# Enhancing Safety and Pedicle Screw Accuracy: A Comprehensive Review of the Waypoint Guided Pedicle System (GPS)™

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## Background

The pedicle screw insertion technique is a fundamental aspect of spinal instrumentation. It is critical that pedicle screws be placed efficiently and accurately because malposition can result in spinal cord or visceral injury that may necessitate reoperation or further postoperative care. Pedicle screws have traditionally been placed via free-hand technique, however, freehand placement has been shown to perforate the pedicle or vertebral body at a rate of 16.8% in the thoracic spine and 9.1% in the lumbar spine.[1] To overcome the limitations of free-hand procedures, use of assistive techniques has rapidly become the standard of care in spinal fusion surgery. These include fluoroscopic and stereotactic navigation as well as robotically-assisted surgery. While these assistive techniques have demonstrated success in increasing visualization of the screw trajectory and decreasing the likelihood of injury[2,3], there are notable disadvantages associated with their use, such as increased radiation exposure, increased costs, the steep learning curve, and equipment failures that can delay or increase operating room time and expenditures.

Waypoint Orthopedics has developed the Guided Pedicle System (GPS)™, a single-use, disposable handheld navigation system that requires no capital investment or large storage area, is vendor-agnostic and requires minimal education. It should not require any changes to current surgical workflow. Waypoint can be used in all spine surgeries requiring pedicle fixation, enabling the health system to provide a new standard of safety that increases hospital health equity within a region.
Most importantly, the WPGS is the first intrapedicular device to provide real-time visualization of the pedicle probe to the surgeon. The safety profile of the device is currently unmatched by any product on the market.

## Purpose

The intent of this paper is to introduce the GPS technology and present an interim analysis of post-market data collected during routine surgical procedures using the GPS and a standard bone awl. The goal is to confirm that users can effectively use the GPS for pilot hole creation during pedicle screw placement.

**Device Description**

***Market Status***

The Waypoint GPS is approved for use in open and MIS Spine surgery by the FDA under K222106.

***Indication for Use***

The Waypoint Guided Pedicle System is indicated for use during pilot pedicle hole drilling to provide the surgeon with visual feedback that indicates a change in color at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The Waypoint GPS is indicated for use in both open and percutaneous (MIS) procedures.

***Description of the GPS Technology***

The Waypoint GPS has a mechanically similar operating principle to a standard manual bone awl. The GPS is distinct from manual surgical instruments due to the internal electronics and custom software designed to provide intraoperative optical feedback to the surgeon during use. The fundamental operating principle relies on the reflection or refraction of broad-band white light emitted from the tip of the probe. White-light continuum generated in an optical fiber provides high spectral intensity and focus ability. The LED and optical fiber in the Waypoint GPS channels white light to an exact location, and photons of a specific wavelength in ratio and intensity are reflected to the sensor. These wavelengths appear on the display tablet as the color information for the respective tissue type. Cortical bone is very dense and homogenous, and the main optical properties are constituted by inorganic elements such as calcium and phosphate. Cancellous bone is highly porous due to the intertrabecular marrow spaces in the osseous scaffold. The interspace is filled with red bone marrow, making it highly vascular consisting of hematopoietic cells and erythrocytes. Erythrocytes are red because of the chromophore hemoglobin[4], which allows the cells to absorb light in the visible part of the spectrum. It is the presence of these chromophores in cancellous bone that allow the differentiation between the types of tissue.[5]

Because cortical bone is homogenous and does not contain the same optical absorbers that cancellous bone does, less of the emitted white light is absorbed, and more is reflected off the bone's surface and returned to the sensor. The result is a tan to pale pink color on the display (Figure 1).

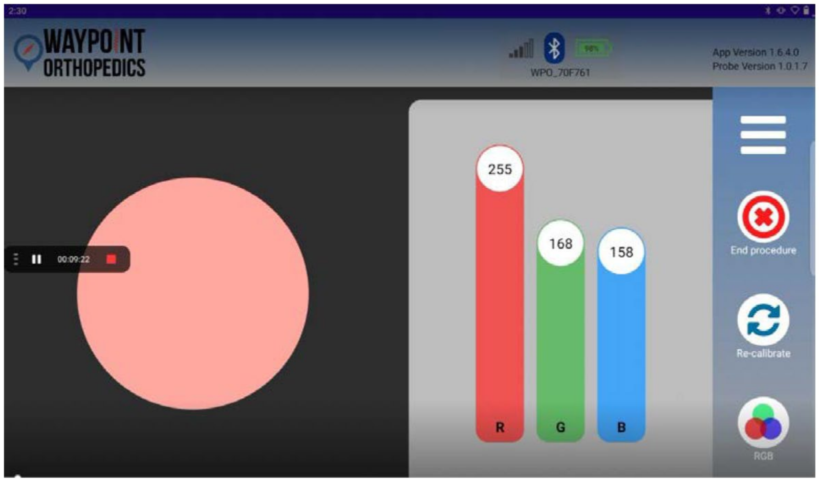


***Figure 1. Visual Feedback from the GPS in Cortical Bone of Sheep.*** *Images were taken from an animal study at the Penn Vet Institute for Medical Translation ( (Kennett Square, PA).*

Conversely, in the case of breach or "void" very little white light is returned to the sensor, resulting in absence of color or a very dark color on the display (Figure 2).

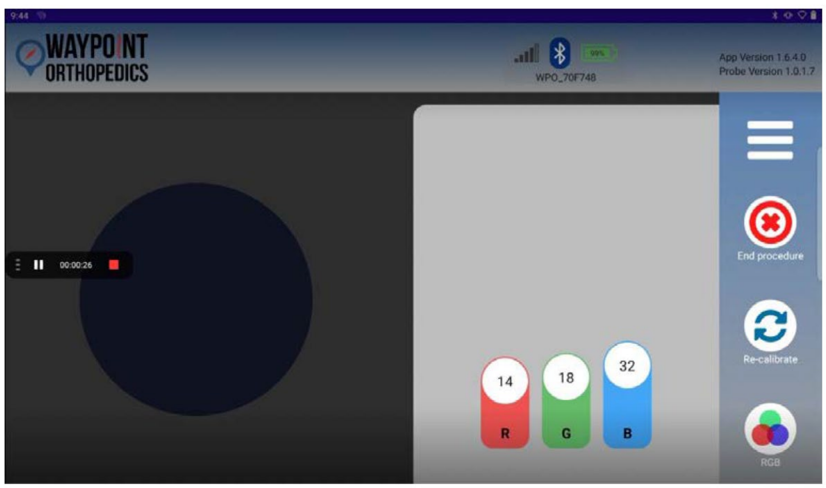


***Figure 2. Visual Feedback from the GPS in Void or Breach of Sheep.*** *Images were taken from an animal study at the Penn Vet Institute for Medical Translation ( (Kennett Square, PA).*

Because cancellous bone contains more hemoglobin (a chromophoric protein), more specific R wavelengths are reflected back to the sensor, resulting in a red to deep red color on the display (Figure 3).

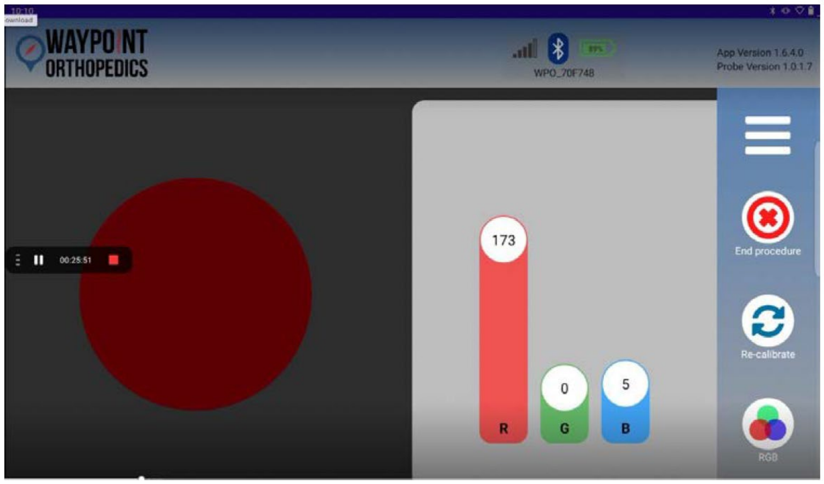


***Figure 3. Visual Feedback from the GPS in Cancellous Bone of Sheep.*** *Images were taken from an animal study at the Penn Vet Institute for Medical Translation (Kennett Square, PA).*

**Procedure**

***Equipment***

Waypoint provided the single-use disposable GPS devices and tablets for use during the procedure. Instructions for Use were provided and reviewed prior to the first surgical procedure.

***Patients***

Patient informed consent was not required. All data collected during the procedure was de-identified. No patient identifiers were collected and there was no post-procedure follow up required.

***Methods***

Surgeons performed the procedures in an operating room using the GPS and a standard bone awl. Pilot holes were placed using a minimum of one (1) GPS procedure and one (1) standard of care procedure per patient. Each patient served as their own control to account for bone density variation. The location and depth of each pilot hole was confirmed prior to pedicle screw placement using fluoroscopy and / or manual verification.

## Results

Nine (9) procedures were performed between August 2023 to September 2024. A total of **62** pilot holes were created for placement of pedicle screws into the lumbar or sacral spine. **Forty-five (45) pilot holes (73%) were created using the GPS system. Seventeen (17) (27%) were created using standard bone awl.** Probe location as indicated by the GPS was confirmed by fluoroscopy and/or manual verification in 100% of the probe tip locations (45 out of 45 procedures)**; resulting in greater than 95% reliability with 90% confidence. There was one (1) incident of breach during pilot hole placement using the GPS system. The GPS device successfully detected the breach and resulted in successful placement of all pedicle screws.**

**There was one bone awl pilot hole placement, and subsequent pedicle screw placement that was low (as detected by x-ray), but did not constitute a breach; resulting in 80% reliability with 90% confidence).**

Results demonstrate that the change in color displayed on the device tablet correlates to the change in color displayed for contact with cortical bone, cancellous bone, or a breach.

## Discussion

The clinical significance of screw malposition has been demonstrated in several studies, with pedicle cortex perforation having catastrophic implications such as neurological, visceral, and vascular complications.[6,7] To overcome these complications, several guided techniques have been developed, but these come with their own set of disadvantages. Sophisticated surgical navigation modalities, like robotic-assisted surgery, are typically reserved for complex cases and are limited to select hospitals who can support their implementation. Even in these health systems, their use is limited to a single procedure, due to equipment turnover constraints. This results in inequity of patients' access to safer procedures.

Alex Vaccaro, MD., President of Rothman Orthopedics Institute had this to say about the cost *($500K - $1.5M)* vs benefit of robotic surgical platforms in a Becker's Spine Review.[8]

*"Given that these costs are not amortized, it is essential to determine if the touted advantages of robotically assisted spine surgery translate to meaningful clinically significant benefits for patients. Healthcare systems are transitioning to value-based reimbursements, and any new surgical technology must be analyzed with respect to the quality and cost of healthcare delivered. Recent literature has failed to find significantly greater improvements in patient-reported outcomes for patients undergoing robotic versus traditional freehand pedicle screw placement. The current body of literature does not provide sufficient evidence to justify the large economic buy-in, as well as the potential harm to patients during the learning curve of adoption"*

The Waypoint GPS is approved for use in both open and percutaneous (MIS) procedures and can offer a navigation option for all cases, not just complex ones. This would enable the health system to provide a better standard of care, thereby increasing access to safer procedures and greater health equity.

The radiation exposure from fluoroscopy during pedicle screw placement has also been extensively studied and reported in the literature. There is risk to both the patient and the surgeon, with the latter potentially facing a higher likelihood of developing adverse side effects[9].

The freehand pedicle screw insertion technique, enabled by Waypoint GPS, is unique in that it does not require intraoperative navigation or repeated fluoroscopy. The use of Waypoint GPS resulted in a higher procedural success rate compared to other freehand techniques in published literature[10]. Wang et al. reported between 4.33% and 6.27% misplacement with various freehand techniques compare to no reported misplacements in this study. In contrast with other screw placement techniques, Waypoint GPS can potentially offer cost savings, reduces operative time and minimizes radiation exposure; similar to or better than those demonstrated by other freehand techniques[10].

The Waypoint GPS combines the advantages of both freehand and assisted navigation techniques. Without the need for capital equipment and extensive training, the GPS can offer significant cost-savings and reduced procedural times while helping to avoid injury caused by misplacement of pedicle screws intraoperatively. When compared with the current practice of screw removal based on neuromonitoring, intraoperative feedback from the GPS could result in reduced time under anesthesia, less blood loss, and reduced radiation exposure for all parties in the operating room.

## Conclusions

The results of this analysis indicate that the Waypoint GPS can be better than the standard of care for creation of pilot holes in spinal fixation procedures and has successfully developed the first real-time, visual validation pedicle cannulation device. Use of the Waypoint GPS offers potential benefits to patients, operators, and hospital systems, and may lead to safer and more affordable spinal fixation procedures overall. The ability of the Waypoint GPS to enhance the robotic surgery experience for the surgeon is also recognized.

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