Cleveland Clinic Innovations

PRODUCT
3D printed patient-specific pedicle screw guide and a semi-automated planning software for maximized screw fixation.

INDICATION
Spinal, Medical Device, Orthopedics, Software, Imaging

VALUE PROPOSITION
- Automated optimized spinal screw placement
- Optimized trajectory maximizing screw fixation.
- 3D Printed Patient-Specific
- Reduction in operation time & radiation exposure

DEVELOPMENT STAGE
- Validation Study
- 3-D printed prototypes
- Cadaver study and data available

INTELLECTUAL PROPERTY
Patent Application Submitted

RELATED PUBLICATIONS
1.NONE

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3D Printed Patient-Specific Pedicle Screw Guide & Semi-Automated Planning Software for Accurate Spinal Placement and Optimal Screw Fixation

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UNMET NEED

Pedicle screws are widely used in surgical procedures in diseases such as spondylolisthesis/spondylolysis, degenerative spine, trauma, and instability to aid in extra support, strengthen fusion, improve 3-column fixation, strength of correction, and maintenance of correction over hooks and subliminal wires. Precise pedicle screw placement is essential to ensure proper fixation and prevent damage to the spinal cavity. Presently, CT-guided navigations are used during surgical procedures, achieving a 90% accuracy rate in determining the correct angular placement. However, these methods overlook the bone density around the screw placement site. There is an unmet medical need for an improved approach that enhanced pedicle screw placement accuracy, reduced operation time and radiation exposure, and considers bone density factors.

SOLUTION

Currently, no product accurately measures bone density nor is there a patient specific guide and planning software for spinal surgeries. A 3D Printed-Specific pedicle screw guide and a semi-automated planning software was developed to improve screw placement, insertion accuracy, and precise determination of maximum bone density, thus facilitating optimized screw fixation during surgical procedures. A study comparing the efficiency of free-hand fluoroscopic-assisted pedicle screw placement with 3D template-guided approach demonstrated the power of the new approach. The 3D method achieved ~95% correct screw positioning, compared to ~70% accuracy in the fluoroscopically assisted group. Furthermore, using the 3D model resulted in reduced operation time and radiation exposure. This advancement shows promise in enhancing spinal surgery outcomes and patient safety.