Project:
TP Trajectory Technique for Thoracic Pedicle Screw Placement Improving Accuracy and Reproducibility

Site: University of Toledo	
Site Director: Vijay Goel, PhD	
PI's name: Baron Lonner, and Vijay K. Goel, PhD	**Proposed Budget: (including 10% indirects)**: $40,000
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Need and Industrial Relevance: Current instrumentation standards for correction of scoliosis and other thoracic spinal deformities include the use of thoracic pedicle screws. The anatomy of the pedicles including their diameter, length, and trajectories in the normal spine as well as the scoliotic spine have been studied and have served as the basis for pedicle screw insertion techniques. A number of techniques to facilitate accurate placement of pedicle screws have been utilized including free-hand technique (FH), funnel technique, the in-out-in technique , fluoroscopically-assisted screw placement, laminoforaminal pedicle palpation, and various other forms of intraoperative navigation techniques including robotics. Each technique has its proponents with the goal of accurate screw placement, efficient placement, and minimization of neurological deficits and re-operation for errant screw placement. Re-operations for errant screw placement have been noted in the early post-operative period in AIS surgery. Breaches of the pedicle in the placement of thoracic pedicle screws have been reported to range from 2 to 15.7%. The accuracy of placement has been shown to depend upon the level of the surgeon's and assistant's experience .Dr. Lonner (PI) and his team have modified the technique for screw placement over the years from a laminoforaminal palpation-assisted approach, to a FH based on anatomical landmarks using a probe, to use of a power drill. More recently, it has become clear that a lateral starting point on the pedicle at the lateral aspect of the superior facet and its junction with the cephalad 1/3 of the transverse process (TP), using the TP as a guide for the trajectory using a power drill has been highly reproducible in the practice of the principal investigator and is termed the TP Trajectory Technique or TPTT. The investigators have found this technique to facilitate screw placement in the scoliotic spine in which rotational deformities make it more difficult for the surgeon to standardize pedicle screw placement. This technique relies on the trajectory of the transverse process which provides a corridor through the pedicle into the vertebral body in the deformed and normal spine.

Project Goals: The principal goal of this study is to describe the TP Trajectory technique and show its reproducibility and accuracy in the hands of an experienced spine surgeon (20 years of experience), a spine surgeon with less than ten years of experience, and a trainee and compare the findings to placement using the more commonly performed FH.

Objectives/Hypotheses: •1. The TP trajectory technique will be more accurate than the FH.
2. The TPTT will be more reproducible than the FH amongst surgeons of differing levels of experience and between left and right sides.
3. Time to screw placement will be equivalent between the two techniques.
4. The TP trajectory technique provide better pullout and de-rotational strength than the traditional

FH technique as well as ease for the de-rotation of the spine due to the larger leverage arm.

Approach (Research Methods): The technique is familiar to the three individuals who will be performing the technique but a brief tutorial on the TPTT will be provided. Each surgeon (one with twenty years of experience, another with 7 years of experience, and a third trainee) will place thoracic pedicle screws in two cadavers each from T12 to T1. On the first cadaver, the surgeon will place the first screw beginning at T12 by the FH , the second screw (T11) by the TPTT and alternating technique through T1. On the contralateral side, the first screw will be placed by the TPTT and the second by FH, etc. This alternation of techniques will minimize the problem of comparing the techniques in separate cadavers in which pedicle size, anatomy, and bone density may be more or less favorable. In the second cadaver, the order of the technique first performed will be reversed for the two sides such that the T12 screw will be performed by the TPTT and the T11 screw by the FH. Following screw placement, CT scan evaluation of each screw will be performed by a radiologist. Implant profile and tissue exposure will be quantified by the surgeons. A screw will be scored for no breach, <2mm, 2-4mm or >4mm perforations. The data will be categorized in a dichotomous manner as breach or no breach as well as by the magnitude of breach as listed above. In addition, the direction of the breach, medial, caudal, lateral, or cephalad will be recorded. Time from creating the pilot hole to completion of screw insertion will be recorded for each screw and for each technique. We will evaluate inter- and intra-variabilities of surgeons' technique and experience for pedicle screw placement.

Upon the completion of the radiographic analysis, the instrumented vertebral column will be harvested and each vertebral body will be isolated from soft tissue and mounted in PMMA in preparation for biomechanical evaluation. Measurements of the leverage arm (VB geometric center to rod) for the TP trajectory technique will be compared to the standard technique (to quantify the de-rotation bending moments and the ease in the de-rotation of the spine with TP trajectory larger leverage arm). Half of the specimens will be used for axial pullout testing along the axis of the screws and the remaining specimen will be subjected to de-rotational force that is perpendicular to the screw axes. The pullout and de-rotational strength of the TP trajectory and standard pedicle screws will be quantified and statistically analyzed using t-test. Statistical analysis

Chi-square test will be used compare the perforations among the 3 surgeons using the same technique, as well as compare the incidence of breaches between the two techniques. T-test (or Wil-Coxon rank sum test) will be used to compare time spent on each screw placement for the two techniques. ANOVA with Bonferroni correction will be used for between surgeons comparison on the time spent on each screw placement.

Milestones:

- Develop protocol and finish pilot testing – Nov 30, 2014
- Finish collecting all data, and pursue the Finite Element Modeling – Feb 28, 2015
- Data Analyses , publications (abstracts and manuscripts) and report – May, 30, 2015

Outcome/Deliverables:
Including:

- *Presentation Update* - beginning of 2015 at the University of Toledo, Ohio
- *Final Report including results* - June 30, 2015

Impact: It will help improve patient outcome for the following reasons.
The TP trajectory technique will be more accurate than the FH; The TPTT will be more reproducible than the FH amongst surgeons of differing levels of experience and between left and right sides.; and The TP trajectory technique provides better pullout and de-rotational strength than the traditional FH technique as well as ease for the derotation of the spine due to the larger leverage arm.

Project Duration & General Budget Outline:

Personnel	$	11,000
Supplies/Specimens	$	20,000
Imaging	$	5,000
Total Direct	$	36,000
Indirects (10%)	$	3,600
Total	$	39,600

Duration: 1 year

Start Date: October 1, 2014

End Date: June 30, 2015

Please send this document along with your *IP Checklist for Projects* to mark.fox@utoledo.edu (Univ of Toledo Patent Technology Associate) and dezba.coughlin@ucsf.edu (CDMI Managing Director)
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