

QUESTION 1

Spinal fusion through screw-based stabilization is a widely-performed and increasingly prevalent surgical technique used to alleviate spinal instabilities and deformities. This procedure generally consists of the placement of screws within the pedicles of the affected vertebra and the joining of these screws by a fixative element such as metal rods. The pedicles of each vertebra are two short processes that connect the body of the spinal vertebra to the posterior elements. In the approximately 500,000 spinal fusion surgeries performed annually in the United States, over 20% of screws are misplaced. This leads to potential postoperative neurological or vascular complications, which necessitate reoperations in 1 to 5% of all patients [1,3]. These reoperations generally occur several months after the initial procedure, when symptoms start to appear, costing the overall health care system more than \$750 million to fix [8]. This figure does not include malpractice lawsuits of up to \$1 million per patient that may be filed due to complications from a malpositioned screw.

Injury locations are not evenly distributed; particularly, lumbar and thoracic vertebral levels are breached. Anatomically, a number of fragile tissues can be damaged as a result of over-penetration or improper direction. Depending on the vertebral level, the pedicles are very close to vital neural and vascular structures, including the azygos vein, intercostal artery, inferior vena cava, and aorta and iliac vessels; medially, the pedicle is proximal to the spinal cord [3]. Even with the use of fluoroscopic guidance, surgeons are only afforded an accuracy of several millimeters, which in some cases extend beyond a 2-4 mm “safe zone” surrounding the cortical walls [4]. Should the probe perforate the surrounding tissues of the vertebra, serious neurological or vascular damage may occur. These complications present acute and chronic detriments to the quality of life. Medial breaches are more severe, as they have the potential to damage the spinal cord and cause radiculopathy, or nerve root malfunction.

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 [7,10]. Founded in December 2012, White Light Medical aims to address the root of the problem: the pedicle probe. Our product, the AccuSpine, is a smarter, safer, and easier-to-use probe which helps the surgeon identify the right path for screw placement. In turn, it reduces operating room time and mitigates radiation exposure, not only enhancing the safety of patients and doctors alike, but also cutting down on the cost of the procedure.

QUESTION 2

The pedicle probe currently used in the vast majority spinal fusions is comprised of a metal penetrating shaft coupled to a rubber grip. It is, simply put, devoid of any technology. There are only two “smart” alternatives on the market, both with negligible market share (less than 1%), which serve to alert the surgeon after a vertebral breach occurs. Because of these uninspired

contemporaries, we set out to design our product from the ground-up, applying knowledge from our diverse backgrounds to create the novel technologies found in the *AccuSpine*.

As will be described in more depth in the following section, the core technology of the *AccuSpine* is the electromechanical detection system, which allows our device to alert the operator before a breach occurs. This combinatorial approach is new to the field; competing products use entirely electrically-based detection systems, which lack the sensitivity to prevent breaches. Because ours is fundamentally a mechanically-based solution, the *AccuSpine* is highly reliable and enables safe and accurate pedicle screw placement across a broad range of patients. In contrast, our competitors' products only serve narrow bands of the population, with specific indications that make their use a guessing game for clinicians.

Complementing this, and currently under development, is a capacitance-sensing, path-finding subsystem which enables our device to determine the makeup of the local anatomy and thus indicate the path for ideal screw placement. This trajectory guidance capability is unique to *AccuSpine* and will serve to supplement or even supplant the use of intra-operative fluoroscopy. Ours is the first pedicle probe to provide intra-surgical navigational assistance—no competing product offers anything close.

We also sought to address concerns we heard time and time again about the usability of our product. The most common complaints we heard were that currently available technologies were difficult to adopt, and required additional equipment and personnel. In response, we worked hard to miniaturize our technology so that the entirety of the aforementioned system is housed in the handle of the probe. This system may be adapted to accommodate variety of handle designs, allowing different shaft styles and designs as per surgeon preference. Use of our device conforms to the standard-of-care, making training a cinch.

In summary, the *AccuSpine* is intended to exceed the capabilities of contemporary pedicle probes and our competitors. Our device is unique in providing both breach prevention and surgical guidance capabilities, which in parallel address even the toughest of patient cases. Moreover, it can be readily adopted by clinicians with minimal need for additional training, fitting easily into the current standard-of-care. 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.

QUESTION 3

The scientific principle behind the *AccuSpine* is based on density differences in the vertebrae. 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 positioned within the lower density bone, which anatomically guarantees breach prevention. This is accomplished using a proprietary electromechanical method to continuously measure changes in force when navigating the probe inside bone. Our device measures torque and linear pushing forces with respect to the shaft, allowing for a holistic evaluation of the forces applied during the surgery. The different forces

and torques being applied to the probe over the course of an operation are systemically monitored and integrated to be specific to the patient. 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. When a particular threshold is reached, which occurs when the surgeon transitions from soft to hard bone, the device sends feedback in the form of a vibration and flashing lights to alert the surgeon of an impending cortical breach.

To complement the breach prevention functionality of our device, we are also developing a path-finding component utilizing capacitance-based measurements. As different tissues exhibit different permittivity, our device will utilize a ring of capacitance-sensing elements, providing 360° awareness to identify directional proximity to cortical bone [5]. This information is relayed to the surgeon via visual cues and auditory signals, providing real-time navigational guidance.

All of our testing protocols have been designed under guidance of Johns Hopkins neurosurgeons to ensure fidelity to the surgical paradigm. Early testing relied on synthetic bone analogues to simulate the structural tissues of the vertebrae. To ensure rigor, we simulated many different patient cases, ranging from healthy to osteoporotic or even tumorous. We have progressed through a number of designs and configurations to address the desired form factor of the probe while improving the accuracy, sensitivity, and stability of the signal being collected from our system. Shown in Figure 6 of the supplemental materials document are force profiles taken from recent testing, illustrating the movement of the probe tip through materials of different densities. In all trials, our device was able to detect cortical wall contact within 1 ms, more than enough time to prevent breaches. The success across a wide range of densities suggests that our device will work across a broad range of patients.

In the past month, we began testing our device with porcine spine, the closest animal analogue to human spine. We were able to gather several trials of data, and have been working on adapting our algorithm to this more complex anatomical paradigm. Initial analysis of our data clearly demonstrates that our device can detect with high fidelity the force variations inherent to cannulation of the vertebrae. Our device is able to withstand and remain sensitive through forces of upwards of 150 lbs. Cadaver testing will soon follow.

QUESTION 4

Our sincere hope is that the *AccuSpine* provides a broad spectrum of benefits extending beyond what is medically-evident. Economically, we project that our device enables reductions in operating time by 15% with projected cost savings of 10% per surgery, an average of \$9,000 per procedure. With 500,000 procedures in the US annually, that means the *AccuSpine* could help save upwards of \$4.5 billion per year in operating room time alone—or \$45 million per percent of market share. This doesn't even factor in when something goes wrong; a reoperation can cost upwards of a \$50,000 and a malpractice lawsuit over a million dollars. Conservative estimates suggest that the combined costs of these are around \$950 million a year. And of course, there are the additional costs of care and therapy for the many patients suffering from surgically-caused pedicle breaches whose cases are not severe enough to merit reoperation. With close to a million Americans suffering from these effects, it would be irresponsible for us to speculate at the

magnitude of the associated costs. Without question, the addressable economic benefit of the *AccuSpine* is immense.

With the *AccuSpine*, we hope to make post-operative complications caused by screw misplacement a thing of the past. This also means that patients no longer have to worry about the painful, potentially debilitating consequences inherent to using current technology in spinal fusions. It translates to a higher quality of life for patients and their families, and peace of mind in the procedural outcomes in the long term. Patients will be able to live happier, more productive lives, and their communities can save and repurpose resources otherwise needed for therapy or rehabilitation. Given the sheer size of the addressable population, the *AccuSpine* delivers benefits to the individual and society as a whole.

QUESTION 5

As the CEO of White Light Medical, Anvesh Annadanam directs the team in device design and collaboration with White Light's many partners. Anvesh brings proven leadership skills and an extensive clinical background, juggling a number of roles ranging from organizing workflows and serving as the bridge between medical advisors and the team. Anvesh has previously worked as Chief Financial Officer at biomedical startup Archon Medical Technologies during development of the *FastStitch*, an award-winning suturing device.

Ravi Gaddipati is White Light's chief engineer. A private consultant for the US Air Force, Ravi brings a wealth of high-level experience in product design and development. With a broad set of skills ranging from CAD and FEM to 3D printing and milling, he is responsible for developing improvements to the design of the probe. Ravi's expertise has played a major role in defining the direction of White Light's *AccuSpine* project.

Luis Herrera leads business development for White Light Medical. Formerly Chief Technology Officer of Archon Medical Technologies, Luis has leveraged his skill in communication to identifying and attracting potential clients. He is also a capable graphics artist, providing crucial figures and illustrations, and video editing. Extending his talents to product development, Luis is also involved in design testing for White Light Medical.

Eric Xie serves as counsel and business strategist. Bringing his experiences from working on the Cleveland Clinic's *Mynal* transcatheter device, he is familiar with the workings of intellectual property and product development. He is extensively involved in professional writing and patent analysis. Eric has provided an efficiency-oriented perspective to product design, and is responsible for CAD modeling and video rendering.

Our clinical consultants are spearheaded by Chetan Bettgowda, MD, PhD, who is a neurosurgeon at the Johns Hopkins Medical Center. Dr. Bettgowda is familiar with various spinal fusion techniques and the latest related technologies. We also have the support of Dr. Sheng-Fu Lo in neurosurgery and Dr. A. Jay Khanna in orthopedic surgery.

Lawrence Aronhime, MBA, is a senior faculty member in business and entrepreneurship, and advises us on technology commercialization. He has successfully transitioned many projects from conception to start-ups.

Richard Wesorick, JD, is a partner at Tarolli, Sundheim, Covell & Tummino LLP with a background in mechanical engineering. He has provided counsel on legal and patent matters, leveraging over 20 years of experience in working with entrepreneurs. Nestor Franco and Tina Tudor of Johns Hopkins Technology Transfer provide additional IP and legal support.

Youseph Yazdi, PhD, MBA, is the director of the Johns Hopkins Center for Bioengineering Innovation and Design, and provides us with engineering and device development guidance. Dr. Yazdi has worked at Johnson & Johnson for 20 years and has experience bringing medical technologies to market. Soumyadiptya Acharya, MD, PhD, and Robert Allen, PhD, are research professors at Johns Hopkins University who provide engineering feedback throughout our design and prototyping process.

We firmly believe that our student team and advisory board have the devotion, skills, and experience necessary to bring this project to fruition.