CDMI
CENTER FOR DISRUPTIVE MUSCULOSKELETAL INNOVATIONS

Development of an innovative posterior pedicle-based screw stabilization for multilevel semi-dynamic stabilization

University: University of Toledo	
PI and Co-PI name(s): **Deniz U. Erbulut, PhD** **Vijay Goel, PhD**	**Proposed Budget:** **(includes 10% indirects)**: **$39,600**
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CDMI trainee name:	**CDMI trainee title: (e.g. grad student, postdoc, SRA)**
CDMI trainee email:	

Need and Industrial Relevance:

Rigid fixation is designed to provide immediate stability following surgery until the fusion mass takes over. However, these systems have been associated with several drawbacks, such as imposing relatively high mechanical stress on the adjacent segment because of the hyper mobility which often leads to long-term degenerative changes at those sites, resulting in a need for additional fusion surgery. Dynamic stabilization systems have been suggested as alternatives to rigid systems for spinal treatment. Dynamic/semi dynamic posterior stabilization for single level has been known as successful treatment for low back pain. However, posterior dynamic/semi dynamic stabilization systems may lead serious problem after multilevel stabilization surgery. One of the complications after the surgery is implant failure due to dynamic loading. Double headed screw could be used within posterior multilevel stabilization system with capability of stabilizing each level independently and, could provide limited motion to each segment for a life time under dynamic loading. Another important application of this concept is as PJK and PJF prevention device. For example, it can be used to reduces PJK for thoracic region, and provide “topping off” for a better outcome.

Project Aims (including Hypotheses):

A project is proposed to develop and evaluate a novel pedicle screw design, double-head pedicle screw, to be used as a component of multilevel posterior stabilization system for various scenarios, as listed above. We will developed the sytem using finite element analysis (FEA), mechanical and *In vitro* testing.

Methods:

A. Optimization of double-headed pedicle screw design using a CAD/Solidworks software
B. Evaluate the design using FEA and compare with others on the market
C. Manufacture the prototypes
D. Mechanical testing of the device according to ASTM and ISO standards
    a. Static and dynamic mechanical testing

E. *In vitro* testing of the optimized design
   a. A number of fresh frozen spines will be used to evaluate kinematics of each intact and instrumented specimens using Optotrack motion capture system at moments 0-10Nm. Calculated ranges of motion will be used to evaluate the stability of the device compared to intact and others.

Milestones:

- Finish design optimization and FE analysis - Dec 30, 2017
- Finish prototypes and mechanical testing – March 2018
- Finish in vitro testing – June 31 2018
- Finish collecting all data – Aug 31 2018
- Data analysis, publications and reports – Oct 2018

Deliverables (must include):

Quarterly presentation updates:

- *December 2017 – conference call*
- *Spring 2018 – Spring Symposium @ UT (conference call option for non-UT teams)*
- *June 2018 – conference call*
- *September 2018 – Fall Symposium @ UCSF (conference call option for non-UCSF teams)*
- *Final written report including results* – November 2, 2018

Specific work product (e.g. protocols, material, device, database)

General Budget Outline:

Example:

Personnel	$	15,000
Supplies	$	12,000
Specimens	$	4,000
Imaging	$	5,000
Total Direct	$	36,000
Indirects (10%)	$	3,600
Total	$	39,600

Start Date: October 15, 2017 **End Date**: September 30, 2018

Please limit this document to 2-3 pages and email it to kimberley.mcintosh@utoledo.edu by September 8th.