomy and fusion (ACDF) or anterior cervical disc replacement (ACDR). In both procedures, access to the cervical spine is achieved through an incision in the anterior neck, followed by careful retraction of the trachea, esophagus, and surrounding soft tissues. In ACDF, the diseased disc is removed and replaced with a bone graft or interbody cage, followed by plate fixation.[5] ACDR similarly removes the damaged disc but replaces it with an artificial disc designed to preserve motion.[6] These procedures are highly effective at relieving neurologic symptoms but rely on sustained retraction of delicate soft tissues, introducing risks that are independent of the underlying disease.

Postoperative complications such as dysphagia and dysphonia are among the most common issues following anterior cervical surgery. Dysphagia occurs in up to 79% of patients in the immediate postoperative period and is associated with older age, female sex, multilevel procedures, and prolonged operative time.[7] These complications are thought to result from excessive or prolonged pressure on the esophagus, trachea, or recurrent laryngeal nerve during retraction. Although often temporary, they can significantly impact quality of life and prolong recovery.

The clinical problem our project addresses is therefore not the cervical pathology itself, but the soft-tissue injury caused by the surgical approach required to treat it. Because surgeons currently lack real-time feedback on retraction force or duration, tissue stress remains a preventable source of postoperative morbidity, highlighting the need for safer retraction monitoring tools.

Existing Solutions Summary

Current efforts to reduce complications during anterior cervical procedures focus on improving surgical access while minimizing soft-tissue injury. Traditional retractors provide the necessary exposure but offer no feedback about how much force is being applied to the trachea, esophagus, and surrounding muscles. As a result, surgeons rely entirely on experience, even though excessive or prolonged retraction is a known contributor to postoperative dysphagia and dysphonia.

Several research groups have explored ways to incorporate sensing elements into retractors to address this issue. Electrical approaches, including piezoresistive fabrics[8], piezoelectric force sensors[9], and capacitive soft-robotic designs[10], have demonstrated the ability to detect applied force with high sensitivity. Optical systems have also been tested, pairing mechanical strain measurements with physiologic indicators such as local tissue oxygenation[11]. In neurosurgery, devices like the SmartBrain Retractor integrate sensing strips onto the retractor surface[12], while simple mechanical concepts, such as deformable silicone retractors[13], offer low-cost alternatives.

Although each of these approaches demonstrates promise, they remain limited by early-stage development, narrow anatomic applications, or lack of clinical validation. None are optimized for the geometry or workflow of ACDF procedures, and no market-ready solution allows surgeons to reliably monitor retraction pressure in real time. This gap underscores the need for a device specifically designed to provide actionable feedback during anterior cervical spine surgery.

Market Assessment Summary

The U.S. market for ACDF retractor systems is relatively small but stable, with clear opportunities for innovation. Based on approximately 6,000 U.S. hospitals and registry data showing that 600-1,200 facilities actively perform ACDF, the estimated addressable hospital market for a reusable, force-sensing ACDF retractor system is approximately $7.2 mission per year, assuming a $4,000 per-set cost, a typical need of ten sets per hospital, and a five-year replacement cycle. Outpatient clinics contribute an additional $1.1 million, resulting in a total domestic market size of roughly $8.3 million. If you factor in servicing and maintenance costs, that value may reach as high as $10 million. While ACDF-specific demand is limited, this technology could be expanded to capture a share of the larger surgical instrumentation market. The total market size for all surgical retractors, not just those with ADCF, is predicted to be around $1.9-2.2 billion, which highlights the potential for incorporating these devices into the larger market.

Several global market trends reinforce this prospect. The market itself is estimated to be expanding at roughly 6.7% CAGR, driven by increases in surgical volume, the aging population, and a demand for more advanced instrumentation. A more concrete metric for our specific niche is the number of ACDF surgeries, which is predicted to increase from 153,288 cases in 2020 to 173,699 cases by 2040, according to ScienceDirect. These factors support a projected 3-5% CAGR growth within the ACDF market for the next 5 years.

Competition within the ACDF retractor market is dominated by Globus Medical, Thompson Surgical, Artisan Medical, and Carnegie Surgical. These companies sell reputable sterilized and warrantied surgical retractors that often come in large surgical instrumentation packages. In addition to these well-established competitors, additional barriers to entry are posed by strict FDA regulations and Class II medical device standards. Despite these challenges, recent developments in the field show that innovation is still achievable. Smaller companies such as Sure Retractors, Inc. and Advanced Surgical Retractor Systems, Inc. have successfully introduced products that boast improvements such as faster setup or increased radiolucency. These devices prove that well-defined technology can still gain traction in competitive landscapes.

Overall, the ACDF retractor market is modest in size but displays steady growth, with clear gaps in technology that current devices do not address. A retractor system capable of providing reliable force and pressure feedback offers a unique opportunity to improve procedure safety and enhance surgeon decision-making. Although the ACDF market is somewhat limited, the fundamental design of this sensing platform has the potential to expand outside of this niche into the much larger general surgical instrumentation market.

Design Specifications

There were several design requirements established from project discussions with mentors and team ideation, which can largely be categorized into safety and essential performance, functional performance, and mechanical integration of the system. Safety and essential performance encompass the standards necessary for use in surgery and clinical procedures, including material sterility, biocompatibility, and maintaining the original function of the retractor without alteration from the added components. Functional performance describes the added value of the new design, including the capability to detect biologically relevant force signals and provide feedback. Further details on the design specifications needed to meet these requirements were ranked according to their importance for clinical adoption, impact, and feasibility of implementation (Table 1). While ordered from highest to lowest priority, many specifications are still highly valued and are green, reflecting the demands of surgical tools. The lowest priority specification, while still relevant in a clinical setting, is marked in red; for compliance and data privacy, we would rely on the hospital to implement data encryption and management. Improvements that would enhance the device but are not essential, marked in yellow, include incorporating more durable components and improving ergonomic preference for the surgeon.

User/Customer Need	Design Specification	Source/Evidence
Sterilizable	Maintain original device sterility; compatible with standard hospital sterilization processes	CDC Infection Control, ANSI/AAMI ST79, ISO 17665/11135
Biocompatible components	All tissue-contacting components must be medical-grade:	FDA Biocompatibility Guidance, ISO 10993-1
Fail-safe operation	Retractor retains full mechanical function in the event of electronic or sensor failure	ISO 14971, IEC 60601-1
Maintain blade profile	Blade geometry and mechanical performance match original retractors	Mentor Feedback
Battery life	System must operate continuously for > 4 hours	IEC 60601-1

Sensitive detection	Sensors detect forces < 0.05 N and capture the full biologically relevant range (1-10 N)	Literature Review
Real-time feedback	Continuous, low-latency (<100–200 ms) sensor updates	IEC 62366-1
Compatible base components	System components attach securely to the existing reusable retractor	Mentor Feedback
Cable management	Cables routed to avoid interference with surgical field	IEC 62366-1
Ergonomics match standard retractor	Added system mass < 0.25 lb; must preserve surgeon grip and maneuverability	IEC 62366-1
Durability	Any reusable components must retain functional integrity after repeated mechanical use and sterilization cycles	IEC 60601-1
Data Security	The record of signals ensures the privacy and protection of the patient	HIPAA

Table 1. Ranking of design specifications.

Preliminary Design Iterations and Evaluation

Since there is no established cause for the post-surgical complications from ACDF/ACDR surgery, preliminary design iterations sought to address multiple possible causes. The primary issue is tissue damage leading to dysphagia and dysphonia. As described above, there are hypotheses that these complications are caused by the mechanical force exerted on the tissue, damage to the nerves in the area, or loss of blood flow to the area during surgery, among other suggestions. Preliminary design ideas sought to address two or even all three of these possible causes of post-surgical complications. To measure mechanical force, the idea was to add force sensors to the retractor blades to provide surgeons with quantitative data on how much force they exert on the retracted tissue. While no benchmark has been set for how much force leads to tissue injury, the data gathered from this design idea could be used to inform clinical trials seeking to find that benchmark. To measure nerve damage, the idea was to incorporate some sort of neural activity sensor similar to what is used for some neurosurgeries. For measuring tissue oxygenation and perfusion, a preliminary design incorporated an optical system similar to a photoplethysmography-based system. Similarly to the case of mechanical force, there is no established benchmark for tissue oxygenation or nerve activity to let surgeons know when these values reach a dangerous level, so the design ideas were intended to enable studies to discover this benchmark rather than alert surgeons when values exceeded the threshold for tissue damage.

While any of these three metrics could offer insight into intra-operative tissue damage, the preliminary design that incorporated all three was deemed not feasible due to space constraints. To simplify the design to a reasonable complexity, the design was altered to address just one of the potential contributing factors to dysphonia and dysphagia: mechanical force applied to the tissue. The final design encompasses two approaches for a tissue-pressure sensing retractor system described below.

Final Design Description

Design 1: Load-Cell in Retractor Rack: Within the retractor rack, there is a removable metal connector, as indicated by red (Figure 2A). We will create a 10 kg load cell in the geometry of the existing component (Figure 2B) and substitute it in place of the original part. When a load is applied by retraction, the load cell bends microscopically, changing the resistance in its strain gauges

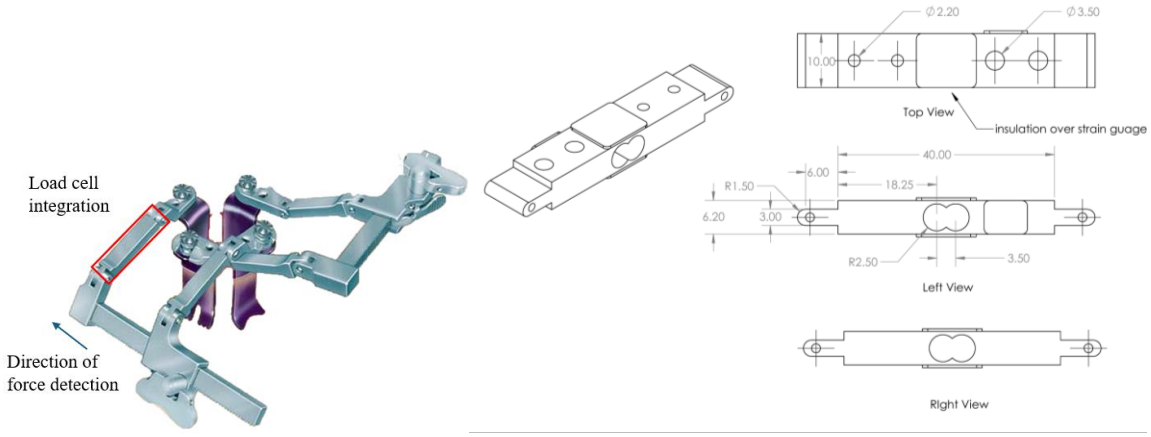

Figure 2. Proposed Design 1. 2A. Current Trimline retractor kit. 2B. CAD drawing of load cell, units MM.

Design 2: Blade with Grid of Piezoelectric Sensors: To incorporate spatial information about the application of the force, we will also fabricate a new blade in the geometry of the original blade with a grid of 8.7 mm piezoelectric sensors integrated on its surface. The grid arrangement will allow the creation of a pressure map of the applied force. for

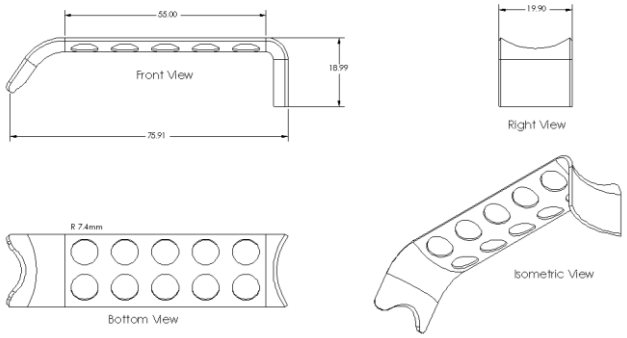

Figure 3. Proposed Design 2. CAD drawing of retractor blade, units MM

For both prototypes, a EFR32BG29 wireless SoC microcontroller will be used to interface with the transducers and provide Bluetooth connectivity to the computer processing unit. This microcontroller is highly efficient and low-power, and it is designed for secure, high-performance wireless networking. It will interface with a computer running the processing code and user interface that will be developed as the transducers are tested.

Fabrication/Development

Design 1: The metal body of the load cell must be precisely machined, which will require the use of and supervision by an advanced mechanical makerspace; we have been in contact with VINSE regarding this possibility. The cell will be fabricated from 316L medical grade stainless steel and CNC-machined to ensure tight tolerances. After machining, an annealing process will be applied, which involves heating and cooling under controlled conditions, to dissipate internal stresses[15]. Next, strain gauges will be bonded to the body using specialized gauge adhesives, such as SG496 or SG401[16]. These adhesives cure within minutes, although some fabrication methods require additional oven curing. Finally, the strain gauges will be wired into a Wheatstone bridge circuit through soldering of the connections.[15]. An instrumentation op-amp will be used for signal amplification.

Item	Quantity	Cost
316 L medical grade stainless steel 20 mm x 100 mm slab	1	$20
Foil strain gauges	4	$30 -$60
Specialized strain gauge adhesive (may be available in the makerspace)	1	$20
Load transfer pads	3	$10
Instrumentation op-amp	1	$5
EFR32BG29 SoC microcontroller (Silicon)	1	$36
Wires and solder	NA	NA
Total Estimated Cost		$125-$155

Table 2. Estimated bill of materials forth Design 1.

Design 2: The blade will be fabricated from 316L stainless steel and CNC-machined. Piezoelectric sensor pads, 7.4 mm in diameter, will be bonded to the blade in a 5x2 grid using a specialized adhesive. We are also investigating smaller sensors to achieve greater spatial resolution, though this increases the complexity of the electric integration, requiring a multiplexer (MUX). Each sensor in the current design will have its own wire to the EFR32BG29 SoC microcontroller, as it has 10 analog input channels, allowing direct acquisition of the sensor signals and the downstream creation of a pressure map.

Item	Quantity	Cost
316 L medical grade stainless steel 6.2 mm x 100 mm slab	1	$20
Piezoelectric sensors from Pololu Electronics	2 packs of 5 (cheapest unit price)	$120.68
EFR32BG29 SoC microcontroller (Silicon Labs)	1	$36
Wires and solder	NA	NA
Final Estimated Cost		$176.88

Table 3. Estimated bill of materials for Design 2

We will use Simplicity Studio, the software built by Silicone Labs, with an integrated IDE for coding to interface with the microcontroller.

Testing

The first set of tests that will be performed are mechanical tests on the retractors, starting with the ASTM E8 test, which verifies the mechanical soundness of the integration of the new components. By testing loads much higher than the expected clinical load, this test verifies that the retractor materials won't fail under a clinical load. The pressure sensor

also needs to be calibrated with the ASTM E74 test, which ensures the accuracy of the pressure sensor readings by comparing it to a ground truth pressure reading. Ensuring accuracy in pressure reading means that surgeons know exactly how much pressure they're applying to the tissue of the patient. The electrical safety of the sensing components is also tested using IEC 60601-1. This test ensures that both the patient and surgeon are unharmed by the electricity used to power the device. Early bench-top iterations will be performed on phantoms that mimic prevertebral soft tissue and the annulus fibrosus, using silicone models and animal tissue available from the grocery store. Next, tests on human cadavers will be performed at the Medtronic site with pressure mapping, according to test ISO 62366-1. By monitoring tissue pressure in a cadaver, real surgical settings can be simulated to verify the operation of the device and identify any problems that may be caused by operating in vivo. The device is then tested on a porcine animal model in the ISO 10993-6 test. Following the use of the device, histopathology is analyzed to determine whether the tissue to which pressure was applied has any significant damage compared to normal tissue. This ISO 14155 test ensures that the sensing function of the retractors is able to inform surgeons of when to release pressure in a way that reduces harm to the patient. The final test in this series is a clinical trial on real human patients undergoing spinal surgery. Once the device is tested on real patients, its safety for clinical adoption is solidified.

Strategy

The strategic focus of this product is to address a clear clinical and economic need in anterior cervical spine procedures by offering a retractor system that not only performs the standard function of holding tissue layers apart but also introduces real-time monitoring abilities that reduce potential postoperative injuries. The intended customer is the hospital purchasing committee, while the end-users are surgeons performing ACDF and ACDR procedures.

Strategically, this device works as an improved version of existing retractor systems by improving safety, reducing costs related to complications, and fitting smoothly into current surgical workflows. Its single-use nature and compatibility with standard ACDF techniques support its ease of adoption and predictable revenue margins. The benefits posed by this device in clinical applications from both economic and operational scopes will favor its adoption into the early market through high-volume ACDF centers, which will build a foundation for expansion into broader U.S. and global spine surgery markets.

Intellectual Property

To better assess the IP landscape surrounding sensor-integrated surgical retractors, we conducted an extensive review of U.S. patents related to force-sensing, tissue-monitoring, or feedback-enabled retractor systems. Several patents describe retractors with embedded sensors, closed-loop feedback mechanisms, optical monitoring components, or disposable sensing modules. Table 4 summarizes the most relevant patents and includes information regarding assignee, key claims, search terms, inventor, and filing information. Although multiple devices utilize force or other physiologic sensors, none of them are explicitly designed for anterior cervical spine procedures. Neither do any devices link a load-cell-based torque measurement to pressure sensing on the retractor blade. The lack of patents characterizing this particular pairing suggests freedom to operate. Existing patents will guide our efforts to further refine our claims as we continue the design process.

Title	Assignee (Company)	Key Claims	Search Terms	Patent #	Inventor	Pub Date	File Date
Retractors with Integrated Sensors							
Retractor Systems with Closed Loop Control	ViOptix, Inc.	A method comprised of determining a parameter, by using the sensor reading signal from the sensor, of a tissue that is retracted by a retractor comprising a sensor.	"sensor"	US 11,672,519 B1	Larry C. Heaton II, Alex Keller, Robert E. Lash, Jimmy Jian-min Mao	6/13/2023	6/9/2020
Force-Indicating Retractor Device and Methods of Use	Smith and Nephew Orthopaedics AG	Joint distraction device comprised of a disposable force sensor and a computing system configured to be placed in communication with a disposable force sensor and receive measurements.	"force sensor"	US 2021/0361273 A1	Branislav Jaramaz, Samuel C. Dumpe, Cedric Corpa de La Fuente, Gary David Carlson Jr., Brett J. Bell, Brian W. McKinnon	11/25/2021	5/7/2021
Retractor Device with Oximeter Sensor and Force Sensor	ViOptix, Inc.; Regents of the University of California	Retractor device that measures oxygen saturation and the amount of force applied to retracted tissue. The tip includes one or more openings for at least one source and detector.	"force sensor"	US 8,977,332 B1	Jimmy Jian-min Mao, Robert E. Lash, Shance Burch	3/10/2015	3/31/2014
Surgical Retractor Assembly Having Tissue Viability Sensor Embedded Therein	N/A	Surgical retractor with a miniature metabolic parameter sensor embedded or removably inset into the blade. The sensor detects physiologic and metabolic parameters to monitor tissue viability of the tissue underlying the retractor.	"sensor"	4,945,896	George F. Gade	8/7/1990	1/24/1989
Retractors without Integrated Sensors							
Lateral Access Retractor and Core Insertion	Stryker European Operations Holdings LLC	Retractor apparatus comprised of a retractor frame, five arms and five rods.	"retractor"	US 11,191,532 B2	Spencer Popejoy, Charles L. Bush Jr., Steven F. Krause	12/7/2021	3/29/2019
Cervical Retractor	NuVasive, Inc.	Anterior cervical retractor comprised of a first medial-lateral retractor body having a base arm and a moving arm and a pair of retractor blades. The retractor blades may have an adjustable angulation.	"retractor"	US 8,974,381 B1	Nathan Lovell, Michael Serra, Michael Brotman, Andrew Wolf, Richard Lazar, Jennifer Simon, Kenneth Rich, Sandeep Kunwar	3/10/2015	6/4/2012
Retractor and/or Distractor for Anterior Cervical Fusion	N/A	Surgical retractor comprised of two arms with finger grip sections and a surgical retractor blade supported by the first arm. Used for retracting tissue adjacent to bone.	"anterior cervical fusion"	US 2003/0149341 A1	Guy L. Clifton	8/7/2003	2/6/2002

Table 4. Summary of relevant patents in the retractor sensor field.

While the domestic market is the primary focus, international expansion will begin with Germany and Japan due to their strong surgical innovation ecosystems, high demand for advanced medical technologies, and established regulatory infrastructures. In Germany, intellectual property would be filed through the European Patent Office (EPO). The proposed protections would include a utility patent covering the pressure-sensing hardware and algorithms, as well as a design patent to cover the retractor-compatible form factor. The EPO provides protection across more than 30 member states, providing a foundation for scalability and exposure within Europe. In Japan, intellectual property would be filed through the Japan Patent Office (JPO). Similarly, the proposed protections would include a utility patent for the pressure-sensing system and a software copyright for the algorithm used to interpret pressure data. Japan's IP system supports hybrid device-software innovation, ensuring an extensive protection through the combination of patent and copyright. This approach aligns with Japan's prominence on software-integrated medical devices and precision engineering.

Regulatory Approval

Our ACDF retractor modification is a Class II surgical instrument intended for use by neurosurgeons performing anterior cervical spine procedures. Its primary function, retracting soft tissue during ACDF, is identical to that of existing spinal retractors, and the addition of pressure and time-under-load monitoring does not change how the device interacts with the patient. Because the device maintains the same indications for use, technological characteristics, and risk profile as current predicate retractors, it falls under FDA Class II and is appropriate for clearance through the 510(k) pathway. Several commercially available Class II spinal retractors, including gSource, Pinnacle, and Stryker, provide a clear basis for substantial equivalence.

Internationally, our device would follow comparable mid-risk classifications. Under the EU Medical Device Regulation (EU-MDR), it would be categorized as a Class IIa non-implantable surgical device, requiring CE marking and conformity assessment similar in scope to the U.S. 510(k). In Japan, the PMDA likewise regulates reusable powered surgical tools as Class II, generally requiring certification through Registered Certification Bodies rather than full premarket approval. Other global markets, including Australia and Canada, classify reusable surgical retractors in equivalent moderate-risk categories with pathways that mirror the U.S.[14] emphasis on demonstrating mechanical safety, electrical safety of accessories, and adherence to basic performance standards. Because the device's core function is well established, and its enhancements do not introduce new clinical risk, global regulatory pathways primarily parallel the U.S. Class II/510(k) approach.

Business Plan

The primary payers for the cervical retractor system will be hospitals, private insurers, Medicare, and Medicaid, as the device is used in well-established, reimbursable ACDF procedures. Hospitals and surgical centers will purchase the

single-use retractor kits directly from Medtronic through their standard supply chain, Reimbursement will be incorporated into the DRG-based payment that hospitals receive from insurers or covered under surgical suppled bundled into ACDF procedural costs. In cases where the device is billed separately, payment will be sought through private insurers and Medicare using the appropriate ICD-10 code.

The cervical retractors will be used in inpatient surgical settings during ACDF procedures that are performed in hospitals and specialized surgical centers. They will be used by orthopedic spine surgeons and operating room staff under sterile conditions. The single-use design eliminates the need for autoclaving and reduces the risks of infection, degradation, and mechanical wear. Since each ACDF surgery would require a new sterile retractor set, this single-design element creates a consistent recurring revenue stream. The retractors would be classified as a Class II medical device and follow the 501(k) pathway by demonstrating considerable equivalence to existing cervical retractors. The presence of embedded sensors may support an additional CPT code if the clinical benefits are validated.

Reimbursement procedures will differ for international markets following global expansion. Germany's SHI/PHI system reimburses new technology through the NUB process for temporary payment while it is evaluated for permanent DRG inclusion. In Japan, reimbursement comes through the National Health Insurance system after approval through the PMD Act and review by Chuikyo to determine pricing.

Ethical and Professional Impact Analysis

Because our device is used during anterior cervical spine surgery, the primary ethical responsibility is ensuring patient safety. Surgeons depend on accurate, reliable tools when operating near the trachea, esophagus, and recurrent laryngeal nerve; therefore, our sensing system must function without interfering with standard retractor performance. As biomedical engineers, we must design the system so that electrical components are well-insulated, fail-safe, and compliant with international safety standards to prevent risks such as electrical shock, mechanical failure, or unintended tissue injury. Proper surgeon training is also essential, since the patient cannot advocate for themselves while unconscious, placing greater professional responsibility on the surgical team.

Globally, improving the safety of ACDF and ACDR procedures can benefit patients across diverse healthcare environments. By designing the sensing attachment to be compatible with existing retractors, the system can be adopted in both high-resource and lower-resource settings without requiring major workflow changes. Clear instructions, ergonomic design, and availability of translated materials help ensure equitable and culturally sensitive implementation. Economically, the device introduces a disposable component, which may increase recurring costs for hospitals. It is therefore important to keep the design simple, manufacturable, and low-cost to avoid creating financial barriers to safer surgical practice. Environmentally, the use of single-use components raises concerns about medical waste. To mitigate this, materials should be recyclable when possible, and the reusable stainless-steel retractors remain part of the workflow to avoid unnecessary replacement of existing tools. From a societal perspective, the device aims to reduce postoperative dysphagia and dysphonia, complications that impact quality of life, speech, swallowing, and the ability to return to work. By providing quantitative feedback during surgery, the system supports the ethical obligation to minimize preventable harm. Additionally, all data collected must comply with HIPAA standards, be encrypted, and be used solely for intraoperative decision-making to protect patient privacy. Our main goal is to create a device that prioritizes safety, affordability, and accessibility while acknowledging environmental and societal impacts. These ethical and professional considerations guide the development of a system intended to improve surgical outcomes without introducing undue risk or burden.

Conclusions and Future Work

The goal of this project was to address a significant unmet clinical need in anterior cervical spine surgery: surgeons currently retract the trachea, esophagus, and surrounding soft tissues without any feedback on the pressure being applied or the duration of tissue loading, both of which contribute to postoperative complications such as dysphagia and dysphonia. Our final design introduces a pressure-sensing modification to a standard ACDF retractor that integrates a compact load cell and a disposable sensing arm to quantify real-time tissue pressure and cumulative time-under-load. This

design preserves the geometry and clinical workflow of existing retractors while adding actionable intraoperative information intended to reduce preventable soft-tissue injury.

While the device demonstrates proof-of-concept feasibility, several limitations remain. First, the sensing interface requires further refinement to ensure consistent measurements under dynamic retraction conditions, including varying angles of approach and soft-tissue heterogeneity. Additionally, our prototype has not yet undergone bench-top validation using synthetic or cadaveric models, so its accuracy and durability under realistic surgical forces remain to be evaluated. Electrical isolation, sterilization compatibility, and the long-term robustness of the sensor enclosure also represent important considerations that must be fully resolved before clinical translation.

Future work for Design II will focus on expanding the sensing capabilities, improving reliability, and preparing the system for rigorous mechanical and clinical testing. The next stage of development will include incorporating multi-sensor arrays to provide distributed pressure mapping along the retractor blade, enabling surgeons to localize peak stress regions more precisely. Parallel efforts will refine the sensor-blade interface, develop a surgeon-facing display for real-time force and time-under-load visualization, and integrate signal filtering to improve measurement stability. Bench-top experiments using tissue analogs will establish baseline accuracy and repeatability, followed by cadaveric trials to evaluate performance in anatomically realistic conditions. Additional milestones include validating sterilization methods, completing risk and safety analyses, and finalizing materials suitable for both disposable and reusable components. Collectively, these efforts will position the device for more advanced prototyping, regulatory preparation, and eventual translation toward improving safety and outcomes in ACDF procedures.

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