Abstract

Of the approximately 500,000 spinal fusion surgeries performed annually in the United States, over 20% of screws are misplaced. This leads to postoperative neurological or vascular complications, which necessitate reoperations in 1 to 5% of patients, costing the American healthcare system over $500 million annually. In the established paradigm, a pedicle probe is inserted manually into the vertebra to create a pilot hole, a trajectory that the screw follows. It is difficult to achieve a stable or even safe trajectory with the limited physical feedback from the probe, so this technique is most often performed under fluoroscopic guidance.

To enable spine surgeons to more accurately place pedicle screws and reduce associated breaches in spinal fusion procedures, we have designed and prototyped AccuSpine, an improved pedicle probe to replace the current "ball-and-stick" model probe. AccuSpine is able to provide feedback regarding its location within the pedicle and alert the surgeon of an impending cortical wall breach with both vibrational and visual feedback. The device consists of a spherical handle incorporating three resistive force transducers to measure forces in multiple axes. When the surgeon pushes the probe from soft to hard bone, a sudden force spike will occur, signifying a breach. The handle also houses the feedback system obtained using a button vibrational motor and four red LED lights that flash, respectively, when a breach is detected. AccuSpine's feature set enables projected reductions in operating time by 15% with projected cost savings of 10% per surgery, an average of $9,000 per procedure.

Company Summary

White Light Medical is a medical device firm that has developed a low-cost, smarter pedicle probe, *AccuSpine*, for the accurate placement of screws in spinal fusion surgeries. Using an electromechanical method, *AccuSpine* continuously measures changes in force coupled with a path-identification algorithm, to alert the surgeon to a potential or impending breach, all in real time, preventing the probe from exiting the vertebrae and causing harm to the patient. Our team aims to reduce screw breach rates, operating room time, and radiation exposure, thus limiting the cost of the procedure while enhancing safety for both patients and doctors.

Clinical Problem

Spinal fusion through screw-based stabilization is a widely-performed and increasingly prevalent surgical technique used to alleviate spinal instabilities and deformities. In the established paradigm, a pedicle probe is used to create the trajectory that the vertebral screw follows. Oftentimes, it can be difficult to achieve a stable, or even safe, trajectory. Of the approximately 500,000 spinal fusion surgeries performed annually in the United States, over 20% of vertebral screws are misplaced, necessitating reoperations in 1 to 5% of all patients [1, 3]. In the established paradigm, a pedicle probe is inserted manually into the vertebra to create a pilot hole, a trajectory that the screw follows. It is difficult to achieve a stable or even safe trajectory with the limited physical feedback from the probe, so this technique is most often performed under fluoroscopic (X-ray) guidance [2]. On average, spine surgeons take about 8-14 fluoroscopic shots per screw, resulting in radiation exposure 10-12 times greater than other musculoskeletal procedures [6,10].

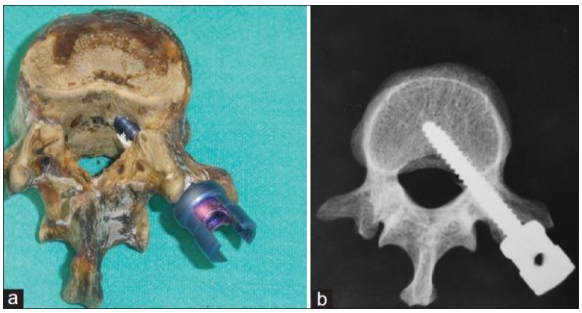

Figure 1: Example of a breach into the spinal canal in a cadaver [9]

Technological Solution: AccuSpine™

The scientific principle behind the *AccuSpine* is based on density differences in the vertebrae. In our studies of human vertebral anatomy, we identified a significant density differential between higher-density cortical bone surrounding the vertebrae and lower-density cancellous bone within the vertebrae [4]. The *AccuSpine* significantly reduces breaches by ensuring that the probe is always positioned within the lower-density bone. This is accomplished using a proprietary electromechanical method to continuously measure changes in force when navigating the probe inside bone. By coupling the force profile with a heuristic path-identification algorithm, the *AccuSpine* can alert the surgeon to a potential or impending breach, all in real time, preventing the probe from exiting the vertebral body.

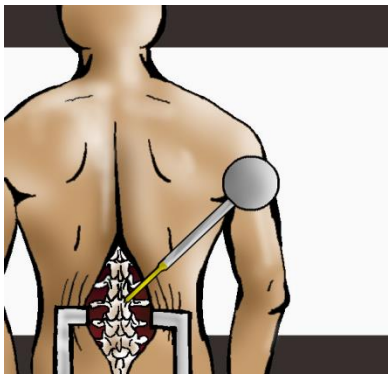

Figure 2: Visual representation of spinal fusion surgery

This information is relayed to the surgeon via visual cues and auditory signals, providing real-time navigational guidance. This trajectory guidance capability is unique to *AccuSpine* and will serve to supplement or even supplant the use of high-cost intra-operative fluoroscopy. The *AccuSpine* is a self-contained solution which transforms spinal fixation, enabling safe and accurate pedicle screw placement across a broad range of patients. It offers peace of mind in the operative outcome, a higher standard of care, and reduced intra-operative radiation exposure.

Market Analysis

With over 500,000 spinal fixation procedures per year and an average reimbursement of $90,000 per procedure, the spinal fixation market presents nearly $50 billion in revenue with an annual growth rate of 5% per year [8]. Of this, the revenue of pedicle probes is estimated at $600 million and is projected to rise steadily with an aging US population. The majority of market share is associated with the archetypical pedicle probe: a metal shaft connected to a rubber grip, such as those produced by DePuy Synthes. While the DePuy probe, is the least expensive, it offers no guidance or breach prevention and relies entirely on imaging.

Figure 3: Exploded view of *AccuSpine*

Currently available pedicle probe alternatives such as Medtronic's Nim-Spine and SpineGuard's PediGuard offer breach detection but not breach prevention through contact with nerves and impedance respectively. These can only be used in a small subset of relatively healthier patients. *AccuSpine* addresses these shortcomings. It offers guidance, breach prevention, and can be used in a broad spectrum of patients, including those with osteoporosis. With a price point targeted at $1050 per unit, we will be able to deliver the premier solution on the market.

Revenue Model

Currently, White Light medical has filed provisional patents to protect the force transduction solution to pedicle breaches and the algorithms used in the differential density calculation of our device. Our device is currently completing bench testing in postmortem porcine spine and is scheduled to begin in vivo testing in large animals by June. We plan to proceed through the 510(k) regulatory pathway as a Class II Medical Device, using the established PediGuard as our predicate device. To begin with the marketing of our device, we will be using a direct to surgeon model. We will then start expanding to nearby academic medical centers. Since *AccuSpine* can reduce complications, operation time, and

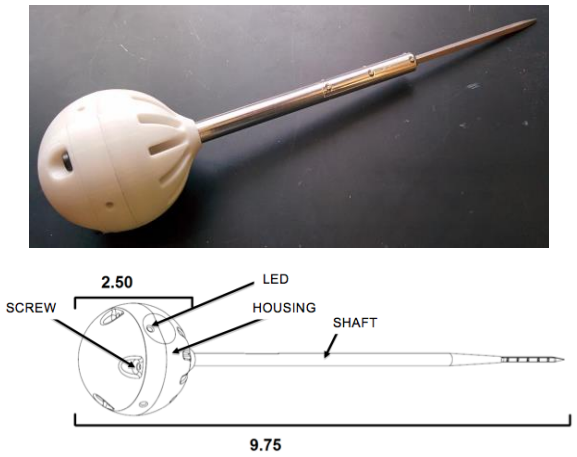

Figure 4: Prototype and labeled view of *AccuSpine*

radiation exposure for surgeons, we believe that observation of these benefits at academic institutions will prompt additional research in to the role of *AccuSpine* as a centerpiece of new and more efficient surgical protocols. To broaden our expansion, we plan to find an industry partner to support the launch of our product. In this role, we will principally serve as suppliers, with profits based off of markups on our product and potential royalties. By using their existing platform and sales and marketing infrastructure, we will be able to reach a larger audience in less time, gaining a crucial advantage in capturing market share.

Documentation and Prototype of Final Design

Over the past year, White Light Medical has developed a functional prototype using computer-aided design and rapid prototyping 3D printing. The device is used by inserting the probe shaft into the opening in the pedicle previously created by a surgical burr and pushing through the softer cancellous bone inside the vertebrae. When it is determined that the shaft comes into contact with denser surrounding cortical bone, the surgeon is alerted by visual and haptic feedback. This can be seen in the following video: http://youtu.be/xTTMoZPBlrI.

At the core of the invention is an electromechanical system that measures the different forces and torques being applied to the probe over the course of the procedure. The torque-sensing force transducers are placed in the space between the rotor and handle, while linear-sensing force transducers are placed between the end of shaft and handle. Both the torque and linear force sensors are activated when the user cannulates through the bone, resulting in a depression of the transducer material and a subsequent decrease in voltage.

An electronics suite is also integrated within the spherical housing. This suite consists of a printed circuit board (PCB) of original design with an integrated microprocessor. The output wires of all three force transducers are connected to the PCB so that data is continuously provided to the microprocessor for analysis. A vibrational motor housed within the handle is wired to the PCB to provide haptic feedback to the user. Upon the detection of the force spike used to determine a breach, the microcontroller communicates with the vibrational motor to relay this feedback. Additionally, an array of LED lights nested circumferentially along the surface of the handle is wired to the PCB to provide visual feedback. These alert systems are controlled by the microprocessor such that when it is determined that a breach is imminent, the vibrational motor and LED are activated.

Proof of Effectiveness

The need for a suitable and affordable pedicle screw placement device is recognized by the medical community as an important and necessary innovation in the field of preventative care medicine. During interviews, surgeons affirmed the dangers of improperly placed screws, recognized the need, and agreed to continue to advise our business. Chetan Bettegowda, MD, PhD, a Johns Hopkins Medical Institute neurosurgeon, attests that “a device would be extremely valuable if it would be able to detect density changes to the side, not only the front, of the tip; there is a value from breach prevention, not just placement. It would not be a huge

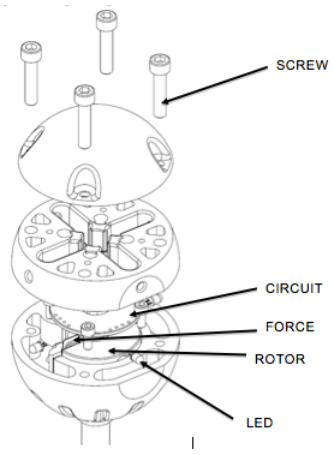

Figure 5: Exploded wireframe view of *AccuSpine*

issue to change the probe's design, if it is proven effective. The community would quickly adopt it."

Prototype creation for *AccuSpine* began in August 2013, with the engineering team shadowing current professionals in the field. The current embodiment of our device is the third iteration of the so-termed "force sensor" idea. In this design, the general layout of the current pedicle probe is maintained (as universally suggested by clinicians), wherein the device externally appears to be a ball-grip handle mounted on a cylindrical shaft. As a proof-of-concept, we have demonstrated the efficacy of force-sensing in a prototype, and have constructed several refined prototypes utilizing our working algorithm alongside a clinical consultant.

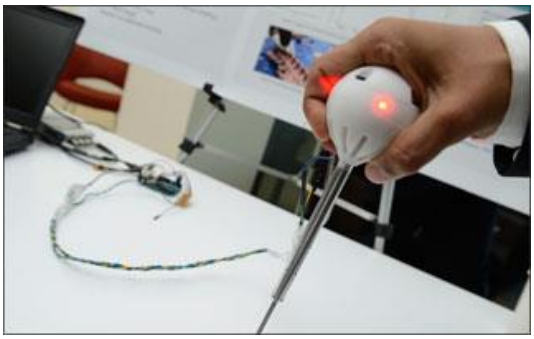

Figure 6: *AccuSpine* in action

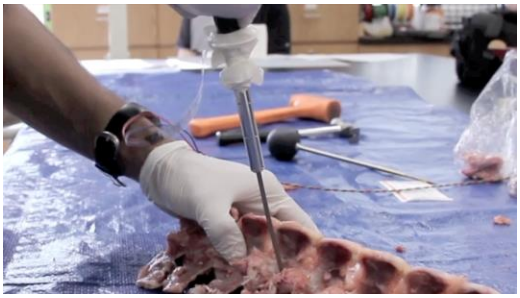

Figure 7: *AccuSpine* pig test

A prototype has been created using 3D printed parts with the circuit and breadboard installed. Testing first began in analogous bone blocks to demonstrate the difference between the spongy cancellous bone and the twice as dense cortical bone. The resulting data show that *AccuSpine* can readily detect the different densities for correct pilot hole creation through our force-sensing algorithm. The next corroborating pre-clinical tests will be done on post-mortem porcine spines in a controlled laboratory setting.

For ease of interpretation, these force profiles are for the longitudinal (pushing) force only, but they clearly illustrate the movement of the probe tip through materials of different densities. Our device is also able to function and remain sensitive through forces of 150 lbs.

Patent Landscape

In determining the patent landscape for pedicle probes, a thorough search was conducted on USPTO and Google Patents using keywords such as "pedicle probe," "gauge," "finder," "seeker," "tool," and "depth" in conjunction with "bone" or "spinal fusion," yielding 20-30 patents. The landscape has been segmented into solution pathways, each pathway generally occupied by a dominant patent, which are summarized below.

8343056 (Ultrasound systems and methods for orthopedic applications, 01/2013) [16]
8249696 (Smart pedicle tool, 08/2012) [17]
8419746 (Exploration device to monitor the penetration of an instrument in an anatomical structure, 04/2013) [18]
8486119 (Implant comprising one or more electrodes and corresponding insertion instrument) [19]

In light of this, the patent landscape for pedicle probes is best described as underdeveloped, comprising a few patents of limited scope. Many of these are written as breach mitigation and/or trajectory-seeking technology for pedicle probes. We have found that *AccuSpine* does not infringe upon any of the major claims in the above patents. We have filed a provisional patent through Johns Hopkins Technology Transfer with the assistance of Cheryl Oliver and Elaine Spector.

Anticipated Regulatory Pathway

The anticipated regulatory pathway for the *AccuSpine* is the FDA 510(k) clearance pathway. This pathway requires medical device manufacturers to notify the FDA about their intention to release a device 90 days prior its entry into the market. We anticipate *AccuSpine* to be classified as Class II with substantial equivalence to SpineGuard's PediGuard Device, which received clearance within one month

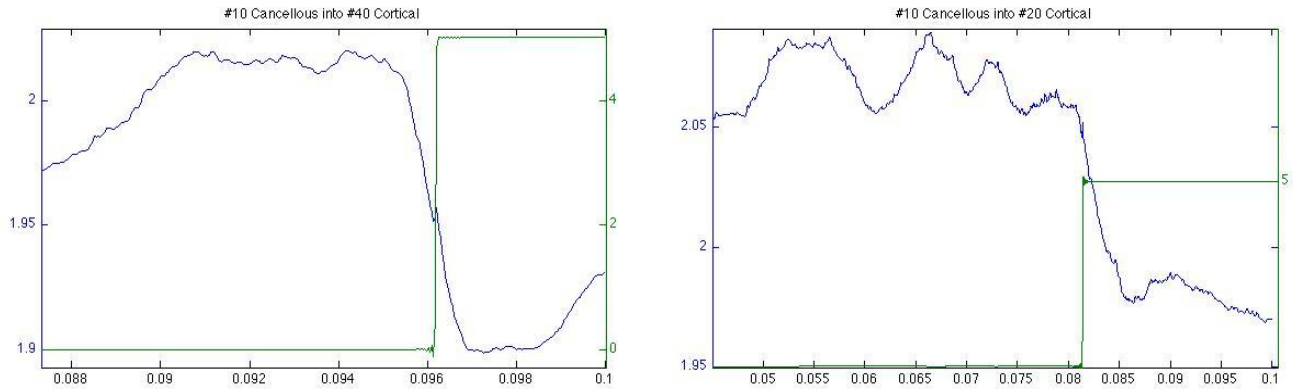

Figure 8: Tests using our device to cannulate through cancellous bone are shown, each with different cancellous and cortical densities. The green line indicates the inteface between cancellous and cortical bone determined by an external electrical switch, whereas the blue line indicates our device's feedback. Note the sharp dip in voltage at the point of contact, which indicates a breach. In all trials, our device was able to detect this breach within 1 ms, more than enough to fulfill our fundamental goal of alerting the surgeon upon 1mm of penetration of cortical bone. Moreover, the successful detection of breaching across a wide range of densities suggests that our device will work across a broad range of patients.

of submission in 2013. [10] Unlike Premarket-Approval (PMA) devices, our device would go through a substantially easier and inexpensive pathway.

Reimbursement through CMS

As the CMS has recently withdrawn reimbursement payments for hospital-borne illnesses, expenses for post-operative complications will now come directly out of the pockets of surgeons, providing further incentive for hospitals to use the *AccuSpine*. While there is no specific CMS reimbursement code for a pedicle probe, the costly complications from malpositioned screws emphasizes the need of a device to improve pedicle screw placement. If a screw breaches and causes pain or paralysis, the surgeons would need to re-instrument the spine at the affected levels to fix the problem. The CMS reimbursement for spinal fusion surgery is about $90,000 per procedure, including reoperation. This is especially important as studies now suggest that up to 5% of patients undergo re-operations due to complications, a number that has been typically masked by hospitals. [1, 3] All of these costs are much more than the $1050 price tag of the *AccuSpine*, which acts to reduce the onset of all of these complications.

Estimated Manufacturing Costs

For prototypes used in device testing in animals or human cadavers, the probe handle will be 3D-printed using ABS-M30i, a biocompatible 3D printing material that is in common use among medical and pharmaceutical engineers and designers. This material works with Fused Deposition Modeling (FDM) Technology to build functional prototypes that have good mechanical strength and can be gamma irradiated or ethylene oxide sterilized.

The device also makes use of FSR-400 variable-resistance force transducers purchased from Images Scientific Instruments to create a force-profile during pedicle probe insertion. These force sensing resistors utilize a polymer thick film (PTF) that decreases in resistance when a force is applied to its active surface. A printed circuit board utilizes a breach-detection algorithm. These components will be incorporated into the handle and can be purchased online.

Finally, the metal rod shaft will be made of medical grade titanium alloy and coated with titanium nitride at the tip to remove some of the metal's surface properties. The shaft will be machined to have a tapered tip similar to that of the DePuy probe, but will be engineered to have a steeper slope so that force data acquisition is faster.

Prototype Budget

Item	Quantity	Amount
Rapid Prototyping		$ 140.00
Machined Shaft	1	$ 260.00
Force Sensors	3	$ 60.00
PCB	1	$ 50.00
Wires, Screws		$ 5.00
LED's	4	$ 5.00
Vibrational Motor	1	$ 5.00
Titanium Nitride Coating		$ 15.00
Total		**$ 540.00**

Potential Market and Impact

While the *AccuSpine* can be used in an array of surgeries involving bone cannulation, we anticipate it will be predominantly used in spinal fusion surgeries. With over 500,000 spinal fixation procedures each year and an average reimbursement of $90,000 per procedure, the spinal fixation market presents nearly $50 billion in revenue with an annual growth rate of 5% per year [8]. Of this, the revenue of pedicle probes is estimated at $600 million and is projected to rise steadily with an aging US population.

Sales Platform

The *AccuSpine* offers distinct advantages to the patient, surgeon, and healthcare provider. By combining breach prevention and navigation, our product offers the unparalleled ability to adapt to specific patients, ensuring a safer surgery with fewer complications and less uncertainty. To the surgeon, we offer a steadfast commitment to ease-of-use and ready incorporation into the surgical workflow. Unlike other spinal probe solutions, *AccuSpine* is intuitive and takes little training to become accustomed to, in large part because its intended use is modeled directly after the current standard-of-care. In addition, *AccuSpine* is completely self-contained; it does not require any additional equipment or personnel cluttering the OR. To the healthcare provider, the *AccuSpine* is instrumental in reducing surgical complications and thus re-operations, which constitute a significant expense among spinal fusions. We will emphasize successful clinical trials with publication in respected journals and exhibition into prominent surgical conferences.

Market Segmentation

Our marketing will emphasize segmentation by benefits. Within the spinal fusion market, our targets are academic medical centers and community hospitals, which are most likely to have final say in purchasing the *AccuSpine*. Academic medical institutions like Johns Hopkins Hospital constitute the minority of hospitals but are looked to as establishing the gold standard of treatment. Adoption of our product as the new standard of care at these centers will spearhead the adoption of the product in other medical institutes. Community hospitals represent the majority of all United States registered hospitals, and are further classified into governmental, not-for-profit, and investor-owned divisions. There are currently 4,999 community hospitals in the United States with 2,894 as not-for-profit, 1,068 as investor-owned, and 1,037 as government owned [11].

Our company emphasizes three aspects of *AccuSpine* to surgeons and hospitals: reduced post-operative complications, reduced intraoperative time, and reduced radiation exposure.

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